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December 6, 2017

IMS-a-51

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 2017 National Conference on Interstate Milk Shipments

The 36th National Conference on Interstate Milk Shipments (NCIMS) was held in Grand Rapids, Michigan, May 12-17, 2017. A total of ninety-eight (98) 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	38	28	3	7	0
II	46	21	3 5-Sent to 2400 Forms Protocol	17	0
III	10	5	1	4	0
JOINT COUNCIL	4	0	0	2	2
TOTAL	98	54	7 5-Sent to 2400 Forms Protocol	30	2

The following Proposals were passed and addressed changes to the *PMO*: 113 (FDA originally non-concurred), 114, 115, 120, 121, 127, 129, 130, 134, 207, 212, 214, 215, 223, 224 (FDA originally non-concurred), 225, 226 (FDA originally non-concurred), 228, 231, 301, JC-2 and JC-4.

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)*: 306 and 307 (Both identified as Procedures changes) 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): 134, 228 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): 309 and JC-2.

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML): 231 and 233.

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: 237, 238, 239, 240 and 242.

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: 206, 216, 219, 220, 241 and 243.

The following Proposals were passed and addressed changes to the Inspection and Rating Forms utilized in the Program:

- FORM FDA 2359-MILK PLANT INSPECTION REPORT (11/15): JC-2.
- FORM FDA 2359h-INTERSTATE MILK SHIPPER'S CHECK RATING REPORT (11/15): JC-2.
- FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT (10/13): JC-2.
- FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/13): JC4.
- FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (10/13): JC-4.

The following Proposals were passed and addressed the formation of a study committee, assignment to a Standing Committee or ad hoc Committee, or the continuation of a Pilot Program:

118: The author requests that the Chair assign to the NCIMS Technical Engineering Review Committee or to a study committee, as approved by the NCIMS Executive Board, the task of thoroughly reviewing and evaluating the text contained with Item 16p and Appendix H of the PMO and to submit a proposal to the 2019 NCIMS Conference that updates and make editorial corrections that will make the text within Item 16p and Appendix H of the PMO more clear, concise, uniform and accurate.

Note: *The NCIMS Executive Board assigned Proposal 118 to the NCIMS Technical Engineering Review Committee.*

213: This proposal requests the Chair to assign this proposal to the Hauling Procedures Committee. This proposal charges the Hauling Procedures Committee to conduct a comprehensive review of Appendix B and FDA Form 2399a and report back to the 2019 NCIMS Conference.

217: This proposal 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 designated Committee is charged to review Appendix N Section VI, pertaining to testing for non-beta-lactam antibiotics with test methods that have not been evaluated by FDA and accepted by the NCIMS, and move this Section to a new appendix (to be lettered). The Committee is charged to clearly delineate testing that is required by Appendix N (currently Beta-lactams) from voluntary testing that is performed using test methods that have not been evaluated by FDA and accepted by the NCIMS.

The product of the committee may be a proposal submitted to the 2019 Conference.

***Note:** The NCIMS Executive Board assigned Proposal 217 back to the NCIMS Appendix N Modification Study Committee.*

230: FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA the task of conducting a comprehensive and thorough review of the *MMSR* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the *MMSR*. The review shall include an assessment of the appropriate point value for the animal food provisions added to Item 15p of the PMO, and subject to the passing of JC-1 or JC-2.

301: The NCIMS Aseptic Program Committee addressing Grade “A” fermented high-acid shelf-stable milk and/or milk products shall expire on December 31, 2019, unless extended by future conference action.

303: FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA the task of conducting a comprehensive and thorough review of the *Procedures* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the *Procedures*.

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

JC-2 and JC-4: Both Proposals aligned the PMO with the requirements of the Food Safety Modernization Act (FSMA) for Preventive Controls for Human Foods (PCHF) Rule.

- JC-2 addresses the PMO, MMSR and Procedures and adds a new Appendix T-Preventive Controls for Human Food Requirements for Grade “A” Milk and Milk Products that states that this *Ordinance*, with Appendices, and the supporting milk plant-specific procedures

required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant's food safety plan shall be in writing and shall be prepared, or its preparation overseen by one (1) or more PCQIs.

- JC-4 addresses Appendix K-HACCP Program of the PMO.

FDA responded in writing to the NCIMS Conference Chair on September 8, 2017 and met with the NCIMS Executive Board on October 11-12, 2017 concerning the Proposals passed during the 2017 Conference. Within FDA's letter dated September 8, 2017, FDA concurred with all the passed Proposals except for Proposals 113, 224 and 226.

113: (FDA originally non-concurred because of a direct conflict with text that was added and to text that was not added to applicable language in Appendix B. of the PMO.) During the October 11-12, 2017 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 113. This provides for the addition of the **NOTE:** added to Item 12p on page 76 of the PMO to the applicable text on page 147 in Appendix B. of the PMO and the deletion of the Note: in c. under 3. Milk Quality Checks on page 141 as this is in direct conflict with the amendment that added the **NOTE:** below this paragraph. Please refer to Proposal 113 on page 56 of this IMS-a.

224 and 226: (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.) During the October 11-12, 2017 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposals 224 and 226. This provides for the deletion of the entire first paragraph, including the new text added in Proposal 224, and adding that new amended text in the first paragraphs under the bold text on pages 376 and 378 within Section VI of Appendix N. Please refer to Proposal 224 on page 71 and Proposal 226 on page 72 of this IMS-a.

The NCIMS Executive Board mutually concurred with FDA on all the Proposals that were originally concurred with by FDA.

All Proposals that were passed and concurred with by FDA and the NCIMS Executive Board, except for the Proposals noted below, 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 December 6, 2018.

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

223: Adds to Appendix N of the PMO the following: "Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station or transfer station, or in-transit prior to the official notification to the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pick-up tanker(s) test negative in accordance with Appendix N."

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's concurrence with the NCIMS Executive Board.*

226: Clarifies options for verifying initial screening test positive results using methods that have not been evaluated by FDA or accepted by NCIMS. Addresses conflicting language in Appendix N, Section VI pertaining to testing for non-Beta lactam drug residues.

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's concurrence with the NCIMS Executive Board.*

228: Clarifies the sampling frequency requirements for Grade "A" raw milk and Grade "A" milk and/or milk products that are not produced on a continuous monthly basis, i.e., intermittently, seasonal, lactating dairy animals are dried off, etc. as required within Section 6-The Examination of Milk and/or Milk Products of the PMO; and sampling frequency requirements for single-service containers and/or closures that are not produced on a continuous monthly basis as required within Appendix J-Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the PMO.

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's concurrence with the NCIMS Executive Board.*

230: FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA the task of conducting a comprehensive and thorough review of the MMSR and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the MMSR. The review shall include an assessment of the appropriate point value for the animal food provisions added to Item 15p of the PMO, and subject to the passing of JC-1 or JC-2.

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's concurrence with the NCIMS Executive Board.*

306: Clarifies that FDA may certify Sampling Surveillance Officers (SSOs) for the following categories: bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers); bulk milk hauler/samplers; or plant samplers (dairy plant samplers and industry plant samplers). It also clarifies that a certified SSO for a specified category may delegate to designated Sampling Surveillance Officers (dSSOs) for the same specified category.

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.*

307: To provide for clarity and transparency, PHS/FDA shall regularly inform and confer with the NCIMS to answer questions and address NCIMS member concerns prior to finalizing a determination of equivalence that a foreign country’s regulatory program and the government oversight of that program have an equivalent effect on the safety of the regulated Grade “A” milk and milk products.

***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.*

JC-2 and JC-4: Both Proposals aligned the PMO with the requirements of the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) Rule.

***Note:** These Proposals shall take effect on September 17, 2018.*

JC-2 and 309: Made changes to the *Constitution* and/or *Bylaws of the NCIMS*.

***Note:** Amendments to the Constitution and Bylaws shall become effective at the close of the Conference at which they are adopted.*

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.

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Proposal: JC-2

Document: 2015 PMO

Pages: x, xiv, xx, xxi, 1, 6, 11, 12, 15, 21, 29, 62, 65, 74-76, 81, 89, 90, 98, 108, 114, 117, 122, 131, 213, 340-342, 359, 396 and 398

Make the following changes to the 2015 PMO:

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ITEM 20p. PERSONNEL – CLEANLINESS AND PRACTICES.....

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**APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND
RETORT PROCESSED AFTER PACKAGING PROGRAM**

APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE “A” MILK AND MILK PRODUCTS

INDEX

ABBREVIATIONS AND ACRONYMS ...

Page xx:

PCC (Petrifilm Coliform Count)
PCQI (Preventive Controls Qualified Individual)
PDD (Position Detection Device) ...

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PVC (Polyvinyl Chloride)
QI (Qualified Individual)
R (Raw) ...

SECTION 1. DEFINITIONS ...

Page 1:

B. ASEPTIC PROCESSING AND PACKAGING: The term “Aseptic Processing and Packaging”, when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, ~~113 and 117~~ and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

C. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade “A” low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~113 and 117~~ and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product. ...

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AA. LOW-ACID ASEPTIC AND RETORT MILK AND/OR MILK PRODUCTS: Milk and/or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under the applicable requirements of 21 CFR Parts 108, ~~113~~

~~and 117 and 113~~. Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and/or milk products that are labeled for storage under refrigerated conditions. ...

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PP. **PERSON:** The word “person” shall include any individual, milk plant operator, partnership, corporation, company, firm, trustee, association or institution.

QQ. **PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL:** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

RR. **QUALIFIED INDIVIDUAL:** A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe milk and/or milk products as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the milk plant.

QQSS. **RATING AGENCY:**

Note: Re-letter remaining Definitions accordingly.

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~~UUWW~~. **RETORT PROCESSED AFTER PACKAGING:** The term “Retort Processed after Packaging”, when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient retort heat processing after packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, ~~440~~ 113 and 117 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

~~VVXX~~. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this *Ordinance*, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade “A” milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~440~~ 113 and 117 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product. ...

Note: Re-letter remaining Definitions accordingly.

AAA. SUPPLY-CHAIN-APPLIED CONTROL: A preventive control for a hazard in a raw material or other ingredients when the hazard in the raw material or other ingredient is controlled before its receipt.

ZZBBB. TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS: ...

Note: Re-letter remaining Definitions accordingly.

EEE. VERY SMALL BUSINESS: A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the three (3) year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee) as outlined in 21 CFR Part 117 subparts A and F.

Note: Re-letter remaining Definitions accordingly.

SECTION 2. ADULTERATED OR MISBRANDED MILK AND/OR MILK PRODUCTS ...

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ADMINISTRATIVE PROCEDURES ...

RECALL PLAN: ~~A milk plant shall establish a written recall plan that shall include procedures as that described in 21 CFR Part 7 (Subpart A and C).~~

NOTE: ~~For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.~~

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

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

a. ~~that, for~~ For those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. of this *Ordinance*.

b. ~~Provided further, that regulatory~~ 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 shall be conducted by the Regulatory Agency in accordance with this *Ordinance* at

least once every six (6) months. (Refer to Appendix S.) The milk plant's Aseptic Processing and Packaging System (APPS) and Retort Processed after Packaging System (RPPS), 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, ~~110~~ and 113 and 117 at a frequency determined by FDA.

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 the Grade "A" PMO Preventive Controls Training for Regulatory Agencies. ...

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

...

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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) within seven (7) working days after the records were created;
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.

ADMINISTRATIVE PROCEDURES ...

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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

Milk plants shall comply with all Items of this Section. ~~The Grade "A" PMO, with Appendices, and the supporting milk plant specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. 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, the APPS or RPPS, 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, ~~110~~ 113 and 117 and 113. Those Items, contained within the APPS and RPPS, 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 assigned responsibility for this function. ...

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ITEM 4p. LIGHTING AND VENTILATION ...

ADMINISTRATIVE PROCEDURES

1. Adequate light sources are provided (natural, artificial or a combination of both) which furnish at least twenty (20) foot-candles (220 lux) of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five (5) foot-candles (55 lux) of light. Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided where milk or milk products are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed.

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT ...

ADMINISTRATIVE PROCEDURES ...

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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 packaging are governed under the applicable provisions of 21 CFR Parts ~~110~~ 113 and 117 and 113 and shall not be subject to this Item. ...

ITEM 12p. CLEANING AND SANITIZATION OF CONTAINERS AND EQUIPMENT

ADMINISTRATIVE PROCEDURES

1. All multi-use containers and utensils are thoroughly cleaned after each use and all

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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 available for at least the previous three (3) months or from the time of the last regulatory inspection, whichever is longer;

- 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 within seven (7) working days after the records were created;
- 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.

In the case of pasteurized storage tanks, which are CIP cleaned at intervals of less than seventy-two (72) hours, the CIP cleaning records required under Item 2.b. of this Section shall be considered adequate. ...

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- 2. Pipelines and/or equipment designed for CIP cleaning meet the following requirements: ...
 - c. Cleaning charts and electronically stored records required by this Section shall be: ~~identified, dated and retained for three (3) months or until the next regulatory inspection, whichever is longer.~~
 - (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 within seven (7) working days after the records were created;
 - (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. ...

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ITEM 15p. PROTECTION FROM CONTAMINATION

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment. All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than Grade "A" milk or milk products in the milk plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the

product-contact surfaces of all containers, utensils and equipment. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk and/or milk products from food allergen cross-contact, including during storage and use, and to ensure proper declaration of food allergens on product labeling. Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be accurately identified, labeled by the common or usual name and held under conditions that will protect against contamination.

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, as well as the potential for food allergen cross-contact of such products in certain facilities, every effort should be made to provide adequate protection for the milk and milk products at all times. ...

ADMINISTRATIVE PROCEDURES ...

15p.(C)

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1. FOOD ALLERGEN CONTROL:

A milk plant operation that handles nondairy food allergens shall implement a written food allergen control plan that includes procedures, practices and processes to control food allergens. Food allergen controls shall include those procedures, practices and processes employed for:

- a. Ensuring protection of ~~food~~ milk and/or milk products from allergen cross-contact, including during storage, handling and use.

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- b. Labeling the finished ~~food~~ milk and/or milk products, including ensuring that the finished ~~food~~ milk and/or milk products is not misbranded under Section 403(w) of the *FFD&CA* with an undeclared food allergen.

- c. Raw materials and ingredients that are food allergens, and rework that contains food allergens, shall be identified and held in a manner that prevents food allergen cross-contact.

- d. Prevention of food allergen cross-contact from insanitary objects, from personnel and from non-milk allergen-containing foods to milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces.

2. ~~ENVIRONMENTAL MONITORING:~~

~~A milk plant shall have a written environmental monitoring program that is implemented and supported by records for milk and/or milk products exposed to the environment when the milk and/or milk products do not subsequently receive a treatment that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:~~

- ~~a. Be supported by scientific information;~~
- ~~b. Include written procedures and records;~~
- ~~c. Identify environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring;~~

- d. ~~Identify the timing and frequency for collecting and testing samples;~~
- e. ~~Identify the environmental pathogen or appropriate indicator microorganism to be tested for;~~
- f. ~~Identify the test(s) conducted, including the analytical method used, and the test result;~~
- g. ~~Identify the laboratory conducting the testing; and,~~
- h. ~~Include corrective action procedures for environmental monitoring test results.~~

~~3. **SUPPLIER CONTROL PROGRAM:**~~

~~A milk plant shall have a supplier control program for raw materials and ingredients that is implemented and supported by records to control food safety hazards. The supplier program shall, at a minimum;~~

- a. ~~Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist that the supplier has, at a minimum, a functional risk based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.~~
- b. ~~Document that a supplier of non milk and/or milk product ingredients has a functional and written food safety program that includes allergen management, if utilized in the milk plant's Grade "A" milk and/or milk products.~~

~~2. **HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD:**~~

- a. ~~Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be held under conditions that will protect against contamination as appropriate for their final use in animal food.~~
- b. ~~Labeling that identifies the by-product shall be affixed to or accompany the human food by-products for use as animal food when distributed.~~
- c. ~~Shipping containers, i.e., totes, drums, tubs, etc., and bulk vehicles used to distribute human food by-products for use as animal food shall be appropriate for transporting the human food by-products for use as animal food and protecting against contamination during transport.~~

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, ~~110~~ 113 and 117 and 113. (Refer to Appendix L. of this Ordinance.) ...

ITEM 16p.(A) BATCH PASTEURIZATION ...

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5. RECORDING THERMOMETER CHARTS

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

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, in place of charts, shall be ~~preserved for a period of three (3) months~~:

- 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 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: ...

2. EQUIPMENT TESTS AND EXAMINATION

The Regulatory Agency shall perform the indicated Tests on the following instruments and devices identified in Table 4 initially upon installation; at least once each three (3) months thereafter, including the remaining days of the month in which the equipment Tests are due; whenever any alteration or replacement is made which may affect the proper operation of the instrument or device; or whenever a regulatory seal has been broken. Provided, that the pasteurization holding time Tests shall be conducted at least once each six (6) months thereafter, including the remaining days of the month in which the equipment Test is due.

The test results for the required pasteurization equipment testing shall be recorded on records that are similar to the reference cited in Appendix M. of this Ordinance. The Regulatory Agency shall provide a copy of the records to the milk plant and the milk plant shall retain these records for at least two (2) years after the date they were created. Offsite storage of these pasteurization equipment testing records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

NOTE: A TPC authorized under the ICP may utilize appropriately trained and TPC authorized in-country regulatory personnel to comply with 2. as cited above. ...

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

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed.

Every ~~refrigerated room or tank or silo~~, in which milk or milk products, whey and whey products, and condensed milk and milk products are stored, shall be equipped with an accurate indicating thermometer.

Every refrigerated room, in which milk and/or milk products are stored, shall be equipped with an accurate indicating thermometer, temperature-measuring device, or temperature-recording device.

...

ADMINISTRATIVE PROCEDURES ...

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7. Each refrigerated room in which ~~pasteurized~~ 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. If a temperature-measuring device or temperature-recording device is being utilized, the cooling 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 within seven (7) working days after the records were created;

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 cooling records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

8. Each storage tank or silo shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank or silo contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H. of this *Ordinance*. ...

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ITEM 20p-PERSONNEL – CLEANLINESS AND PRACTICES

No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an illness, open lesion, including boils, sores or infected wounds, shall work in any processing area in any capacity where there is a likelihood of such person contaminating milk or milk products or milk or milk product-contact surfaces with pathogenic organisms unless conditions such as open lesions, boils and infected wounds are adequately covered, e.g., by an impermeable cover. Personnel shall be instructed to report such health conditions to their supervisors. Hands shall be thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the

handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products, containers, utensils and equipment shall wear clean outer garments suitable to the operation in a manner that protects against food allergen cross-contact and against the contamination of milk and/or milk products, milk or milk product-contact surfaces or milk or milk product packaging materials. Unsecured jewelry and the storage of clothing or other personal belongings shall not be permitted in those areas cited above. All persons, while engaged in the processing of milk or milk products, shall wear adequate hair nets, caps, beard covers or other effective hair coverings restraints and shall not use tobacco or chewing gum.

PUBLIC HEALTH REASON

Clean clothing and clean hands, including clean fingernails, reduce the possibility of milk or milk products, containers, utensils and equipment becoming contaminated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an illness, open lesion, including boils, sores or infected wounds shall work in any processing area in any capacity where there is a likelihood of such person contaminating milk or milk products or milk or milk product-contact surfaces with pathogenic organisms, unless conditions such as open lesions, boils and infected wounds are adequately covered, e.g., by an impermeable cover. Personnel shall be instructed to report such health conditions to their supervisors. (Refer to Sections 13. and 14. of this Ordinance.)

42. Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.

23. Each employee washes their hands following a visit to the toilet room and prior to resuming work.

34. All persons while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products containers, utensils, and equipment wear clean outer garments suitable to the operation in a manner that protects against food allergen cross-contact and against the contamination of milk and/or milk products, milk or milk product-contact surfaces or milk or milk product packaging materials. Unsecured jewelry and the storage of clothing or other personal belongings shall not be permitted in these areas.

45. The use of tobacco products, chewing gum or eating food or drinking beverages is prohibited in all rooms in which milk and milk products are handled, processed or stored, or in which milk or milk product containers, utensils and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, milk and milk product storage, cooling and dry storage ingredients, single-service article storage and container/utensil wash-up areas. Any person engaged in the processing of milk or milk products wears adequate hair nets, caps, beard covers or other effective hair coverings restraints.

56. Specially provided clean rubbers or boot covers, clean coveralls, and white cap, clean cloth or paper, are worn whenever it is necessary to enter the drying chambers. Such articles of clothing are stored in such a manner as to be protected from contamination. Boot covers, which have come into contact with areas other than those within the dryer, are not considered clean. ...

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

ADMINISTRATIVE PROCEDURES ...

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11. Aseptically processed and packaged low-acid 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 NCIMS Aseptic Pilot Program addressing aseptically processed and packaged fermented high-acid milk and/or milk products regulated under the applicable requirements of 21 CFR Parts 108 and/or ~~H0~~ 117 shall expire on December 31, 2017, unless extended by future conference action. ...

APPENDIX F. CLEANING AND SANITIZATION ...

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**III. EVAPORATING, DRYING AND DRY PRODUCT
EQUIPMENT CLEANING**

CLEANING

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 ~~should be identified, dated, and retained for three (3) months~~ 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 within seven (7) working days after the records were created;

(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.

- c. ~~During each official inspection the Regulatory Agency should examine and initial the pH recording charts to verify the time of exposure to the cleaning solutions and their pH. ...~~

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

D. FABRICATION PLANT STANDARDS ...

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4. LIGHTING AND VENTILATION

a. All rooms shall be adequately lighted either by natural light, artificial light, or both. A minimum of twenty (20) foot-candles (220 lux) should be maintained in fabricating areas and five (5) foot-candles (55 lux) in storage areas. Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided in fabricating areas. Packaging, sealing, wrapping, labeling and similar procedures are considered part of the fabricating area.

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10. LOCKER AND LUNCHROOMS ...

b. Eating, drinking beverages and/or storage of food are prohibited in fabricating and storage areas. ...

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12. PERSONNEL – PRACTICES ...

b. All personnel shall wear clean outer garments suitable to the operation in a manner that protects against the contamination of milk or milk product packaging materials and effective hair nets, caps, beard covers or other effective hair restraints.

c. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an illness, open infected cut or lesion, including boils, sores or infected wounds shall work in any processing area in any capacity where there is a likelihood of such person contaminating product or product-contact surfaces with pathogenic organisms. (Refer to Sections 13. and 14. of this *Ordinance*.)

d. The use of tobacco products or chewing gum is prohibited in fabricating, regrind and storage areas.

e. Unsecured jewelry shall not be permitted in fabricating areas. ...

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APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS, THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT*, AND THE *FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT* ...

21 CFR PART 108 – EMERGENCY PERMIT CONTROL

21 CFR PART ~~110~~ 117 – CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR ~~IN-MANUFACTURING, PACKING, OR HOLDING~~ HUMAN FOOD

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

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSING AFTER PACKAGING PROGRAM ...

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 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, 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, ~~110~~ 113 and 117 ~~and 113~~. The milk plant's APPS and/or RPPS, 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, ~~110~~ 113 and 117 ~~and 113~~ at a frequency determined by FDA. ...

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***NOTE:** In areas of the milk plant where these Items are dedicated only to the APPS and/or RPPS, respectively, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~).

APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE "A" MILK AND MILK PRODUCTS

Food Safety Plan:

This *Ordinance*, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. The milk plant's food safety plan shall be in writing and shall be prepared, or its preparation overseen by one (1) or more PCQIs. The milk plant's written food safety plan and its contents shall include the following:

1. The written Recall Plan;
2. The written Hazard Analysis;
3. The written Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
4. The written Supply-Chain Program, as appropriate, for hazards not addressed by this *Ordinance*;

5. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by this Ordinance;
6. The written Corrective Action Procedures, as appropriate, for hazards not addressed by this Ordinance; and
7. The written Verification Procedures, as appropriate, for hazards not addressed by this Ordinance.

The owner, operator or person in charge of the milk plant shall sign and date the food safety plan:

1. Upon initial completion; and
2. Upon any modifications.

A reanalysis of the milk plant's written food safety plan as a whole shall be conducted at least once every three (3) years. A reanalysis of the milk plant's written food safety plan as a whole, or the applicable portion of the food safety plan shall be conducted:

1. Whenever a significant change in activities conducted creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
2. Whenever the milk plant becomes aware of new information about potential hazards associated with the milk and/or milk products;
3. Whenever appropriate after an unanticipated food safety problem;
4. Whenever the milk plant finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective; and
5. When FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

A PCQI shall perform, or oversee, all the reanalysis cited above.

The milk plant's current written food safety plan is considered a record and shall remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location. The food safety plan shall be retained at the milk plant for at least two (2) years after its use is discontinued.

Recall Plan:

A milk plant shall establish a written recall plan that shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate for the milk plant:

1. Directly notify the direct consignee of the milk and/or milk product(s) being recalled, including how to return or dispose of the affected milk and/or milk product(s);
2. Notify the public about any hazard presented by the milk and/or milk product(s) when appropriate to protect public health;
3. Conduct effectiveness checks to verify that the recall is carried out; and
4. Appropriately dispose of recalled milk and/or milk product(s), i.e. reprocessing or rework if allowed for within this Ordinance, diverting to a use that does not present a milk safety concern, or destroying the milk and/or milk product(s).

NOTE: For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

Hazard Analysis:

A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. A milk plant may group similar types of milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical. The hazard identification shall consider:

1. Known or reasonably foreseeable hazards that include:
 - a. Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
 - b. Chemical hazards, including radiological hazards, substances such as pesticides and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
 - c. Physical hazards, such as stones, glass and metal fragments; and
2. Known or reasonably foreseeable hazards that may be present in milk and/or milk products for any of the following reasons:
 - a. The hazard occurs naturally;
 - b. The hazard may be unintentionally introduced; or
 - c. The hazard may be intentionally introduced for purposes of economic gain.

Preventive Controls:

A milk plant shall identify and implement written preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the milk and/or milk products processed, packaged or held will not be adulterated under Section 402 of the *FFD&CA* or misbranded under Section 403(w) of the *FFD&CA*. Preventive controls include:

1. Controls at critical control points (CCPs); and
2. Controls, other than those at CCPs, that are also appropriate for food safety.

Preventive controls shall include, as appropriate to the milk plant and the milk and/or milk products:

1. Process controls that include procedures, practices and processes to ensure the control of parameters during operation;
2. Food allergen controls that include procedures, practices and processes to control food allergens as referenced in Item 15p.(C) of this *Ordinance*;
3. Sanitation controls that include procedures, practices and processes to ensure that the milk plant is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee practices and food allergen hazards;

4. Supply-chain controls as referenced in this Appendix;
5. Recall plan; and
6. Other controls, such as employee hygiene training and other current GMPs.

Monitoring:

The milk plant shall establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls and shall monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. The milk plant shall document the monitoring of preventive controls to verify that monitoring is being conducted as required and that the required monitoring records are being reviewed within seven (7) working days after the records are created.

Corrective Actions:

The milk plant shall establish and implement written corrective action procedures that shall be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

1. The presence of a pathogen or appropriate indicator organism detected as a result of product testing; and
2. The presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring.

The corrective action procedures shall describe the steps to be taken to ensure that:

1. Appropriate action is taken to identify and correct a problem that has occurred with the implementation of a preventive control;
2. Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;
3. All affected milk and/or milk products are evaluated for safety;
4. All affected milk and/or milk products are prevented from entering into commerce, if the milk plant cannot ensure that the affected milk and/or milk products are not adulterated under Section 402 of the *FFD&CA* or misbranded under Section 403(w) of the *FFD&CA*.

The milk plant shall document all corrective actions and, when appropriate, corrections taken and that the required corrective action and corrections records are being reviewed within seven (7) working days after the records are created.

Verification:

Verification activities shall include, as appropriate to the nature of the preventive control and its role in the milk plant's food safety system:

1. Validation;
2. Verification that monitoring is being conducted as required;

3. Verification that appropriate decisions about corrective actions are being made as required;
4. Verification that the preventive controls are consistently implemented and are effective and significantly minimizing or preventing the hazards; and
5. Reanalysis.

The milk plant shall conduct finished milk and milk product testing as appropriate to the milk plant, the milk and/or milk products, and the nature of the preventive control and its role in the milk plant's food safety system for a pathogen or appropriate indicator organism or other hazard. The milk plant shall establish and implement written procedures for finished milk and milk product testing as appropriate and the procedure shall:

1. Be scientifically valid;
2. Identify the test microorganism(s) or other analyte(s);
3. Specify the procedures for identifying samples, including their relationship to specific lots of milk and/or milk products;
4. Include the procedures for sampling, including the number of samples and the sampling frequency;
5. Identify the test(s) conducted, including the analytical method(s) used;
6. Identify the laboratory conducting the testing; and
7. Include the corrective action procedures for the presence of a pathogen or appropriate indicator organism detected as a result of product testing.

The milk plant shall document all verification activities that are conducted in their records.

Validation:

The milk plant shall validate that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the milk plant's food safety system. The validation of the preventive controls shall be performed by or under the oversight of a PCQI:

1. Prior to the implementation of the food safety plan;
2. When necessary to demonstrate the control measures can be implemented as designed within ninety (90) days after production of the applicable milk or milk product first begins;
3. Whenever a change to the control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazard; and
4. Whenever a reanalysis of the food safety plan reveals the need to do so.

The milk plant does not need to validate the following:

1. The food allergen controls;
2. The sanitation controls;
3. The recall plan;
4. The supply-chain program; and
5. Pasteurization as defined in Item 16p of this *Ordinance*.

The milk plant shall document in their records all validation activities that are conducted.

Records:

The milk plant shall establish and maintain the following records documenting the implementation of the food safety plan:

1. The food safety plan;
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;
4. Records that document verification, including, as applicable, those related to:
 - a. Validation;
 - b. Verification of monitoring;
 - c. Verification of corrective actions;
 - d. Calibration of process monitoring and verification instruments;
 - e. Product testing as appropriate;
 - f. Environmental monitoring;
 - g. Records review; and
 - h. Reanalysis;
5. Records that document the supply-chain program;
6. Records that document the applicable training for milk plant employees and the PCQI(s), including the date of training, the type of training and the person(s) trained.

Records that are required in the milk plant's food safety plan 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. Onsite and available for review by the Regulatory Agency. Electronic records are considered to be onsite if they are accessible from an onsite location; and
3. Retained for at least two (2) years after the date they were created. Offsite storage of these records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

Monitoring and corrective action records shall be reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records were created.

Qualification of Individuals:

1. The owner, operator or person-in-charge of a milk plant shall ensure that all individuals who receive, handle, process, package, etc. milk and/or milk products are qualified to perform their assigned duties.
2. Each individual engaged in the receiving, handling, processing, packaging, etc. of milk and/or milk products, including temporary and seasonal personnel, or in the supervision thereof shall:
 - a. Have the education, training, or experience or combination thereof necessary to receive, handle, process, package, etc. milk and/or milk products as appropriate to the individual's assigned duties; and

- b. Receive training in the principles of food hygiene and food safety, including the importance of employee health and personnel hygiene, as appropriate to the milk and/or milk products, the milk plant and the individual's assigned duties.
3. Responsibility for ensuring compliance by individuals with the requirements shall be clearly assigned to supervisory personnel who have the education, training, or experience or combination thereof, necessary to supervise the production of clean and safe milk and milk products.
4. Records that document training shall be established, maintained and retained at the milk plant for at least two (2) years after the date they were prepared.

The following milk plant's food safety plan activities are required to be performed or overseen by one (1) or more PCQIs:

1. Preparation of the food safety plan;
2. Validation that the preventive controls identified and implemented are adequate to control the hazards appropriate to the nature of the preventive control and its role in the milk plant's food safety system;
3. Review of records; and
4. The reanalysis of the food safety plan;

Environmental Monitoring:

A milk plant shall have a written environmental monitoring program that is implemented and supported by records for ready to eat milk and/or milk products exposed to the environment prior to packaging and the packaged milk and/or milk products do not subsequently receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:

1. Be scientifically valid;
2. Identify the test microorganism(s);
3. Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites shall be adequate to determine whether preventive controls are effective;
4. Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples shall be adequate to determine whether preventive controls are effective;
5. Identify the test(s) conducted, including the analytical method used;
6. Identify the laboratory conducting the testing; and
7. Include the corrective action procedures for the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring.

Supply-Chain Program:

A milk plant shall establish and implement a written risk-based supply-chain program for those raw materials and other ingredients for which the milk plant has identified a hazard requiring a supply-chain-applied control. The supply-chain program shall, at a minimum:

1. Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.
2. Document that a supplier of non-milk and/or milk product ingredients utilized in the milk plant's Grade "A" milk and/or milk products has a functional and written food safety program that provides assurances that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented and also includes food allergen management.
3. A supply-chain program shall include:
 - a. Using approved suppliers. The milk plant shall approve suppliers, and document that approval, before receiving raw materials and other ingredients;
 - b. Determine appropriate supplier verification activities to include determining the frequency of conducting the activity;
 - c. Conducting and documenting supplier verification activities before using raw materials and other ingredients. One or more of the following are appropriate supplier verification activities for raw materials and other ingredients:
 - (i) Onsite audits (annually for serious hazards unless there is a written determination that other verification activities and/or less frequent on-site auditing provide adequate assurance that the hazards are controlled);
 - (ii) Sampling and testing of the raw material or other ingredient;
 - (iii) Review of the supplier's relevant food safety records; and
 - (iv) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.
 - d. When applicable, verifying a supply-chain-applied control applied by an entity other than the milk plant's supplier and documenting that verification.
 - e. Include written procedures for receiving raw materials and other ingredients and document that those procedures are being followed.

If the milk plant determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or other relevant food safety information that the supplier is not controlling hazards that the milk plant has identified as requiring a supply-chain-applied control, the milk plant shall take and document prompt action to ensure that raw materials or other ingredients from the supplier do not cause milk and/or milk products that are manufactured or processed to be adulterated under section 402 or misbranded under section 403(w) of the FFD&CA.

NOTE: A very small business is exempt from this Appendix.

Document: 2015 MMSR

Pages: ii, iii, vii, 2, 5, 13, 18 and 19

Make the following changes to the 2015 MMSR:

TABLE OF CONTENTS ...

Page ii:

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

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

a. Record Review

23. COLLECTION OF DATA

a. Recording of Inspection Data

b. Recording of Laboratory and Other Test Data

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

Page iii:

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

34. COMPUTATION OF SANITATION COMPLIANCE RATINGS

ABBREVIATIONS AND ACRONYMS ...

Page vii:

PCQI (Preventive Controls Qualified Individual)

pH (Potential Hydrogen-acid/alkaline balance of a solution) ...

A. DEFINITIONS ...

Page 2:

4. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product. ...

Page 5:

24. **PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL:** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

2425. **RATING AGENCY:** ...

Note: Renumber remaining Definitions accordingly.

2829. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product. ...

Note: Renumber remaining Definitions accordingly.

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

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING MILK PLANT, RECEIVING STATION AND TRANSFER STATION COMPLIANCE WITH APPENDIX N. OF THE GRADE "A" PMO ...

Page 13:

c. Industry Notification

If a load of milk was found to have a positive drug residue, determine if the permit holder of the BTU or attached supply that the dairy farms are attached to, was properly notified.

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

During a PHS/FDA check rating/audit, 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:

a. Record Review

Determine from records stored in a manner as required in the *Grade "A" PMO* that the milk plant's food safety plan is in compliance. Significant deficiencies involving one (1) or more of the following constitutes grounds for the re-inspection of a milk plant's IMS listing. Milk plants shall be deemed in compliance if the following criteria are met:

- 1.) The milk plant's food safety plan is in writing and was prepared, or its preparation overseen by one (1) or more preventive controls qualified individuals (PCQIs).
- 2.) The milk plant's written food safety plan and its contents included the following:
 - A.) The written Recall Plan;
 - B.) The written Hazard Analysis;
 - C.) The written Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - D.) The written Supply-Chain Program, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - E.) The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;
 - F.) The written Corrective Action Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*; and
 - G.) The written Verification Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*.
- 3.) A reanalysis of the milk plant's food safety plan, as a whole, or portion of the food safety plan, was conducted as required and was performed, or overseen, by a PCQI.
- 4.) The milk plant has a written Hazard Analysis for each kind or group of milk and/or milk products processed. A milk plant may group similar types of milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical.
- 5.) The milk plant has controls at identified critical points (CCPs) and other preventive controls, as appropriate to the milk plant and the milk and/or milk products, for hazards not addressed by the *Grade "A" PMO*.
- 6.) The milk plant has established and implemented written procedures, including the frequency with which they are to be performed, for monitoring the preventive control and monitoring the preventive controls with adequate frequency to provide assurance that they are consistently performed, for hazards not addressed by the *Grade "A" PMO*.
- 7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented, for hazards not addressed by the *Grade "A" PMO*.
- 8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards, for hazards not addressed by the *Grade "A" PMO*.
- 9.) The milk plant has validated that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the milk plant's food safety system, for hazards not addressed by the *Grade "A" PMO*.
- 10.) The milk plant has established and is maintaining the required records documenting the implementation of the food safety plan. These records have not been falsified, for hazards not addressed by the *Grade "A" PMO*.

If the milk plant is determined not to be in substantial compliance with Appendix T. of the *Grade "A" PMO*, 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.

NOTE: If a re-inspection/re-audit is required following a PHS/FDA check rating/audit because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall initially be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and then shall achieve a SCR 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*.

23. COLLECTION OF DATA ...

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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

1.) Inspection Criteria ...

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 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, 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~~ 113 and 117 ~~and 113~~ 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, the APPS and/or RPPS, 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~~ 113 and 117 ~~and 113~~. The rest of the milk plant, including the receiving area, shall be inspected in accordance with the *Grade "A" PMO* and rated and listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing and Packaging Program and Retort Processed after Packaging Program of the *Grade "A" PMO*.) ...

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34. COMPUTATION OF SANITATION COMPLIANCE RATINGS ...

Document: 2015 PROCEDURES
Pages: 2, 6-8, 24, 25, 30, 31, 50, 52, 53 and 59

Make the following changes to the 2015 PROCEDURES:

SECTION III. DEFINITIONS ...

Page 2:

C. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product. ...

Page 6:

BB. RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS): For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product. ...

Page 7:

SECTION IV. OVERSIGHT AND RESPONSIBILITIES ...

A. PHS/FDA RESPONSIBILITIES

1. Standardization of Personnel ...

PHS/FDA shall standardize at least every three (3) years the rating procedures of: ...

c. PHS/FDA shall standardize, in accordance with Section V., ~~FG~~ and ~~GH~~, the evaluation procedures of LEOs and SSOs.

Page 8:

d. PHS/FDA shall standardize, in accordance with Section V, ~~H~~, the certification procedures of SSCs. ...

SECTION V. QUALIFICATIONS AND CERTIFICATIONS ...

D. MILK SANITATION PERSONNEL ...

3. A SRO applicant for initial certification shall be evaluated by PHS/FDA personnel in ...

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d. If HACCP certified for plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization plants for a SRO, one (1) mock-listing audit conducted separate from an official HACCP listing audit is required. (Refer to Section VIII., E. ~~6~~7. for additional HACCP certification procedures.) ...

Page 25:

8. A certified SRO shall be re-certification once each three (3) years by PHS/FDA ...

d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization milk plants for a SRO, one (1) re-certification audit is required. The re-certification 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 personnel and SRO. (Refer to Section VIII., E. ~~6~~7. for additional HACCP certification procedures.) ...

E. DRUG RESIDUE COMPLIANCE

A milk plant desiring a rating of their supply shall comply with Appendix N. of the *Grade "A" PMO*.

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 on a PHS/FDA check rating. Check ratings and any required re-inspection to determine compliance with Appendix T. shall be conducted only by personnel who have completed PHS/FDA *Grade "A" PMO* Preventive Controls training for Regulatory Agencies.

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

FG. SAMPLING SURVEILLANCE PERSONNEL ...

GH. MILK LABORATORY EVALUATION PERSONNEL ...

HJ. SINGLE-SERVICE CONSULTANT PERSONNEL ...

Page 30:

3. The SSC's certification may be revoked by PHS/FDA upon findings that the SSC: ...

The hearing procedure for revoking the certification of a SSC shall follow Section V., HJ.

Page 31:

HJ. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, LEO OR SSC ...

Re-letter remaining Items accordingly.

SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEM FOR IMS LISTED SHIPPERS ...

E. QUALIFICATIONS AND CERTIFICATIONS ...

Page 50:

5. Drug Residue Compliance

A shipper desiring a listing audit of their supply shall comply with Appendix N. of the *Grade "A" PMO*.

6. Food Safety Plan Compliance

An NCIMS HACCP IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined on a PHS/FDA audit.

NOTE: If a re-audit is required following a PHS/FDA audit because of the NCIMS HACCP IMS listed milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall initially be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and then shall receive an acceptable listing audit on a re-audit in order to be eligible for a listing on the *IMS List*.

67. Certification Procedures for SROs Who Will Conduct HACCP Listing Audits ...

Page 52:

78. Sampling Surveillance Personnel

Section V., ~~FG~~. shall apply as written.

Page 53:

89. Milk Laboratory Evaluation Personnel

Section V., ~~GH~~. shall apply as written.

Renumber remaining Items accordingly.

SECTION IX. PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM ...

C. THIRD PARTY CERTIFIER (TPC) RESPONSIBILITIES ...

2. Qualifications of TPC Personnel ...

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c. Sampling Surveillance Personnel

TPC personnel conducting sampling surveillance activities shall meet the qualification and certification requirements set forth in Section V., ~~FG~~, and Section VIII., E.78, if applicable, of this document.

d. Milk Laboratory Evaluation Personnel

TPC personnel conducting milk laboratory evaluation activities shall meet the qualification and certification requirements set forth in Section V., ~~GH~~, and Section VIII., E. 89, if applicable, of this document and those of the *EML*. ...

FORMS: 2359, 2359h and 2359i

Make the following changes to the FDA FORMS:

FORM FDA 2359-MILK PLANT INSPECTION REPORT (11/2015)

15c.

Food allergen control (a)

~~Environmental monitoring.....~~ (b)

Supplier Control program (c)

Human food by-products for
use as animal food (b) _____

**FORM FDA 2359h-INTERSTATE MILK SHIPPER's CHECK RATING REPORT
(11/2015)**

Add a new box with the following text:

FOOD SAFETY PLAN/PREVENTIVE CONTROLS

IS THIS MILK PLANT IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T?

YES NO

15c.AB (In two (2) locations.)

FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT (10/2013)

Add a new box with the following text:

FOOD SAFETY PLAN/PREVENTIVE CONTROLS

WHEN APPLICABLE, IS THIS MILK PLANT IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T?

YES NO

Note: This Proposal shall take effect on September 17, 2018.

Document: 2015 BYLAWS

Page: 84

Make the following changes to the 2015 BYLAWS:

Page 84:

ARTICLE VI ----- DUTIES AND RESPONSIBILITIES OF COUNCILS ...

SECTION 3. Council III shall deal with Proposals submitted to the Conference regarding Sections 11, 17, and 18 and Appendices ~~K~~, ~~and S~~ and T of the *Grade "A" Pasteurized Milk Ordinance*; the *Constitution and Bylaws*; the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*; issues of reciprocity; Proposals addressing the International Certification Program; and Proposals assigned from the Program Committee.

Note: This change to the BYLAWS becomes effective at the close of the Conference at which it has been adopted (May 17, 2017).

Proposal: 215
Document: 2015 PMO
Pages: xii, 48, 60, 69, 87, 118, 184, 186, 187, 222, 223 and 341

Make the following changes to the 2015 PMO:

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APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS.....

I. INDIVIDUAL WATER SUPPLIES AND CATEGORY I. WATER THAT IS USED FOR POTABLE WATER PURPOSES, WHICH HAS BEEN RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN A MILK PLANT AS DEFINED IN APPENDIX D. OF THIS ORDINANCE – BACTERIOLOGICAL.....

II. RECLAIMED WATER AND RECIRCULATED COOLING WATER – BACTERIOLOGICAL.....

III. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST.....

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

ITEM 8r. WATER SUPPLY ...

ADMINISTRATIVE PROCEDURES ...

Page 48:

7. Samples for bacteriological examination of individual water supplies and reclaimed water from heat exchanger processes or compressors on dairy farms as defined in Appendix D. of this Ordinance are taken upon the initial approval of the physical structure or water system, based upon the requirements of this ~~Ordinance~~ Ordinance; when any repair or alteration of the water supply system has been made; and at least once every three (3) ~~years~~ year period for individual water supplies and at least once every six (6) month period for reclaimed water, thereafter. Provided, that individual water supplies with buried well casing seals, installed prior to the adoption of this Section, shall be tested at ~~intervals no greater than~~ least once every six (6) months ~~month period~~ apart. Whenever such samples indicate either the presence of E. coli bacteria or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this Section.

Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) ~~months~~ month period. Bacteriological examinations shall be conducted in a laboratory acceptable to the Regulatory Agency. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated three (3) year or six (6) month period, respectively, plus the remaining days of the month in which the sample is due. ...

ITEM 18r. RAW MILK COOLING ...

ADMINISTRATIVE PROCEDURES ...

Page 60:

2. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested ~~semiannually~~ at least once every six (6) month period and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken under the direction of the Regulatory Agency and examination shall be conducted in a laboratory acceptable to the Regulatory Agency. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating cooling water systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either USP Grade, Food Grade or generally-recognized-as-safe (GRAS). To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due. ...

STANDARDS FOR GRADE “A” PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING LOW-ACID MILK AND/OR MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGING LOW-ACID MILK AND/OR MILK PRODUCTS ...

ITEM 7p. WATER SUPPLY ...

ADMINISTRATIVE PROCEDURES⁸ ...

Page 69:

8. Samples for bacteriological testing of individual water supplies and Category I and II, when required, water that has been reclaimed from milk and milk products and from heat exchangers of compressors in milk plants as defined in Appendix D. of this Ordinance are taken upon the initial approval of the physical structure or water system; ~~each~~ at least once every six (6) months month period thereafter; and when any repair or alteration of the water ~~supply~~ system has been made. Provided, that when water is hauled to the milk plant, such water shall be sampled for bacteriological examination at the point of use and submitted to an official laboratory at least four (4) times in separate months during any consecutive six (6) ~~months~~ month period. Samples shall

be taken by the Regulatory Agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

ITEM 15p. PROTECTION FROM CONTAMINATION ...

ADMINISTRATIVE PROCEDURES ...

15p.(B) ...

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2. Except as permitted in Item 16p, there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products not completely separated from pasteurized milk and milk products shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of Pasteurization.

In the case of water that comes in contact with pasteurized milk and/or milk products it shall:

- a. Meet at least the minimum times and temperatures provided for in the definition of Pasteurization in equipment that may not meet Item 16p; or
- b. Meet the requirements found in Appendix H., Section IX. of this *Ordinance*; or
- c. Have undergone an equivalent process found acceptable by FDA and the Regulatory Agency; or
- d. Have undergone a hazard evaluation and safety assessment of the specific milk plant's water supply, which may come from an individual water supply, municipal water system or Category I. water that is used for potable water purposes, which has been reclaimed from milk and milk products and from heat exchangers or compressors in the milk plant as defined in Appendix D. of this Ordinance, and application involved and has undergone an additional treatment to destroy or remove bacteria acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product¹⁰. Supporting information shall be submitted to and approved by the Regulatory Agency. The supporting information may include, but is not limited to the following:

- (1) Statement of proposal;
- (2) Intended use;
- (3) Review of equipment to be used in the process;
- (4) Diagram of the process of interest;
- (5) Documentation that the specific milk plant's source water supply shall meet or exceed meets or exceeds the EPA Safe Drinking Water Bacteriological Standards. ~~The Safety Assessment~~ safety assessment shall include a comparison of samples from the facility's specific milk plant's water source supply, pasteurized water, and proposed pasteurized equivalent water. Water samples of the pasteurized equivalent water shall be collected daily for two (2) weeks following approval of the initial installation and at least once every six (6) months month period thereafter; and

(6) Protocol for the continued monitoring of criteria and procedures. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system.

...

ITEM 17p. WATER SUPPLY ...

ADMINISTRATIVE PROCEDURES ...

Page 118:

11. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested ~~semiannually~~ at least once every six (6) month period and shall comply with the Bacteriological Standards of Appendix G. of this *Ordinance*. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be USP Grade, Food Grade or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

APPENDIX D. STANDARDS FOR WATER SOURCES ...

Page 184:

V. WATER RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN MILK PLANTS ...

CATEGORY I. USED FOR POTABLE WATER PURPOSES

Reclaimed water to be used for potable water purposes, including the production of culinary steam, shall meet the following requirements and shall be documented:

1. Water shall comply with the Bacteriological Standards of Appendix G. of this *Ordinance*, and, in addition, shall not exceed a total plate count of 500 per milliliter (500/mL).
2. Samples shall be collected daily for two (2) weeks following initial approval of the installation and ~~semi-annually~~ at least once every six (6) month period thereafter. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. ...

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CATEGORY II. USED FOR LIMITED PURPOSES

Reclaimed water may be used for the following limited purposes including: ...

Provided that for these uses, Items 3-11 of Category I are satisfied and shall be documented. Or, in the case of reclaimed water from heat exchangers or compressors, Items 5-11 are satisfied and shall be documented.

1. There is no carry-over of water from one (1) day to the next, and any water collected is used promptly; or
 - a. The temperature of all water in the storage and distribution system is maintained either at 7°C (45°F) or below, or at 63°C (145°F) or higher by automatic means; or
 - b. The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, or UV disinfection that complies with the criteria in Appendix D. of this *Ordinance*, prior to the water entering the storage tank; or
 - c. The water shall comply with the Bacteriological Standards of Appendix G. of this *Ordinance* and, in addition, shall not exceed a total plate count of 500 per milliliter (500/mL). Samples shall be collected daily for two (2) weeks following initial approval of the installation and ~~semi-annually~~ at least once every six (6) month period thereafter. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. All physical, chemical and microbiological tests shall be conducted in accordance with the latest edition of *SMEWW*; and that,
2. Distribution lines and hose stations are clearly identified as “limited use reclaimed water”; and
....

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VI. WATER RECLAIMED FROM HEAT EXCHANGER PROCESSES OR COMPRESSORS ON GRADE “A” DAIRY FARMS

Potable water utilized for heat exchange purposes in plate or other type heat exchangers or compressors on Grade “A” dairy farms may be salvaged for the milking operation if the following criteria are met: ...

6. The water shall comply with the Bacteriological Standards of Appendix G. of this *Ordinance*.
7. Samples shall be collected and analyzed prior to initial approval and ~~semi-annually~~ at least once every six (6) month period thereafter.
8. Approved chemicals, such as chlorine, with a suitable retention period, or UV disinfection that complies with the criteria in Appendix D. of this *Ordinance* may be used to suppress the development of bacterial growth and prevent the development of tastes and odors. ...

Page 222:

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

I. INDIVIDUAL WATER SUPPLIES AND CATEGORY I. WATER THAT IS USED FOR POTABLE WATER PURPOSES, WHICH HAS BEEN RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN A MILK PLANT AS DEFINED IN APPENDIX D. OF THIS *ORDINANCE* - BACTERIOLOGICAL

Reference: Section 7., Items 8r, ~~and~~ 7p, and 15p; and Appendix J, Section D., Item 7 of this Ordinance.

Application: To individual water supplies, used by dairy farms, milk plants, receiving stations, transfer stations, ~~and~~ milk tank truck cleaning facilities and single-service containers and/or closures fabrication plants; and to Category 1 water used in milk plants.

Frequency: Initially, Water water shall be tested for the presence of total coliform and if positive for total coliforms the water shall be tested for E. coli initially; after any repair, modification or disinfection of the individual water supplies of dairy farms, milk plants, receiving stations, transfer stations, ~~and~~ milk tank truck cleaning facilities and single-service containers and/or closures fabrication plants; and thereafter, semiannually at least once every six (6) month period for all milk ~~plants~~ plant's, receiving ~~stations~~ station's, transfer ~~stations~~ station's, and milk tank truck cleaning ~~facilities~~ facility's individual water supplies and Category 1 water use in milk plants; at least once every twelve (12) month period for single-service containers and/or closures fabrication plants; and at least once every three (3) years year period on dairy farms thereafter. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month, twelve (12) month, or three (3) year period, respectively, plus the remaining days of the month in which the sample is due.

Criteria: The water shall be tested for the presence of total coliform initially and if positive for total coliform the same sample shall be tested for E. coli. A MPN of total coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Multiple Tube Fermentation (MTF) technique, or one (1) of the Chromogenic Substrate multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one (1) vessel containing 100 mL is tested using the MTF technique or one (1) of the Chromogenic Substrate multiple tube procedures. A MPN of E. coli organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Fluorogenic Substrate multiple tube procedures; a direct count of less than 1 per 100 mL using the MF Fluorogenic Substrate multiple tube technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one (1) vessel containing 100 mL is tested using the Fluorogenic Substrate. Any sample producing a bacteriological result of Too Numerous To Count (TNTC) or Confluent Growth (CG) by the MF technique; or turbidity in a presumptive test with no gas production and with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC), from the same sample or subsequent resample, of less than 500 colony forming units (CFU) per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA/NCIMS 2400 Forms. (Refer to M-a-98, latest revision.)

Corrective Action: When the laboratory report ~~on~~ for the water sample indicates that the sample is positive for total coliform but negative for the presence of E. coli or indicates a HPC of greater than 500 CFU per mL on a sample that had previously been invalidated, the water system in question shall be considered at risk for pathogenic contamination and shall ~~again~~ be physically inspected by the facility and necessary corrections made by the facility until subsequent samples are bacteriologically satisfactory. This inspection shall be documented and completed within thirty (30) days of the date of the positive test result. If ~~the~~ this initial inspection and corrective action

are completed, but the water in question is still testing positive for total coliform but negative for E. coli, the facility Regulatory Agency shall continue to investigate conduct a physical inspection of the water supply in question and the facility shall correct any problems identified until a subsequent sample is bacteriologically satisfactory. When the laboratory report ~~on~~ for the water sample indicates that the sample is positive for both total coliform and E. coli, or the facility has failed to complete the water system inspection within thirty (30) days of the initial positive test result, the water is considered unsatisfactory. The water system in question shall be physically inspected by the Regulatory Agency and necessary corrections made by the facility until a subsequent sample is bacteriologically satisfactory.

Page 223:

II. RECLAIMED WATER AND RECIRCULATED COOLING WATER – BACTERIOLOGICAL

Reference: Section 7., Items 8r, 18r, 7p and 17p; and Appendix J, Section D., Item 7 of this Ordinance.

Application: To reclaimed water and recirculated cooling water, used in milk plants, receiving stations, transfer stations, single-service containers and/or closures fabrication plants (water baths) and on dairy farms.

Frequency: Initially; after any repair, modification or disinfection of the reclaimed water and/or recirculated cooling water supplies of dairy farms, milk plants, receiving stations, ~~and~~ transfer stations and single-service containers and/or closures fabrication plants (water baths); and reclaimed water and recirculated cooling water used in milk plants, receiving stations, transfer stations, single-service containers and/or closures fabrication plants (water baths) and on dairy farms shall be tested semiannually at least once every six (6) month period thereafter. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

Criteria: The reclaimed water and recirculated cooling water shall be tested for the presence of total coliform. A MPN of total coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the MTF technique, or one (1) of the Chromogenic Substrate multiple tube procedures; a direct count of less than 1 per 100 mL using the MF technique; or a P/A determination indicating less than 1 per 100 mL when one (1) vessel containing 100 mL is tested using the MTF technique or one (1) of the Chromogenic Substrate multiple tube procedures. The Chromogenic Substrate multiple tube procedures are not acceptable for recirculated cooling water. Any sample producing a bacteriological result of TNTC or CG by the MF technique; or turbidity in a presumptive test with no gas production and with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a HPC₂ from the same sample or subsequent resample, of less than 500 CFU per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water, or the applicable FDA/NCIMS 2400 Forms. (Refer to M-a-98, latest revision.)

Corrective Action: When the laboratory report ~~on~~ for the reclaimed water or recirculated cooling water sample is indicates that the sample is unsatisfactory, the reclaimed water or recirculated cooling water supply in question shall again be physically inspected by the Regulatory Agency and necessary corrections made by the facility until a subsequent samples sample is are bacteriologically satisfactory. ...

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

D. FABRICATION PLANT STANDARDS

Page 341:

7. WATER SUPPLY ...

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; ~~each~~ at least once every twelve (12) months month period thereafter; and when any repair or alteration of the individual water supply system has been made. The examination of the sample shall be conducted in an Officially Designated Laboratory. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated twelve (12) month period plus the remaining days of the month in which the sample is due.

d. Water baths utilizing recirculated water for cooling product-contact surfaces shall comply with the bacteriological standards outlined in Appendix G. of this *Ordinance* and shall be tested ~~semi-annually~~ at least once every six (6) month period. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

e. Records of all required water tests shall be maintained at a location acceptable to the Rating/Regulatory Agency for a period of two (2) years. ...

.....
Proposal: 134
Document: 2015 PMO
Pages: xix and 380-384

Make the following changes to the 2015 PMO:

ABBREVIATIONS AND ACRONYMS

Page xix:

~~I.U.~~ IU (International Units) ...

MC (Milk Company)
mcg (micrograms) ...

APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS

PROCESS/METHODS OF VITAMIN ADDITION

Vitamin fortification can be accomplished by the addition of vitamins at many different points in the processing system, preferably after separation, including at the ~~pasteurizing vat~~ batch pasteurizer, ~~to the~~ HTST, HHST or UP pasteurization system constant-level tank, or on a continuous basis into the pipeline after standardization and prior to pasteurization in accordance with the manufacturer's recommendations. Both batch addition and addition with metering pumps can be used. The batch addition procedure requires an accurate measurement of the volume of milk to be fortified, an accurate measurement of the vitamin concentrate, and proper mixing. When a vitamin metering pump(s) is used with within an HTST, ~~or~~ HHST or UP ~~unit~~ pasteurization system the vitamin metering pump(s) shall be installed so as to be activated only when the ~~unit~~ pasteurization system is in forward-flow. The addition of vitamins shall be accomplished prior to pasteurization in accordance with the manufacturer's recommendations.

The problem of under fortification is often related to the point in the pasteurization system where fortification takes place. Vitamins A and D are fat-soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins are susceptible to this migration problem.

If vitamins are added in the proper amount before separation and standardization, and the product is separated and standardized, then the ~~low-fat~~ lowfat milk and/or milk product will tend to be under fortified and the high fat milk and/or milk product over fortified. Water-soluble vitamin concentrates can minimize this problem if vitamins are added before separation. Processors who use this procedure should perform confirmatory assays to ensure proper fortification levels of each milk and/or milk product.

Many HTST, HHST or UP pasteurization systems are now ~~being used with~~ using in-line fat standardization, which also makes possible switching, without stopping, from milk ~~and/or~~ milk products being fortified with ~~Vitamin~~ vitamin D to those being fortified with both vitamins A and D. These pasteurization systems require metered injection of the proper vitamins at a point after standardization and before pasteurization. Sanitary positive-displacement pumps are available for this purpose.

There are two (2) types available:

1. The first is a piston type metering pump without valves. It is equipped with a micrometer, which allows accurate and reproducible amounts of vitamins to be added based on the rate of product flow through the system.
2. The other type is a peristaltic pump that offers precise control. This precise control is possible since the volume can be controlled by the tubing size and the pump speed. This system simplifies cleaning, since only the tube is in contact with the vitamin concentrates.

These positive-displacement pumps have a history of reproducibility and reliability. All metering pumps should be designed to conform with this *Ordinance*.

The recommended injection point for the vitamins is after separation and prior to homogenization. This allows the homogenization process to distribute the vitamins throughout the milk. A check-valve is recommended to prevent milk from contaminating the vitamin concentrate.

Separate pumps, tubing and check-valves are recommended when multiple types of vitamin concentrates are injected. (Refer to Figure 58.)

Pumps should be calibrated based on the pasteurization system flow rate. If flow rates change for different milk or milk products, additional vitamin pumps may be needed. Re-calibration of the metering pumps is not recommended without verifying the accuracy. Routine calibration of metering pumps is recommended. The following are recommended to achieve desired vitamin fortification levels:

1. Management shall be committed to proper fortification and concerned with both over and under levels.
2. Design the system correctly for proper vitamin addition in which concentrate is added after standardization and before pasteurization.
3. Written procedures and training should be provided to all employees responsible for vitamin fortification for each milk and/or milk product to be fortified. These procedures should focus on milk or milk product start-up and milk or milk product change-over.
4. Maintain accurate records of vitamins used and milk and/or milk products produced, checked daily against theoretical use. Care should be taken that adequate fortification of small ~~run~~ batches of milk or milk products like skim milk is not masked by much larger ~~volumes~~ volume batches of reduced-fat (2%) or other partly skimmed milk or milk products.

BATCH ADDITION

Use only calibrated measuring devices, such as plastic graduated cylinders or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e., if 8 mL is added, a 10 mL graduated cylinder would be appropriate. Measuring devices should be rinsed with the milk or milk product being fortified to insure no residual concentrate is left.

METERING PUMPS

Use an accurate, sanitary, positive-displacement metering pump with a scheduled cleaning procedure after use. ~~For batch addition, use only accurate, calibrated measuring devices, such as plastic graduated cylinders, or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e., if 8 mL is added, a 10 mL graduated cylinder would be appropriate. Measuring devices should be rinsed with the milk or milk product being fortified to insure no residual concentrate is left.~~

Use a check-valve on the injection line to prevent milk or milk product from being pushed back into the injection line. ~~This depends on the pump displacement.~~

Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows.

Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace the tubing regularly.

Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis. A regular systematic cleaning and sanitizing schedule shall be maintained for these vessels, pumps and tubing.

Vitamin concentrates should be stored and held in accordance with the manufacturer's recommendations for maximum shelf life.

~~Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows.~~

Analyze finished milk and/or milk products regularly. Results should be reported in International Units (~~I.U.~~ IU)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory; one that is familiar with the handling and testing of vitamin fortified ~~dairy~~ milk and milk products.

Care shall be taken when reprocessing reclaimed milk and/or milk product products so vitamin A and/or D 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.

GOOD MANUFACTURING PRACTICES

Good manufacturing practices require that the vitamin A and D levels be in compliance with 21 CFR 131.110-Milk, which states: “(b) *Vitamin addition (Optional)*. (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 ~~I.U.~~ International Units thereof within limits of good manufacturing ~~practices~~ practice. (2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 ~~I.U.~~ International Units thereof within limits of good manufacturing practice.”

~~For the purpose of label claims, compliance for nutritional labeling of food 21 CFR 101.9 applies, and states:~~

~~“(3) (i) *Class I. Added nutrients in fortified or fabricated foods; and*~~

~~(4) (i) *Class I vitamins, mineral, protein, dietary fiber, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.~~

Therefore, if added, the acceptable range for vitamins A and D, in the standardized milk products listed in 21 CFR, 131.110 Milk, 131.111 Acidified Milk, 131.112 Cultured Milk, 131.127 Nonfat Dry Milk Fortified with Vitamin A and D (vitamin addition not optional), 131.200 Yogurt, 131.203 Lowfat Yogurt, and 131. 206 Nonfat Yogurt are as follows:

~~* 100% – 150 % of label claims = (400 – 600 I.U. per quart for vitamin D and 2000 – 3000 I.U. per quart for vitamin A).~~

~~*Within method variability~~

Fluid milk ~~products~~ found below 100% (2000 IU (600 mcg) per quart) or above 150% (3000 IU (900 mcg) per quart) for vitamin A ~~of the required values or label claims~~ or found below 100% (400 IU (10 mcg) per quart) or above 840 IU (21 mcg) per quart* for vitamin D₃ ~~should~~ shall be resampled and the cause of the problem determined.

*A five percent (5%) overage addition of vitamin D₃, i.e. up to 840 IU (21 mcg) per quart will be allowed, based on expected method repeatability.

(Refer to M-a-98, latest revision, for the specific milk that has FDA validated and NCIMS accepted test methods for vitamins A and/or D.)

Additionally, 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term (b)-Nutrient addition states: "That nutrients ~~Nutrients must 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. ~~for products which combine a nutrient content claim, i.e., lowfat, non-fat, or reduced fat, with a standardized term, i.e., milk, sour cream, eggnog.~~ The addition of nutrients shall be reflected in the ingredient statement." Therefore, ~~vitamins~~ vitamin A and D shall be added to dairy milk and milk products from which fat has been removed; such as, reduced fat, ~~lowfat,~~ and nonfat/skim dairy milk and milk products, in an amount necessary to replace the amount of ~~these vitamins~~ vitamin A lost in the removal of fat.

TESTING METHODS

Test methods used for the detection of vitamins A and/or D shall be acceptable to FDA or other official methodologies that give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by FDA and which is acceptable to the Regulatory Agency. (Refer to M-a-98, latest revision, for the specific milk ~~and/or milk products~~ that ~~have~~ has FDA validated and NCIMS accepted test methods for vitamins A and/or D.)

TYPE OF VITAMIN CONCENTRATES AVAILABLE

A number of different types of vitamin concentrates are available. All contain vitamin D and/or vitamin A palmitate ~~with a carrier consisting of any of the following: butter oil, corn oil, evaporated milk, non-fat dry milk, polysorbate 80, propylene glycol and glycerol monooleate.~~ It is best to store all vitamin concentrates under refrigeration unless the manufacturer's directions indicate otherwise. To achieve adequate dispersion, viscous vitamin concentrates should be brought to room temperature before addition.

NEED FOR ADDITION

Vitamin A is fat-soluble. It will dissolve when mixed with fat and will not dissolve in water. For this reason, Vitamin vitamin A is found in whole milk and to a lesser degree in ~~low-fat~~ lowfat and absent in ~~non-fat~~ nonfat, unless these milk products are fortified.

Vitamin A performs many functions. One is to enable the retina of the eye to respond to dim light. Deficiency of vitamin A produces night blindness. Vitamin A is also involved in the ability of the eye to discern color.

Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of ~~fresh~~ milk with Vitamin D is acknowledged to have virtually eliminated rickets in milk drinking children. ~~Since normal~~ Adequate levels of Vitamin vitamin D are necessary for optimal calcium absorption in children, ~~it~~ It is also known that ~~these levels are required as one~~ the requirement for vitamin D

increases ~~in~~ with age up to the age of 70. ~~It~~ Adequate levels of vitamin D ~~has~~ have been associated with reducing the incidence of osteoporosis ~~in premenopausal women.~~

~~Vitamin A performs many functions. One is to enable the retina of the eye to respond to dim light. Deficiency of Vitamin A produces night blindness. Vitamin A is also involved in the ability of the eye to discern color.~~

Excessive levels of ~~Vitamins~~ vitamins A and D in fluid milk can be a potential threat to public health. Over fortification with levels of ~~Vitamin~~ vitamin A over 6000 ~~I.U.~~ IU (1800 mcg) per quart and ~~Vitamin~~ vitamin D over 800 ~~I.U.~~ 1500 IU (37.5 mcg) per quart in fluid milk should be referred to FDA for a health hazard review.

PROBLEMS INVOLVED WITH FORTIFICATION

Milk and milk products that contain a large proportion of fat are relatively good dietary sources of ~~Vitamin~~ vitamin A, but as is the case with other natural foods, the ~~Vitamin~~ vitamin D content of unfortified milk is quite low. As with other milk components, ~~Vitamin~~ vitamin A and D levels are affected by breed, season, diet, lactation and in the case of ~~Vitamin~~ vitamin D, animal exposure to sunlight.

In general, when lactating animals are transferred from pasture to winter rations in the fall, a decline in the ~~Vitamin~~ vitamin A and D levels can be expected in the raw milk. This occurs slowly through the winter season until the animals are once more on pasture in the spring. With the proper selection of feed and diet concentrates this effect can be kept to a minimum. Natural levels of ~~Vitamin~~ vitamin A range from 400 ~~I.U.~~ IU (12 mcg)/quart in winter to 1200 ~~I.U.~~ IU (360 mcg)/quart in summer, and ~~Vitamin~~ vitamin D, 5 ~~I.U.~~ IU (.125 mcg)/quart in winter to 40 ~~I.U.~~ IU (1 mcg)/quart in summer. These are approximate ranges to indicate possible seasonal variations. Because of seasonal and other variations in natural vitamin levels it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices. Vitamin concentrate potency degrades with time. Concentrates should be stored in accordance with manufacturer's recommendation to maintain label potency. Vitamin concentrate potency should be verified by the vitamin supplier.

Vitamin D is very stable in homogenized ~~whole~~ milk and is not affected by pasteurization or other processing procedures. Vitamin D in fortified homogenized ~~whole~~ milk will remain constant with little or no loss of vitamin potency during long periods of proper storage. No loss of vitamin D will be experienced under normal shelf life periods.

Vitamin A and D fortified reduced fat and nonfat/skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in ~~whole~~ milk. In fluid reduced fat and nonfat/skim ~~or low fat~~ milk, added vitamin A deteriorates gradually during normal storage of the milk at 4.5°C (40°F) in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers. The photo destruction of added vitamin A is dependent on the intensity and wave-length of light and the milk source. The use of amber or brown glass bottles, pigmented plastic containers formulated with specific light barriers and colored paper cartons retard this destruction. Vitamin A losses in reduced fat milk (2%) from five (5) dairy plants ranged from 8% to 31% when ~~they~~ the five (5) reduced fat milks were exposed to 200 foot-candles (220 lux) of fluorescent light for twenty-four (24) hours in opaque plastic containers. Use of pigmented light-blocking containers or ~~gold~~ UV light-blocking shields over fluorescent tubes practically eliminated these losses.

NOTE: Figure 58 details a two (2) speed vitamin fortification installation using two (2) pumps and two (2) vitamin concentrate sources. This enables changing from different vitamin concentrates and different speed pumps via the adjustment of three-way valves.

Recommendations:

1. Use a sanitary check-valve(s) to separate ~~milk lines~~ milk lines from vitamin concentrates.
2. All milk or milk product-contact surfaces ~~should~~ shall be of a sanitary design, easily cleanable and available for inspection. ...

Document: 2015 MMSR
Page: 105

Make the following changes to the 2015 MMSR:

Page 105:

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3. PERMITS, Section 5. INSPECTION OF MILK PLANTS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS and Section 16. PENALTIES). Prorate by enforcement action(s) in compliance. ...

PRODUCT COMPLIANCE ...

Category II: Permit Suspension ...

- c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended.
- d. Violation of Vitamin Fortification Levels (Refer to ~~M-I-92-13~~ Appendix O. of the *Grade "A" PMO*): Determine the cause and re-sample or withhold product from the market. ...

.....
Proposal: 207
Document: 2015 PMO
Pages: 2, 3, 6, 26, 139 and 141

Make the following changes to the 2015 PMO:

Page 2:

E. BULK MILK HAULER/SAMPER: ~~A bulk milk hauler/sampler is any person who collects~~ 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 raw milk products. This person is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Page 3:

O. DAIRY PLANT SAMPLER: A person responsible for the collection of official samples for regulatory purposes outlined in Section 6. of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every ~~two (2) year~~ twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Dairy plant samplers that are also Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSOs) are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

Page 6:

V. INDUSTRY PLANT SAMPLER: 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. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every ~~two (2) year~~ twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Page 26:

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

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative official “Universal” sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-line-sampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk milk tank and/or silo, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of a representative official “Universal” sample related to samples collected from direct loaded milk tank trucks either at the dairy farm or receiving milk plant, receiving station or transfer station, if acceptable to the Regulatory Agency.

APPENDIX B. MILK SAMPLING, HAULING, AND TRANSPORTATION ..

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 ~~each two (2) year~~ 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.

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 bulk milk hauler/sampler is ~~any a person who collects~~ 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 ~~each two (2) year~~ 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*. ~~These industry~~ Industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once ~~each two (2) year~~ 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), ~~which is derived from the most current edition of *SMEDP*~~ 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.

Page 141:

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:

.....
Proposal: 231
Document: 2015 PMO
Page: 10

Make the following changes to the 2015 PMO:

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; and ~~commingled milk tank truck~~ 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 ~~and bacterial~~ limits.

Document: 2015 EML
Page: 4

Make the following changes to the 2015 EML:

Page 4:

10. OFFICIALLY DESIGNATED LABORATORY: 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; and ~~commingled milk tank truck~~ 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: 228
Document: 2015 PMO
Pages: 27 and 339

Make the following changes to the 2015 PMO:

Page 27:

NOTE: If the production of Grade “A” raw milk or any Grade “A” ~~condensed or dry milk or milk product,~~ as defined in this *Ordinance*, is not on a continuous yearly monthly basis, ~~at least five (5) samples shall be taken within a continuous production period~~ and; therefore, cannot meet this Section’s sampling frequency requirement that during any consecutive six (6) months, at least four (4) samples of the Grade “A” raw milk or Grade “A” milk or milk product 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, then a sample of the Grade “A” raw milk or Grade “A” milk or milk product shall be collected during each month of production. ...

Page 339:

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

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

NOTE: If the production of single-service containers and closures is not on a continuous monthly basis and; therefore, cannot meet this Section’s sampling frequency requirement that during any consecutive six (6) months, at least four (4) sample sets shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, then at least one (1) sample set shall be collected during each month of production. ...

Make the following changes to the 2015 MMSR:

Page 95:

8. At least four (4) samples collected in at least four (4) separate months from each dairy farm's milk supply, during any consecutive six (6) months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

a. Four (4) samples taken from each dairy farm during any consecutive six (6) month period. However, if the production of Grade "A" raw milk is not on a continuous monthly basis and; therefore, cannot meet the PMO sampling frequency as cited, then a sample of the Grade "A" raw milk shall be collected during each month of production for any consecutive six (6) month period. (Use *MMSR*, Page 10 as a guide.)

NOTE: Use *MMSR*, Section B., 2., e.2.), as a guide for frequency determination.

b. Required bacterial counts, somatic cell counts, drug residue and cooling temperature checks performed on each sample in an official or officially designated laboratory. ...

PART II. MILK PLANT ...

Page 102:

7. Samples of each milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.) ...

b. During any consecutive six (6) months, at least four (4) samples of each Grade "A" milk and/or milk product processed, as defined in Sections 1. and 6. of the *Grade "A" PMO* shall be collected 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. However, if the production of any Grade "A" ~~condensed or dry milk or milk~~ product, as defined in the *Grade "A" PMO*, is not on a continuous yearly monthly basis, ~~at least five (5) samples shall be taken within a continuous production period~~ and; therefore, cannot meet the PMO sampling frequency requirement as cited, then a sample of the Grade "A" milk or milk product shall be collected during each month of production. ...

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's concurrence with the NCIMS Executive Board.

.....

Proposal: 113
Document: 2015 PMO
Pages: 76 and 141

Make the following changes to the 2015 PMO:

Page 76:

All milk tank trucks that transport Grade "A" milk and/or milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. 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.

Page 141:

3. Milk Quality Checks: ...

c. Record milk temperature, collection time (optionally, in military time (24 hour clock) Note: The collection time for a direct load farm shall be defined as when the tanker is picked up from the farm), 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 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 weight ticket shall be defined as when the milk tank truck is picked up from the dairy farm.

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED SEPTEMBER 8, 2017

FDA non-concurred with this Proposal strictly based on the need for granting FDA editorial license to add the added text from page 76 to the similar text within Appendix B. of the PMO and to delete the text in the first Note: within 3. **Milk Quality Checks** on page 141, as this is in direct conflict

with the amended version of the **NOTE:** that was added by Committee and Council action and passed by the voting delegates. FDA believes that this proposed change is warranted and appropriate to maintain the consistency in the language and the conventions of the NCIMS documents. FDA also believes that this suggested wording deletion does not change the intent of the Proposal as passed at the 2017 NCIMS Conference.

NOTE: The text that is ~~struck through~~ was to be deleted from the current text in the PMO and the text that is underlined was text that was to be added to the PMO as addressed in the individual Proposal as passed at the conference. The text that is ~~double struck through~~ is text that is to be deleted from the PMO and/or text of the passed Proposal and 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.

FDA met with the NCIMS Executive Board on October 11-12, 2017 concerning this Proposal as passed during the 2017 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 113 as follows:

Page 76:

All milk tank trucks that transport Grade “A” milk and/or milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. 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.

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION...

Page 141:

3. Milk Quality Checks: ...

c. Record milk temperature, collection time (optionally, in military time (24 hour clock) ~~Note: The collection time for a direct load farm shall be defined as when the tanker is picked up from the farm~~), 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 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 weight ticket shall be defined as when the milk tank truck is picked up from the dairy farm.

VI. MILK TANK TRUCK PERMITTING AND INSPECTION ...

MILK TANK TRUCK STANDARDS: ...

3. Equipment Construction, Cleaning, Sanitizing and Repair: ...

Page 147:

b. Cleaning and Sanitizing Requirements ...

(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. ...



Proposal: 114
Document: 2015 PMO
Page: 77

Make the following changes to the 2015 PMO:

Page 77:

NOTE: The NSDA, Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested ~~monthly~~ at least once every (3) month period by the Regulatory Agency.



Proposal: 115
Document: 2015 PMO
Page: 80

Make the following changes to the 2015 PMO:

Page 80:

~~e. Single service glass containers shall be sanitized immediately prior to filling. Sanitizing solutions shall be removed from the container prior to filling. Inverted draining, sterile air evacuation or other effective methods acceptable to the Regulatory Agency may accomplish this.~~

Re-Letter the remaining Items.



Proposal: 120
Document: 2015 PMO
Page: 101

Make the following changes to the 2015 PMO:

Page 101:

Modify paragraph (3) of ITEM 16p.(B),2,c. as follows:

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

.....

Proposal: 121
Document: 2015 PMO
Pages: 101, 323, 325 and 328

Make the following changes to the 2015 PMO:

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

2. AUTOMATIC MILK CONTROLLER ...

Page 101:

d. Holding Tube ...

(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 ~~of an~~ inch per foot). ...

APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS -TESTS ...

II. TESTING PROCEDURES ...

11.3 CALCULATED PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING INDIRECT HEATING ...

Page 323:

5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible

steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

NOTE: 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 ~~of an inch~~) per foot). ~~If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water. ...~~

11.4 CALCULATED PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING DIRECT HEATING ...

Page 325:

5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

NOTE: 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 ~~of an inch~~) per foot). ~~If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water. ...~~

11.5 HHST PASTEURIZATION SYSTEMS HOLDING TIME USING DIRECT STEAM INFUSION HEATING WITH A STEAM PRESSURE RELIEF POP-OFF VALVE AND A VACUUM CHAMBER ORIFICE IN PLACE OF A TIMING PUMP ...

Page 328:

9. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

NOTE: 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 ~~of an inch~~) per foot). ~~If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water. ...~~

.....
Proposal: 301
Document: 2015 PMO
Page: 131

Make the following changes to the 2015 PMO:

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

ADMINISTRATIVE PROCEDURES ...

Page 131:

11. Aseptically processed and packaged low-acid 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 source(s) of the milk and/or milk products used to produce aseptically processed and packaged low-acid milk and/or milk products shall be IMS listed. ... For milk plants that produce aseptically processed and packaged Grade “A” low-acid 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 Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing ~~aseptically processed and packaged~~ Grade “A” fermented high-acid shelf stable milk and/or milk products ~~regulated under 21 CFR Parts 108 and/or 110~~ shall expire on December 31, ~~2017~~ 2019, unless extended by future conference action. ...

.....
Proposal: 212
Document: 2015 PMO
Page: 141

Make the following changes to the 2015 PMO:

Page 141:

- 2. Equipment Requirements:**
- a. Sample rack and compartment to hold all samples collected. ...
 - f. Approved sanitizing agent and sample dipper container.
 - g. ~~Watch~~ An accurate device for timing milk agitation.

.....
Proposal: 214
Document: 2015 PMO
Page: 212

Make the following changes to the 2015 PMO:

Insert the following language in Appendix F I. METHODS OF SANITIZATION after the description under the heading HOT WATER:

Page 212:

LIGHT

Pulsed Light as described in 21 CFR 179.41 may be safely used for the treatment of foods. Pulsed light used as a sanitizer for food packaging should not affect the packaging materials in a manner that allows migration of packaging components to food at a level considered to be unsafe. Because glass is a durable and impermeable material to the migration of any substances to food, the use of pulsed light to sanitize the single-service glass containers for milk and/or milk products would unlikely pose any safety concerns.

Thus, pulsed light may be safely used on single-service glass containers providing that the following provisions are met:

1. The interior surface of Single-Service Glass Containers shall be treated to a minimum fluence of 1 J/cm².
2. Daily the pulsed light treatment system shall be checked by a calibrated sensor to ensure the required minimum treatment of each container as stated in 1. The sensor shall be calibrated annually against a standard traceable to recognized standard such as National Institute of Standards and Technology (NIST). A record of the calibration shall be available for inspection by the Regulatory Agency.

The pulsed light generator shall meet the requirements of 40 CFR 152.500 Requirements for Devices. The dairy plant shall maintain documentation demonstrating that the device is in compliance with 40 CFR 152.500. The manufacturer of the device generating the pulsed light shall be registered as required by 40 CFR 152.500 and subject to the applicable record keeping requirements. The pulsed light generating device shall be subject to the labeling requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 2(q)(1) and 40 CFR 156 including the manufacturer’s registration number.

Add Appropriate Information to, Abbreviations and Acronyms (FIFRA), and Appendix L (FIFRA Section 2(q) (1) and 40 CFR 156).

.....
Proposal: 127
Document: 2015 PMO
Page: 234

Make the following changes to the 2015 PMO:

Page 234:

11. 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 timing system's flow promoting device(s) shall be located upstream from the magnetic flow meter.~~

21. 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.

(Editorial note: Renumber remaining Items accordingly.)

.....

Proposal: 129
Document: 2015 PMO
Page: 246

Make the following changes to the 2015 PMO:

Page 246:

When used for air agitation, tubing used to introduce air into the product and/or product zone shall be sanitary piping that conforms to the requirements of Item 10p, ~~Section 7~~, of this *Ordinance*. There shall ~~not~~ be no any threads on product-contact surfaces. When drilled or perforated pipe is used, internal drilling burrs shall be removed and the orifices shall be chamfered on the outer surface of the pipe. If the volume of the air from the compressing equipment is in excess of that required for satisfactory agitation, suitable means shall be employed to eliminate the excess volume.

In milk plants and receiving stations, when air under pressure is used for the movement of milk and/or milk products to and/or from a milk storage tank(s)/silo(s), a single final filter may service multiple points of application at milk storage tank(s)/silo(s) provided that a sanitary check valve is installed immediately downstream of the final filter and all sanitary piping, fittings, and connections downstream from the sanitary check valve shall conform to the requirements of Item 10p of this *Ordinance* and are cleaned and sanitized at least once each day used, in accordance with Item 12p of this *Ordinance*.

NOTE: For additional details, refer to the *3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product-Contact Surfaces* 604-## and *3-A Accepted Practices for Spray Drying Systems* 607-##.

.....

Proposal: 130
Document: 2015 PMO
Pages: 267-269

Make the following changes to the 2015 PMO:

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES FOR OTHER EQUIPMENT ...

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS ...

Page 267:

GLOSSARY

Address: A numerical label on each memory location of the computer. The computer uses this address when communicating with the input or output.

Computer: A very large number of on-off switches arranged in a manner to sequentially perform logical and numerical functions.

Data Network: A telecommunication network that allows networked computing devices to exchange data with each other.

Default Mode: The pre-described position of some memory locations during start-up and standby operations of the computer. ...

Page 268:

CRITERIA ...

3. A separate public health computer shall be used on each HTST and HHST pasteurization system. Only the public health computer may provide control over the public health devices and functions of the HTST and HHST pasteurization system.

a. Any other non-public health computer or ~~Human Machine Interface~~ human machine interface may request a function of a device (valve, pump, etc.) within the HTST or HHST pasteurization system ~~through a hard-wired input;~~ however, this request would be granted or denied by the logic in the public health computer depending on the current status of the public health computer program and the Ordinance's public health (~~Ordinance~~) requirements.

b. The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems.

c. Digital outputs from other computer systems may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer.

d. The wiring connections shall be provided with isolation protection such as relays, diodes, or optical-coupling devices to prevent the public health outputs from being driven by other non-public health computer systems.

Page 269:

4. ~~The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems and~~ All public health outputs or devices within the HTST or HHST pasteurization system, such as solenoids, motor controls, and frequency drives, shall be controlled by direct dedicated hard-wiring or data network from the output terminal bus of the public health

computer to the device. This includes solenoids, motor speed controls, such as frequency drives, and motors located within the HTST or HHST pasteurization system. The wiring connections shall be provided with isolation protection such as relays, diodes, or optical coupling devices to prevent the public health outputs from being driven by the other computer system. Digital outputs from another computer may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer. This section shall not be interpreted to prohibit control of the motor speed controls, such as frequency drives, by non-public health computer systems provided that the regulatory limits cannot be altered or disabled. The dedicated hard-wired connection to the public health computer may be point-to-point to each device or multiple devices may be connected through a data network dedicated to the HTST or HHST pasteurization system.

- a. When a data network is used, any electronic switching equipment (switches, routers, hubs, etc.) associated with the data network shall be placed in an enclosure sealed by the Regulatory Agency.
- b. Non-public health computers and/or devices that are not associated with the public health control functions of the individual pasteurization system shall not be connected to the data network.
- c. In the case of devices that have the capability to be electronically reprogrammed to disable or modify regulatory limits, this functionality shall be disabled by a hardware switch that has been sealed by the Regulatory Agency.
- d. All data network cables or ports enabling connectivity to the public health computer shall be sealed by the Regulatory Agency to prevent any other device connections.

.....

Proposal: JC-4
Document: 2015 PMO
Pages: 347, 349, 350, 352, 353 and 357

Make the following changes to the 2015 PMO:

Page 347:

PREREQUISITE PROGRAMS (PPS): Prior to the implementation of a HACCP Plan, there is a requirement for milk plants, receiving stations and transfer stations to develop, document and implement written PPs. PPs provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in Federal and State regulations and guidelines.

PPs, and the HACCP System in total, address public health concerns such as those identified in 21 CFR Part 7, Recalls; Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; Part 110, Good Manufacturing Practices (GMPs) 117 CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD; Part 113, Thermally Processed Low Acid Foods Packaged in Hermetically Sealed Containers; Part 131, Milk and Cream; the *Grade "A" PMO*; and the current edition of the NACMCF HACCP Principles and Application Guidelines. ...

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 349:

~~3. **Other Programs:** Each milk plant shall have and implement other programs that are necessary to ensure the HACCP system is operating as intended. The other programs shall include:~~

~~a. A written environmental monitoring program that is implemented and supported by records for milk and/or milk products exposed to the environment when the milk and/or milk products does not subsequently receive a treatment that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:~~

- ~~(1) Be supported by scientific information;~~
- ~~(2) Include written procedures and records;~~
- ~~(3) Identify environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring;~~
- ~~(4) Identify the timing and frequency for collecting and testing samples;~~
- ~~(5) Identify the environmental pathogen or appropriate indicator microorganism to be tested for;~~
- ~~(6) Identify the test(s) conducted, including the analytical method used, and the test result;~~
- ~~(7) Identify the laboratory conducting the testing; and~~
- ~~(8) Include corrective action procedures for environmental monitoring test results.~~

~~b. A supplier program that shall, at a minimum, address the following:~~

- ~~(1) Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist, that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.~~
- ~~(2) Document that a supplier of non-milk and/or milk product ingredients has a functional and written food safety program that includes allergen management, if utilized in the milk plant's Grade "A" milk and/or milk products.~~

~~c. A written recall plan that, at a minimum, shall meet 21 CFR Part 7 (Subparts A and C).~~

NOTE: For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at:

<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

Page 350:

HAZARD ANALYSIS: ...

A hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that,

in the absence of these controls, the hazard will occur in the particular type of milk and/or milk product being processed. The hazard analysis shall be developed by an individual(s) trained in accordance with this Appendix and shall be subject to the record keeping requirements as described in this Appendix.

The Hazard Analysis shall at a minimum provide compliance with 21 CFR 117 Subpart C. (117.130 Hazard Analysis). ...

Page 352:

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).

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, 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, 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~~ 113 and 117 and 113. at a frequency determined by FDA.

a. Verification activities shall include:

- (1) The calibration of CCP process-monitoring instruments, i.e., pasteurization tests, etc.;
- (2) At the option of the milk plant, receiving station or transfer station, the performance of periodic end-product or in-process testing;
- (3) A review, including signing and dating, by an individual who has been trained in accordance with the training requirements of this Appendix, of the records that document:
 - i) The Monitoring of CCPs: The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the recorded document values are within the CLs. This review shall occur at a frequency that is appropriate to the importance of the record and as specified in the HACCP Plan; however, these reviews shall take place within seven (7) working days after the records were created.
 - ii) The Taking of Corrective Action: The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective action(s) was taken in accordance with the corrective action requirements cited before. This review shall occur at a frequency that is appropriate to the importance of the record. A centralized deviation log is required; and these reviews shall take place within seven (7) working days after the records were created.
 - iii) The calibrating of any process monitoring instruments used at CCPs and the performance of any periodic end-product or in-process testing that is part of the milk plant, receiving station or transfer station's verification activities. Review of calibration records shall occur within a reasonable time after the records are made.

The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the milk plant's, receiving station's or transfer station's written procedures. ~~These reviews shall occur within a reasonable time after the records are made.~~

(4) The taking of corrective action procedures whenever any verification procedure establishes the need to take a corrective action.

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.

Verifications shall at a minimum provide compliance with 21 CFR 117 Subpart C. (117.155 and 117.165 Verification).

Page 353:

3. Validation of the Hazard Analysis: Whenever a milk plant, receiving station or transfer station does not have a HACCP Plan, because a hazard analysis has revealed no hazards that are reasonably likely to occur, the milk plant, receiving station or transfer station shall reassess the adequacy of the hazard analysis whenever there are any changes in the process that could reasonably affect whether a hazard exists. Such changes may include changes in the following: ...

g. Consumer complaints.

A qualified individual(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 Validation). ...

Page 357

***NOTE:** Examples of Other Applicable NCIMS Requirements:

1. Raw Milk Supply Source;
2. Labeling Compliance;
3. Adulteration;
4. Licensing Requirements;
5. Drug Residue Testing and Trace Back Requirements;
6. Regulatory Samples in Compliance;
7. Approved Laboratory Utilized for the Required Regulatory Tests; and
8. Pasteurization Equipment Design and Installation.
9. Holding and Distribution of Human Food By-Products for Use as Animal Food
10. The following items as outlined in Appendix T.
 - a. Written Recall Plan
 - b. Written Risk Based Supply Chain Program
 - c. Written Environmental Monitoring Program
 - d. Any other applicable requirements

No Document

In addition, the NCIMS HACCP Implementation Committee shall update the audit report form(s) as needed and implement them after acceptance by the Executive Board.

Note: This Proposal shall take effective on September 17, 2018.

.....
Proposal: 223
Document: 2015 PMO
Pages: 363, 366 and 378

Make the following changes to the 2015 PMO:

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES ...

Page 363:

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. ...

Page 366:

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. ...

Page 378:

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE: ...

... 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) and/or use of the violative individual producer's milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for 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. Whenever a drug residue test is verified screening positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations. ...

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's concurrence with the NCIMS Executive Board.

.....
Proposal: 224
Document: 2015 PMO
Page: 376

Make the following changes to the 2015 PMO:

Page 376:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

Provided, that until at least 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, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that ~~the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing or tolerance levels.~~ the following conditions are met:

1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. target testing or non-zero tolerance levels are available, the test method manufacturer's data indicates that testing sensitivity is at or below those levels.

**FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO
THE NCIMS CHAIR DATED SEPTEMBER 8, 2017**

FDA non-concurred with this Proposal as it creates a direct conflict with the solution to Proposal 226 and; thereof, does not provide guidance to FDA of what text shall be incorporated into the PMO. Proposal 224 added text to the first paragraph and Proposal 226 deleted the entire paragraph. FDA believes that this proposed change is warranted and appropriate to maintain consistency in the language and the conventions of the NCIMS documents. FDA also believes that this suggested wording correction does not change the intent of Proposals 224 and 226 as passed at the 2017 NCIMS Conference.

NOTE: The text that is ~~struck through~~ was to be deleted from the current text in the PMO and the text that is underlined was text that was to be added to the PMO as addressed in the individual Proposals as passed at the conference. The text that is ~~double struck through~~ is text that is to be deleted from the PMO and/or text of the passed Proposal and 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.

FDA met with the NCIMS Executive Board on October 11-12, 2017 concerning this Proposal as passed during the 2017 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal 224 as follows:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

~~Provided, that until at least 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-1-85, latest revision, and M-1-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing or tolerance levels. the following conditions are met:~~

- ~~1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and~~
- ~~2. When U.S. target testing or non-zero tolerance levels are available, the test method manufacturer's data indicates that testing sensitivity is at or below those levels.~~

Please refer to Proposal 226 for additional FDA's proposed wording changes from Proposal 224, which were incorporated into Proposal 226.

.....

Proposal: 226
Document: 2015 PMO
Pages: 376-378

Make the following changes to the 2015 PMO:

Page 376:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

~~Provided, that until at least 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, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.~~

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues ~~with the documented permission of the Regulatory Agency(ies).~~ provided that the test method manufacturer's data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels. In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

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, or M-I-92-11 in raw milk, One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

Option 1:

~~1.~~ If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive

(+) and negative (-) controls that give the proper results using the same test method on the same sample. ...

Page 377:

Option 2:

2. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. ...

Page 378:

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues ~~with the documented permission of the Regulatory Agency(ies)~~ provided that the test method manufacturer's data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels. In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue.

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, or M-I-92-11 in raw milk, Option 3 shall not be used for non-Beta lactam screening or verification.

Option 3:

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. ...

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's concurrence with the NCIMS Executive Board.

**FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO
THE NCIMS CHAIR DATED SEPTEMBER 8, 2017**

FDA non-concurred with this Proposal as it creates a direct conflict with the solution to Proposal 224 and; thereof, does not provide guidance to FDA of what text shall be incorporated into the PMO. Proposal 226 deleted the entire paragraph and Proposal 224 added text to the first paragraph. FDA believes that this proposed change is warranted and appropriate to maintain consistency in the language and the conventions of the NCIMS documents. FDA also believes that this suggested wording correction does not change the intent of Proposals 224 and 226 as passed at the 2017 NCIMS Conference.

NOTE: The text that is ~~struck through~~ was to be deleted from the current text in the PMO and the text that is underlined was text that was to be added to the PMO as addressed in the individual Proposals as passed at the conference. The text that is ~~double struck through~~ is text that is to be deleted from the PMO and/or text of the passed Proposal and 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.

FDA met with the NCIMS Executive Board on October 11-12, 2017 concerning this Proposal as passed during the 2017 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposals 224 and 226 as follows:

Page 376:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

~~Provided, that until at least 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, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.~~

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues ~~with the documented permission of the Regulatory Agency(ies). provided that the test method manufacturer's data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels~~ following conditions are met:

1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. target testing levels or non-zero tolerances are available, the test method manufacturer's data indicates that testing sensitivity is at or below those concentrations.

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

Note: The remaining text as originally passed stays the same.

Page 378:

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues ~~with the documented permission of the Regulatory Agency(ies) provided that the test method manufacturer's data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels~~ following conditions are met:

1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. target testing levels or non-zero tolerances are available, the test method manufacturer's data indicates that testing sensitivity is at or below those concentrations.

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue.

Note: The remaining text as originally passed stays the same.

.....

Proposal: 225
Document: 2015 PMO
Pages: 376 and 378

Make the following changes to the 2015 PMO:

Page 376:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS ...

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION): ...

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation. Whenever the user of the test method and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed. ...

Page 378:

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE: ...

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and

the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue. Whenever the user of the test method and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed. ...

.....
Proposal: 306
Document: 2015 PROCEDURES
Pages: 23-28 and 31

PROCEDURES CHANGE

Make the following changes to the 2015 PROCEDURES:

SECTION V. QUALIFICATION AND CERTIFICATIONS ...

Page 23:

D. MILK SANITATION RATING PERSONNEL ...

2. Have been certified by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories:

a. Dairy farms;

b. ~~milk pasteurization~~ Milk plants, including HACCP and/or aseptic processing and packaging, and/or retort processed after packaging, and/or single-service container and closure manufacturers, if appropriate; ~~dairy farms and~~

c. ~~transfer~~ Transfer/receiving stations, including HACCP if appropriate.

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

Page 24:

3. A SRO applicant for initial certification shall be evaluated by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The applicant 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 dairy facilities, applicable to the category(ies) for which the applicant is being certified:

a. Twenty-five (25) producer dairies. Milking time evaluations should be included.

- b. Five (5) ~~pasteurization~~ 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, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) ~~pasteurization~~ milk plants.
 - c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required five (5) ~~pasteurization~~ milk plants.
 - d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for ~~pasteurization~~ milk plants for a SRO, one (1) mock-listing audit conducted separate from an official HACCP listing audit is required. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)
 - e. One (1) single-service ~~container~~ containers and ~~closure~~ closures manufacturing plant, if applicable.
 - f. Five (5) receiving and/or transfer stations if certification is only for these types of facilities. ...
5. Applicants shall also have attended a course on “Milk Pasteurization Controls and Tests” and demonstrate proficiency in applying pasteurization equipment tests in at least one (1) ~~pasteurization~~ milk plant, including demonstrating knowledge of milk and/or milk product flow through individual pasteurization systems. ...

Page 25:

8. A certified SRO shall be ~~re-certified~~ recertified once each three (3) years by PHS/FDA personnel in an independent side-by-side comparison of dairy facilities using the items listed on the appropriate inspection or evaluation report form. The ~~applicant~~ SRO 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 dairy facilities, applicable to the category(ies) for which the applicant is being recertified:
- a. Ten (10) producer dairies. Milking time evaluations should be included.
 - b. Three (3) ~~pasteurization~~ 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, if applicable, should be included in these evaluations.
 - c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) ~~pasteurization~~ milk plants.
 - d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for ~~pasteurization~~ milk plants for a SRO, one (1) ~~re-certification~~ recertification audit is required. The ~~re-certification~~ recertification audit can

be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA personnel and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)

e. One (1) single-service ~~container~~ containers and ~~closure~~ closures manufacturing plant, if applicable.

f. Three (3) receiving and/or transfer stations if certification is only for these types of facilities.

9. The requirements listed in 8. above will be dependent on a SROs range of responsibilities and the category(ies) in which they are being ~~certified~~ recertified. ...

10. To be ~~re-certified~~ recertified, a certified SRO shall have during the three (3) year period attended at least one (1) PHS/FDA Regional Milk Seminar, attended at least one (1) training course, which includes the auditing of milk plant NCIMS HACCP Systems and NCIMS HACCP IMS listing, if applicable, and attended at least one (1) PHS/FDA training course on “Special Problems in Milk Protection” or other training judged by PHS/FDA to be equivalent and appropriate.

11. Should PHS/FDA determine that a certified SRO has failed to demonstrate proficiency in the ~~above applicable re-certification~~ recertification procedures cited in 8. above; PHS/FDA ~~may~~ shall require the certified SRO to perform the applicable initial certification procedures cited in 3. above.

Page 26:

F. SAMPLING SURVEILLANCE PERSONNEL

Evaluation of sampling practices shall be made by certified sampling surveillance personnel who meet the following requirements:

1. 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 delegated Sampling Surveillance Regulatory Agency Official (dSSO).

~~2.~~ Have submitted to PHS/FDA a written request for certification including the following: applicant name and contact information, education, training, work experience, ~~and~~ a list of training courses attended and the category for which certification is being requested.

~~3.~~ Have been certified by PHS/FDA as a SSO and hold a valid certificate of qualification in one (1) of the following categories:

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

The PHS/FDA shall issue a certificate, valid for three (3) years, to each individual who meets the criteria listed in 34. and 46. below, as applicable.

34. Initial Certification: A SSO applicant for initial certification shall be evaluated 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 applicant 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 that the applicant is being certified for, at dairy facilities:

a. Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

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

c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

d. ~~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 delegated Sampling Surveillance Regulatory Agency Official (dSSO).~~

5. The requirements listed in 4. above will be dependent upon the applicant's range of responsibilities and the category in which the applicant is being certified.

46. 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 re-certified~~ recertified once each three (3) years 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 ~~applicant~~ 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 that the SSO is being recertified for, at dairy facilities:

a. Three (3) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

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

c. One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

~~d. 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.~~

7. The requirements listed in 6. above will be dependent upon the SSO's range of responsibilities and the category for which the SSO is being recertified.

8. Should PHS/FDA determine that the certified SSO has failed to demonstrate proficiency in the recertification procedures cited in 6. above; PHS/FDA shall require the certified SSO to perform the initial certification procedures cited in 4. above.

Page 27:

~~59. The 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 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.~~

NOTE: The delegation to industry certified personnel is not applicable to TPCs.

~~The SSO may delegate the inspection of Dairy Plant Samplers and Industry Plant Samplers to other qualified State or TPC Regulatory Agency personnel.~~

When the delegation of sampling surveillance responsibilities is necessary, the SSO certified by PHS/FDA, shall initially certify responsible individuals in one (1) of the following categories following the same procedures that govern initial SSO certification ~~listed in a. below.:~~

a. Bulk milk hauler/samplers and plant samplers (dairy plant samplers and industry plant samplers);

b. Bulk milk hauler/samplers; or

c. Plant samplers (dairy plant samplers and industry plant samplers).

~~Individuals dSSOs~~ shall be ~~re-certified~~ recertified every three (3) years in accordance with the procedures listed in c. below. Reports of all joint evaluations shall be submitted to PHS/FDA.

a. Initial Certification: The applicant for the delegation of sampling surveillance responsibilities shall be evaluated 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 applicant 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 the applicant is being certified for, at dairy facilities:

1.) Five (5) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

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

3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

b. The requirements listed under Initial Certification above will be dependent on the applicant's range of responsibilities and the ~~category(ies)~~ category in which ~~they are~~ the applicant is being certified.

c. ~~Re-certification~~ Recertification: A certified ~~applicant for the delegation of sampling surveillance responsibilities~~ dSSO shall be ~~re-certification~~ recertified once each three (3) years 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 ~~applicant~~ 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 that the dSSO is being recertified for, at dairy facilities:

1.) Two (2) bulk milk hauler/samplers during a routine milk pick-up at a producer dairy, if applicable.

Page 28:

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

3.) One (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) ~~pasteurization~~ milk plant, if applicable.

d. The requirements listed under recertification above will be dependent on the applicant's dSSO's range of responsibilities and the ~~category(ies)~~ category in which they are the dSSO ~~is being certified~~ recertified.

e. Should the SSO determine that the dSSO has failed to demonstrate proficiency in the recertification procedures cited under Recertification above; the SSO shall require the dSSO to perform the initial certification procedures cited under Initial Certification above.

G. 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 ~~3~~ 4 of the *EML*.) ...

Page 31:

I. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO, SSO, LEO, OR SSC

1. Certification Hearing Panel Members

Representatives from the following organizations will comprise the Certification Hearing Panel:

- a. The Regional Food and Drug Director or designee.
- b. The Director of the ~~Division of Federal State Relations~~ Office of Partnerships or designee.
- c. The Director of the Division of ~~Plant and Dairy, Egg and Meat Products~~ Food Safety or designee.

2. Notification of Intent to Revoke PHS/FDA Certification and an Opportunity for a Hearing

If the PHS/FDA Standard (Regional Milk Specialist, or PHS/FDA MST personnel, or member of LPET, respectively) makes an initial determination to revoke certification, PHS/FDA shall notify the SRO, SSO, LEO, or SSC in writing of its intent to revoke his or her certification. The notification shall specify: ...

3. Request for a Hearing

The SRO, SSO, LEO, or SSC, after being notified of PHS/FDA's intent to revoke his or her certification, may request a hearing. This request shall be received by the Director of the Division of ~~Plant and Dairy, Egg and Meat Products~~ Food Safety within fifteen (15)

days of the date the SRO, SSO, LEO, or SSC receives written notification of the intent to revoke his or her certification. The hearing request shall identify one (1) or more substantial issues of fact for which a hearing is requested. ...

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's concurrence with the NCIMS Executive Board.

.....
Proposal: 307
Document: 2015 PROCEDURES
Page: 35

PROCEDURES CHANGE

Make the following changes to the 2015 PROCEDURES:

Page 35:

D. PROCEDURES PURPOSE IN EACH PARTICIPATING NON-U.S. COUNTRY OR POLITICAL SUBDIVISION

For the purpose of these *Procedures* and NCIMS in total, each participating non-U.S. country or political subdivision thereof shall be considered as a State with all the rights, duties, responsibilities, and privileges of a State, providing the governing regulatory body of such non-U.S. country or political subdivision thereof shall meet the requirements of Part A. of this Section by establishing a MOU with PHS/FDA, which provides an acceptable basis for NCIMS to verify equivalence in the State or Local area concerned.

The determination that a foreign country's public health regulatory program, and the government oversight of that program ~~has~~ have an equivalent effect on the safety of the regulated milk or milk product is the responsibility of PHS/FDA. To provide clarity and transparency, PHS/FDA shall regularly inform and confer with NCIMS to answer questions and address NCIMS member concerns prior to finalizing a determination of equivalence. This engagement shall include general reporting on PHS/FDA's work, an opportunity for receiving and answering questions and addressing concerns of NCIMS members and issuing a notice to the NCIMS Executive Board prior to the intent to issue an approval of equivalence determination.

PHS/FDA shall publish for public review and comment such proposed equivalence determinations through the *Federal Register*.

The foreign government shall provide adequate assurance that the level of public health protection provided by the NCIMS program is met by their program. When PHS/FDA determines that a foreign country's milk regulatory program and government oversight of that

program are is equivalent, PMO defined milk and milk products from that country are accepted in the IMS program.

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's concurrence with the NCIMS Executive Board.

.....
Proposal: 309
Document: 2015 CONSTITUTION AND BYLAWS
Pages: 77, 78 and 85

Make the following changes to the 2015 CONSTITUTION OF THE NCIMS:

ARTICLE IV ----- VOTING DELEGATES, EXECUTIVE BOARD, OFFICERS, EXECUTIVE SECRETARY, COMMITTEES, COUNCILS, AND PROGRAM CHAIR

Page 77:

SECTION 10. Each Council shall have a voting membership of twenty (20) members to be appointed by the Chair with the approval of the Board. ...

Subd. 3. Each Council member shall be eligible to serve on a specific Council through no more than five (5) consecutive biennial meetings of the Conference. On an individual basis, when a new member is not available to serve, the term limit may be waived by the unanimous consent of the Board.

SECTION 11. Each Council shall have a Council Chair and a Vice Chair who are appointed by the Chair and confirmed by the Board. The Council Chairs and Vice Chairs shall serve on the Councils as non-voting members. After each biennial meeting of the Conference, each Council Chair shall select twenty (20) Council members from qualified Conference registrants and offer their names for Chair appointment and Board confirmation. Careful attention must be given by the Council Chair in the selection of Council members to achieve the discipline balance required in Article IV, Section 10. of this *Constitution*.

Page 78:

Subd. 1. Council Chairs and Vice Chairs shall after appointment serve through two (2) consecutive biennial meetings of the Conference. Council Chairs and Vice Chairs may exceed the limit of five (5) consecutive biennial meetings cited in Article IV, Section 10. of this *Constitution* only to fulfill their terms as Chair and/or Vice Chair. ...

Make the following changes to the 2015 BYLAWS OF THE NCIMS:

ARTICLE VI ----- DUTIES AND RESPONSIBILITIES OF COUNCILS

Page 85:

SECTION 5. The Chair of each Council shall appoint a minimum of four (4), but no more than eight (8), alternate Council members representing a one (1) or two (2) dairy processor processors, a one (1) or two (2) dairy producer producers, a one (1) or two (2) Regulatory Agency Agencies and a one (1) or two (2) Rating Agency Agencies for review and approval by the NCIMS Executive Board prior to each Conference. Alternate Council members shall be seated to cast votes during periods of temporary absence of Council members and shall be designated to replace Council members for the entire Conference if they cannot attend. Alternates must be affiliated with the current Conference and meet the same eligibility requirements to serve on a Council as the member for whom they will temporarily replace. Alternates shall be required to be in attendance at the Conference and be present at each Council meeting, even if not called upon by the Council Chair to temporarily replace an existing Council member. Alternates are only eligible to replace existing Council members from the same stakeholder group and shall be seated for the entire Conference as a temporary replacement for the original Council member. Council Chairs are encouraged to consider Council alternates when recommending permanent Council replacements to the Board for approval. ...

Note: For purposes of calculating serving on Council through no more than five (5) consecutive biennial meetings, the 2017 Conference will count as the first of the five (5) meetings.



Proposal: 233
Document: 2015 EML
Pages: iv, v, 7, 13-15, 18, 31 and 32

Make the following changes to the 2015 EML:
Page iv:

ABBREVIATION AND ACRONYMS ...

IS (Industry Supervisor)
ISO (International Standards Organization) ...

Page v:

Procedures (Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments)

PT (Proficiency Testing)

QA (Quality Assurance) ...

Page 7:

5. Analysts meet the performance levels of the proficiency testing (PT) program (SECTION 3). The LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved. ...

Page 13:

SPLIT SAMPLE ANALYSIS **(Proficiency Testing Studies)**

Evaluation criteria of split sample results vary on the type of data such as qualitative (Found or Not Found) or quantitative data. The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Peel Plate AC (PPAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), TEMPO AC (TAC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), and Electronic Phosphatase Count, and Vitamins A and D₃ results are quantitatively reported. of each certified analyst shall fall within the limits shown in Table 2, page 32. The vitamin A and D₃ results of each analyst shall be calculated by z-scores, which are based on ISO Standards, and are calculated for individual set of split samples. The quantitative results of each certified analyst shall meet acceptance criteria determined by protocols based on International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories. Generally, various international standards and guidelines do not address comparison of qualitative proficiency testing studies.

Determination of Assigned Value and Standard Deviation and Evaluation of Analysts Reporting Quantitative Data:

1. The robust mean (x_{pt}) and standard deviation of the PT (σ_{pt}) are calculated according to Algorithm A and x_{pt} is used as the assigned value for quantitative data. At least 80% of participants must submit quantitative results in order for the statistical calculations for x_{pt} and σ_{pt} to be executed. If this criterion is not met, those quantitative results will not be scored.
2. Algorithm A according to ISO 13528:2015 is used to calculate x_{pt} (x^* = robust average) and σ_{pt} (s^* = robust standard deviation). Other options for calculating mean and standard deviation are outlined in ISO 13528:2015. Calculations for microbiological testing are typically carried out on data that have been log transformed. Calculations for chemical testing are typically carried out on data that have undergone no transformation. Along with x_{pt} and σ_{pt} , values for standard uncertainty ($u(x_{pt})$) divided by σ_{pt} are calculated to ensure use of z-scores is appropriate. When $u(x_{pt})/\sigma_{pt} \leq 0.3$, the uncertainty of the assigned value may be considered to be negligible. If $u(x_{pt})/\sigma_{pt} > 0.3$, either z' scores will be calculated ($z_i' = (x_i - x_{pt}) / (\sqrt{\sigma_{pt}^2 +$

$u2(x_{pt})$) to take into account uncertainty of the assigned value or participants will be informed that uncertainty of the assigned value is not negligible and impact on scoring will be addressed.

3. Performance Evaluation for Quantitative Data

- a. The z-score value summarizes how many standard deviations from the mean the reported value is located. This is known as standardizing; thus, analysts receive standard z-scores. The formula for z-score calculation is as follows: $z_i = (x_i - x_{pt}) / \sigma_{pt}$ (where x_i is the reported value, x_{pt} is the PT mean/assigned value, and σ_{pt} is the standard deviation for the PT, also referred to as target s.d.) (ISO 13528:2015). Data with a normal distribution have 95 % of values within 2σ of the mean and 99.7 % of values within 3σ (ISO 22117). According to ISO guidelines, results with a z-score greater than $|2|$ are considered questionable because only 5% of correct measurements are expected to be that different from the assigned value. Results with a z-score greater than $|3|$ are considered unsatisfactory because only 0.3 % of correct measurements are expected to be that different from the assigned value (see ISO/IEC 17043:2010, B.4).

Determination of Assigned Value and Evaluation of Analysts reporting Qualitative Data:

1. Assigned values are determined by one of the following (ISO 13528:2015 11.3.1): participant consensus, expert laboratory results and/or performance criterion based on expert judgement
 - a. Participant Consensus: The consensus value for qualitative PT studies conducted by the FDA Moffett Campus PT Laboratory is defined as 80% agreement of responses (per sample) (ISO 17043:2010 B.2.4). Consensus for a particular sample must be at least 80% for accurate scoring of results (42 CFR §493.911(c).1). The assigned value is determined using the consensus results of participants and the results of expert lab(s). In those PT samples where consensus among participant results is less than 80%, participant performance will not be evaluated. These guidelines accommodate for situations in which an analyte was spiked, but recovery is fractional among participants possibly due to differences in methodology, inhomogeneity, instability, etc.
 - b. Expert Laboratory Results: The results from PT provider laboratory may be considered in absence of equivalent to those of an expert, or reference, laboratory. Results from three separate sets of analyses will be considered during the determination of assigned values for qualitative PTs: Bulk scale trials, Pre-shipment analytical tests and Post-shipment analytical tests
 - c. Performance Criterion based on Expert Judgement: It is preferred that expert judgement comes from a panel or advisory group of qualified experts. In some cases, a single expert may be designated to determine the assigned value. Significant disagreement among a group of qualified experts for a PT sample must be noted, and if agreement cannot be reached, the PT sample will not be used to evaluate participant performance.

Evaluation of Analysts:

The evaluation of participant performance in qualitative PT studies is often dependent on the nature of the PT study report and the objective of the study. Therefore, the objective of the PT study and method for determining assigned value will be documented in the PT Planning prior to final shipment of PT samples. Proper planning will ensure the evaluation criteria for the PT scheme meets the objectives of the PT scheme. The origin or source of the final PT samples will also be documented in the PT Planning for traceability.

The interpretation of analyst results is as follows:

- a. No color = Analysts/labs with z-score where $|z| \leq 2$ is acceptable and indicates that the performance of the analyst or laboratory is satisfactory.
- b. Yellow = Analysts/labs with z-scores $2 < |z| < 3$ are given a “warning signal” (ISO 13528)
- c. Red = Analysts/labs with z-scores $|z| \geq 3$ are given an “action signal” (ISO 13528)

Page 14:

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test ~~is required~~ for statistical analysis is recommended.
2. ~~Determine the logarithm of each test sample for the SPC, PAC, PPAC, PLC, BSC, TAC, SPLC, DMSCC, ESCC and Electronic Phosphatase Count using a table of common logarithms and list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for each sample.~~
3. ~~Determine for each sample for each test whether there are results outside of the Rejection Limit (L1). Rejection results are identified by applying to each analyst's result the limit (sample mean \pm L1). Results falling outside the limit are classified as outliers and are unacceptable. Note, by sample and test, the analysts who have results outside of the limits.~~
4. ~~Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean \pm L2). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.~~
5. ~~Using Table 3, page 32, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L1 or L2 or both limits.~~

- ~~6. Analysts certified for vitamin analysis shall meet the acceptance criteria using z scores.~~
72. An acceptable annual proficiency testing program for the BSC (all NCIMS approved models), shall meet the following applicable criteria. ...
- ~~8. The annual proficiency testing (PT) program for vitamins A and D₃ shall be based on z scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.~~

Page 15:

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the *Grade "A" PMO* shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the SPC, PAC, PPAC, PLC, BSC, TAC, SPLC, DMSCC, and ESCC and Electronic Phosphatase Count analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in ~~Tables 2 and 3~~ Table 2, page 32.
2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using drug other than beta-lactam, samples shall be spiked in duplicate. See Table ~~32~~, page 32.
3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) ~~within the specified limits in Table 2, page 32.~~
4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table ~~32~~, page 32.
5. CISs certified to perform *Grade "A" PMO*, Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table ~~32~~, page 32.
6. Analysts certified to perform vitamins A and D₃ tests shall detect samples that contain vitamins A and D₃ and shall meet the acceptance limits and performance levels shown in Table 2, page 32. ~~for the calculated z scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations. ...~~

Page 18:

SPLIT SAMPLE ANALYSIS

The multiple tube fermentation (Lauryl Tryptose Broth or Chromogenic substrate), membrane filtration and heterotrophic plate count result of each laboratory shall meet the criteria specified for microbiological split samples on pages 13 - xx fall within the limits shown in Table 2, page 32.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test ~~is required~~ for statistical analysis is recommended.
2. ~~Determine the logarithm for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.~~
3. ~~Determine for each sample for each test whether there are results outside of the Rejection Limit (L₁). Rejection results are identified by applying to each laboratory's result the limit (sample mean \pm L₁). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have results outside of the limits.)~~
4. ~~Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L₂). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean \pm L₂). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.~~
52. Using Table 3, page 32, list indicate all laboratories analysts who ~~that~~ have more than the maximum number of sample results per test classified as unacceptable ~~by either the L₁ or L₂ or both limits.~~
63. Laboratories accredited for dairy water analysis shall meet the acceptance ~~limits (L₁ and L₂)~~ and performance levels shown in ~~Tables 2 and 3~~ Table 2, page 32.

LABORATORY PERFORMANCE LEVEL

Laboratories accredited to perform the examinations of dairy water for coliforms required by the PMO shall meet the following performance levels on an annual basis.

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance ~~limits~~ and performance levels shown in ~~Tables 2 and 3~~, page 32. ...

Page 31:

TABLE 1: RECOMMENDED SPLIT SAMPLE COMPOSITION

PRODUCTS	<u>RECOMMENDED</u> <u>MINIMUM</u> NUMBER OF SAMPLES	DUPLICATES	ANALYSIS	<u>RECOMMENDED</u> <u>MINIMUM</u> NUMBER OF PRODUCT SAMPLES ANALYZED
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	1-8

Page 32:

TABLE 2: STATISTICAL LIMITS

TEST	REJECTION LIMIT 1 (L₁)*	REJECTION LIMIT 2 (L₂)*
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins	**	**
Electronic Phosphatase Count	0.300	0.200
Dairy water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.

** Limits for vitamin test results shall be based on z scores. Acceptable results shall be within plus or minus two (2) standard deviations.

TABLE 32: MAXIMUM NUMBER OF UNACCEPTABLE RESULTS

NUMBER OF RESULTS PER TEST (N)	MAXIMUM NUMBER OF UNACCEPTABLE RESULTS PER TEST FOR APPROVAL
5 – 10	1
11 – 20	2
21 – 30	3

Proposal: 237
Document: FDA/NCIMS 2400 FORMS

Send to FDA/NCIMS 2400 FORMS Protocol.

New FDA/NCIMS 2400 FORM (automated, flow cytometry based individual bacteria count (IBC), BactoCount IBC (BCC) (Raw Commingled Cow Milk Only)).

.....
Proposal: 238
Document: FDA/NCIMS 2400 FORMS

Send to FDA/NCIMS 2400 FORMS Protocol.

New FDA/NCIMS 2400 FORM (semi-automated, flow cytometry based individual bacteria count (IBC) method, BactoCount IBCm (BCMC), (Raw Commingled Cow Milk Only)).

.....
Proposal: 239
Document: FDA/NCIMS 2400 FORMS
Pages: 1-3

Send to FDA/NCIMS 2400 FORMS Protocol.

Add Bentley Somacount™ FC to FDA/NCIMS 2400 FORM (Electronic Somatic Cell Count).

.....
Proposal: 240
Document: FDA/NCIMS 2400 FORMS

Send to FDA/NCIMS 2400 FORMS Protocol.

Add 3M™ Pertrifilm™ Rapid Aerobic Count Plate to FDA/NCIMS 2400 FORM (Cultural Procedures-General Requirements).

.....
Proposal: 242
Document: FDA/NCIMS 2400 FORMS

Send to FDA/NCIMS 2400 FORMS Protocol.

Add 3M™ Pertrifilm™ Rapid Aerobic Count Plate to FDA/NCIMS 2400 FORM (Pasteurized Milk Containers, Closures and Packaging).

Proposal: 243
Document: FDA/NCIMS 2400 FORMS
Pages: 18 and 19

FDA/NCIMS 2400 FORM (Cultural Procedures-General Requirements):

Page 18:

29. ...

e. Petrifilm™ plate storage

1. ~~Refrigerate unopened packages of Petrifilm plates at or below 8°C; if frozen, allow 30 min room temperature thaw time before opening packages~~ Follow manufacturer's instruction for storage

Page 19:

4. ~~Store opened (re-sealed) packages $\leq 25^{\circ}\text{C}$.~~

5. ~~**Do not refrigerate opened packages.** If laboratory temperature exceeds 25°C , store resealed pouches of Petrifilm plates in freezer. Allow plates to acclimate to room temperature before using~~

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Proposal: 118
Document: No Document Referenced

The author requests that the Chair assign to the NCIMS Technical Engineering Review Committee or to a study committee, as approved by the NCIMS Executive Board, the task of thoroughly reviewing and evaluating the text contained within Item 16p and Appendix H of the PMO and to submit a proposal to the 2019 NCIMS Conference that updates and make editorial corrections that will make the text within Item 16p and Appendix H of the PMO more clear, concise, uniform and accurate.

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Proposal: 206
Document: No Document Referenced

Amend proposal to accept the method and if accepted, adopt into the conference documents.

This Proposal seeks approval to include the BactoCount IBC (BCC) and the BactoCount IBCm (BCMC) as alternative methods to enumerate bacteria in raw milk.

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Proposal: 213
Document: No Document Referenced

This proposal requests the Chair to assign this proposal to the Hauling Procedures Committee. This proposal charges the Hauling Procedures Committee to conduct a comprehensive review of Appendix B and FDA Form 2399a and report back to the 2019 NCIMS Conference.

.....

Proposal: 216
Document: No Document Referenced

Amend proposal to accept the method and if accepted, adopt into the conference documents.

This Proposal seeks approval (addition to M-a-85, latest revision) for the use of the AccuPoint® Advanced Alkaline Phosphatase electronic test for the detection of alkaline phosphatase in pasteurized fluid dairy products (all matrices defined within M-a-98).

.....

Proposal: 217
Document: No Document Referenced

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

The designated Committee is charged to review Appendix N Section VI, pertaining to testing for non-beta-lactam antibiotics with test methods that have not been evaluated by FDA and accepted by the NCIMS, and move this Section to a new appendix (to be lettered). The Committee is charged to clearly delineate testing that is required by Appendix N (currently Beta-lactams) from voluntary testing that is performed using test methods that have not been evaluated by FDA and accepted by the NCIMS.

The product of the committee may be a proposal submitted to the 2019 Conference.

.....

Proposal: 219
Document: No Document Referenced

Amend proposal to accept the method and if accepted, adopt into the conference documents.

This Proposal seeks approval (addition to M-a-85, latest revision) for BetaStar® Advanced for Beta-lactams test for the use of detecting beta-lactam drug residues in raw, commingled bovine milk.

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Proposal: 220
Document: No Document Referenced

Amend proposal to accept the method and if accepted, adopt into the conference documents.

This Proposal seeks approval (addition to M-a-85, latest revision) for the use of the BetaStar® Advanced for Tetracyclines test to detect tetracycline drug residues in raw, commingled bovine milk.

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Proposal: 230
Document: No Document Referenced

FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implemental Committee to work with FDA the task of conducting a comprehensive and thorough review of the *MMSR* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the *MMSR*. The review shall include an assessment of the appropriate point value for the animal feed provisions added to Section 15p of the PMO, and subject to the passing of JC-1 or JC-2.

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's concurrence with the NCIMS Executive Board.

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Proposal: 241
Document: No Document Referenced

Amend proposal to accept the method and if accepted, adopt into the conference documents.

A new method and FDA/NCIMS 2400 Form (3M™ Petriflim™ Rapid Aerobic Count Plate Count).

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Proposal: 303
Document: No Document Referenced

FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA the task of conducting a comprehensive and thorough review of the *Procedures* and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the *Procedures*.

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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 Web Site 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 Robert.Hennes@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Robert Hennes", written in a cursive style.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Milk and Milk Products Branch