36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-1 *New Procedure
Committee:	Constitutions & Bylaws/ Liaison/ MMSR

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

A. Summary of Proposal

This Proposal adds additional text and clarification to the PMO to essentially make the PMO compliant with FSMA regulations and the Preventive Controls for Human Foods (PCHF) final rule. The additions are based on the provisions of the final rule that was published after the 2015 NCIMS Conference and the gap analysis conducted by FDA MST comparing the final rule to the 2015 PMO. It adds text and guidance from the PCHF final rule related to a food safety plan and hazard analysis to a new Appendix T within the PMO. It also adds text to the MMSR, Procedures and NCIMS Bylaws addressing changes to implement the new standards.

This Proposal reflects the changes suggested by the Liaison Committee following discussions between the Liaison Committee and FDA, which were agreed to and are supported by FDA.

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

At the 2015 Conference, FDA made a commitment to the NCIMS to compare the 2015 PMO to the final PCHF rule and to prepare a gap analysis. The gap analysis evaluated the differences between the requirements of the PCHF final rule and the 2015 PMO requirements. It identified as gaps the absence within the PMO of provisions directed toward a recall plan, food allergen control, environmental monitoring, supply-chain program, holding and distribution of human food by-products for use as animal food, records, employee training for example. Also, the gap analysis included requirements in the current Good Manufacturing Practices (cGMP) of the PCHF final rule that are currently not adequately addressed in the PMO, such as requirements relative to protective lighting; indicating thermometer, temperature-measuring device or temperature-recording device in refrigerated rooms; person

affected with any disease in a communicable form; and record keeping. This gap analysis was completed and provided to the Liaison Committee and the NCIMS Executive Board along with a draft Proposal written by FDA, which was designed to address the gaps identified.
As with the 2015 Conference, FDA considers that this original draft Proposal can be used as a starting point for consideration and discussion by the Liaison Committee and FDA to develop a mutually acceptable Proposal, which would operate to make the PMO as FSMA-compliant as it needs to be. These suggested text modifications to the PMO were included so that it will include all of the requirements in the PCHF final rule. This Proposal reflects the changes suggested by the Liaison Committee following discussions between the Liaison Committee and FDA, which were agreed to and are supported by FDA.

The FSMA final rule was published in the Federal Register (FR) announcement on page 55908, Volume 80, Number 180, issued September 17, 2015.

In the FR announcement on page 55986, Volume 80, Number 180, issued September 17, 2015, FDA states that NCIMS has initiated work to modify the PMO and that work is expected to include all of the requirements in a final PCHF rule. FDA has committed resources to work with the appropriate NCIMS Committees to make the necessary changes. FDA extended the compliance date for PMO-regulated facilities to comply with the requirement of the PCHF rule to September 17, 2018. The extended compliance date is not equivalent to an exemption. Regardless of whether the PMO is modified to include the requirements of the final PCHF rule by the extended compliance date, PMO facilities must comply with the PCHF rule on September 17, 2018. Because the provisions of the final rule will not be established until the date of the final rule (September 17, 2015), any changes made to the 2015 PMO (e.g., to incorporate the provisions that were proposed in the 2014 supplemental preventive controls notice) before September 17, 2015 may need revision to reflect the final provisions of the final rule.

Should the PMO be rendered fully FSMA-compliant at the 2017 Conference, FDA considers that it will not be necessary for FDA District personnel to enter Grade “A” milk plants to conduct FSMA-based Grade “A” milk and milk products compliance inspections. Instead, the Grade “A” milk safety program itself would operate as per normal to ensure compliance with the PMO and thereby additionally ensure compliance with FSMA rules. FDA does not anticipate a need for any changes to the rating and check-rating system currently utilized by NCIMS.

FDA plans to train Regulatory Agency personnel, Milk Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists and others associated with the Grade “A” Milk Safety Program some time in 2018. The goal is to train all involved close in time to the compliance date of September 17, 2018. Planning for this effort is already underway and the estimates for the numbers of people who would need to be trained were provided to DHRD and OP.

C. Proposed Solution			
Changes to be made on page(s):	x, xiv, xx, xxi, 1, 6, 11, 12, 15, 21, 29, 62, 65, 74-76, 81, 89, 90, 98, 114, 117, 122, 131, 213, 262,340,	of the (X - one of the following):	
X	2015 PMO		2015 EML
X	2015 MMSR		2400 Forms
X	2015 Procedures	X	2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

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ITEM 20p. PERSONNEL – CLEANLINESS <u>AND PRACTICES</u>…….

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<u>APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE "A" MILK AND MILK PRODUCTS</u> <u>…….</u>

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ABBREVIATIONS AND ACRONYMS …

Page xx:

PCC (Petrifilm Colifom Count)
<u>PCQI (Preventive Controls Qualified Individual)</u>
PDD (Postion 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, ~~110~~ 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, ~~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. …

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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, ~~110~~ 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.

~~QQ~~SS. **RATING AGENCY:** ….
Note: *Re-letter remaining Definitions accordingly.*

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~~UU~~WW. **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, ~~110~~ 113 and 117 ~~and 113~~ and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

~~VV~~XX. **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, ~~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: *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.

~~ZZ~~BBB. **TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS:** ….

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~~ describe ~~in 21 CFR Part 7 (Subpart A and C).~~ 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. …

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SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS …

3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, 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*. Provided further, that regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged 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~~ 113 and 117 ~~and 113~~ at a frequency determined by FDA. …

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:

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 preventive controls qualified individual (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 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.

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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. Storage tanks, which are used to store raw milk and/or milk products or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk and/or milk products or heat-treated milk products, shall be equipped with a seven (7) day temperature-recording device complying with the specifications of Appendix H., IV. of this *Ordinance*. Electronic records that comply with the applicable provisions of Appendix H., IV. and V. of this *Ordinance*, with or without hard copy, may be used in place of the seven (7) day temperature-recording records. Otherwise provided, evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four (44) hours, and records shall be available to verify that the operation time does not exceed forty-four (44) hours. …

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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. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these microorganisms may be found in the milk plant environment if measures are not taken to minimize the risk of contamination by these microorganisms. Contamination of milk from the environment can result in milkborne illness. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and/or milk product or equipment with which the milk and/or milk product comes in contact; such contamination can result in adverse health consequences. Food allergens can cause mild

to severe adverse reactions and sometimes may cause life threatening reactions. Thus it is important not only to declare all food allergens on milk and milk product labels, but also to prevent cross-contact of milk and milk products so they do not contain undeclared food allergens.

ADMINISTRATIVE PROCEDURES …

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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 and cross-contamination from insanitary objects and from personnel to milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces and from raw milk and/or milk products to pasteurized milk and/or milk products.

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~~ scientifically valid;

b. ~~Include written procedures and records~~ Identify the test microorganism(s);

c. Identify ~~environmental monitoring~~ the locations ~~and the number of sample~~ 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;

d. 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;

e. ~~Identify the environmental pathogen or appropriate indicator microorganism to be tested for;~~ Identify the test(s) conducted, including the analytical method used;

f. ~~Identify the test(s) conducted, including the analytical method used, and the test result;~~ Identify the laboratory conducting the testing; and

g. ~~Identify the laboratory conducting the testing; and~~ Include the corrective action procedures for the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring.

~~h. Include corrective action procedures for environmental monitoring test results~~.

3. **~~SUPPLIER~~ SUPPLY-CHAIN ~~CONTROL~~ PROGRAM:**

A milk plant shall ~~have~~ establish and implement a ~~supplier~~ written risk-based supply-chain ~~control~~ program for those raw materials and other ingredients for which the milk plant has identified a hazard requiring a supply-chain-applied control ~~that is implemented and supported by records to control food safety hazards~~. The ~~supplier~~ supply-chain ~~control~~ 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 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~~, if utilized in the milk plant's Grade "A" milk and/or milk products~~.

c. A supply-chain program shall include:

(i) Using approved suppliers. The milk plant shall approve suppliers, and document that approval, before receiving raw materials and other ingredients;

(ii) Determine appropriate supplier verification activities to include determining the frequency of conducting the activity;

(iii)Conducting and documenting supplier verification activities. The following are appropriate supplier verification activities for raw materials and other ingredients;

A) Onsite audits shall be conducted before using the raw materials or other ingredient from the supplier and at least annual thereafter;

B) Sampling and testing of the raw material or other ingredient;

C) Review of the supplier's relevant food safety records; and

D) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(iv)When applicable, verifying a supply-chain-applied control applied by an entity other than the milk plant's supplier and documenting that verification.

(v) 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*.

4. **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, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution shall be designed, constructed of appropriate materials, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution shall be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food shall be accurately identified.

b. Labeling that identifies the by-product by the common or usual name shall be affixed to and accompany 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 examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or bulk vehicle when the milk plant is responsible for transporting the human food by-products for use as animal food.

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 …

ADMINISTRATIVE PROCEDURES …

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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.~~

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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

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All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) 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*.)
~~1~~2. Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.
~~2~~3. Each employee washes their hands following a visit to the toilet room and prior to resuming work.
~~3~~4. 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.
~~4~~5. 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.
~~5~~6. 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 sources(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. Aseptically processed and packaged low-acid milk and/or milk products shall be labeled "Grade "A"" and meet Section 4. labeling requirements of this *Ordinance*. The milk plant or portion of the milk plant that is producing aseptically processed and packaged low-acid milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings shall be equal to ninety percent (90%) or higher on the re-rating or the supply is considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" low-acid 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 fermented high-acid milk and/or milk products regulated under the applicable requirements of 21 CFR Parts 108 and/or ~~110~~ 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 H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT …

IV. THERMOMETER SPECIFICATIONS …

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INDICATING THERMOMETERS USED IN REFRIGERATED ROOMS WHERE MILK AND/OR MILK PRODUCTS ARE STORED

Scale Range: Shall have a span not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees), including normal storage temperatures, ± 3°C (± 5°F), with extensions of scale on either side permitted if graduated in not more than 1°C (2°F) divisions.
Temperature Scale Divisions: Spaced not less than 1.6 millimeters (0.0625 of an inch) apart between 0°C (32°F) and 13°C (55°F).
Accuracy: Within ± 1°C (± 2°F), throughout the specified scale ranges.

TEMPERATURE-RECORDING DEVICES USED IN REFRIGERATED ROOMS WHERE MILK AND/OR MILK PRODUCTS ARE STORED

Case: Moisture proof under operating conditions in milk plants.
Chart Scale: Shall have a scale span of not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees) including normal storage temperature, ± 3°C (± 5°F), graduated in not more than 1°C (2°F) divisions. Lines spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line. They shall be graduated in time scale divisions of not more than one (1) hour, having a chord of
straight-line length of not less than 3.2 millimeters (0.125 of an inch) at 5°C (41°F). These charts shall be capable of recording temperatures between 0°C (32°F) and 13°C (55°F).
Temperature Accuracy: Within ± 1°C (± 2°F), between the specified range limits.
Pen-Arm Setting Device: Easily accessible and simple to adjust.
Pen and Chart Paper: Designed to make a line not over .635 millimeters (0.025 of an inch) wide when in proper adjustment and easy to maintain.
Temperature Sensor: Protected against damage.
Stem Fittings: A pressure-tight seat or other suitable sanitary fitting with no threads exposed.
Chart Speed: The circular chart shall make one (1) revolution in not more than seven (7) days and shall be graduated for a maximum record of seven (7) days. Strip chart shall move not less than 2.54 centimeters (1 inch) per hour and may be used continuously for one (1) calendar month. …

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 Hazard Analysis;

2. The written Recall Plan;
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 of 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.

Hazard Analysis:

A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. 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 Item 15p.(C) of this *Ordinance*;
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 or 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);
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:
   a. 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; and
4. The supply-chain program.
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 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
3. 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.

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, packaging, 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;
1. 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;
2. Review of records; and
3. The reanalysis of the food safety plan;

NOTE: Please refer to 21 CFR 117-Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food for additional information and requirements related to a milk plant's required food safety plan and preventive controls. …

MAKE THE FOLLOWING CHANGES TO FORM FDA 2359-MILK PLANT INSPECTION REPORT (11/2015)

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

15c.
Food allergen control …….. (a) ___
Environmental monitoring..... (b) ___
~~Supplier~~ Supply-chain ~~Control~~
program ……. (c) ___
Human food by-products for
use as animal food …… (d) ___

MAKE THE FOLLOWING CHANGES TO THE 2015 MMSR:

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

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ABBREVIATIONS AND ACRONYMS …

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PCQI (Preventive Controls Qualified Individual)
pH (Potential Hydrogen-acid/alkaline balance of a solution) …

A. DEFINITIONS …

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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. …

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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.

~~24~~25. R**ATING AGENCY: …**

Note: *Renumber remaining Definitions accordingly.*

~~28~~29. **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 …

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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 an IMS rating/listing audit or 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. If the milk plant is not in compliance, a rating/listing audit or check rating/FDA audit is not to be completed and the Rating Agency shall immediately deny or withdraw the milk plant's IMS listing.

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 denial or withdrawal 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 Hazard Anaylsis;

B.) The written Recall Plan;

C.) The written Preventive Controls, as appropriate, for hazards not addressed by PMO;

D.) The written Supply-Chain Program, as appropriate, for hazards not addressed by PMO;

E.) The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by PMO;

F.) The written Corrective Action Procedures, as appropriate, for hazards not addressed by PMO; and

G.) he written Verification Procedures, as appropriate, for hazards not addressed by 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.

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.

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 monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.
7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented.
8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards.
9.) The milk plant has 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.
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.
11.) A series of observations that leads to a finding of a potential food safety system failure that is likely to result in a compromise to milk and/or milk product safety.

~~2~~3. COLLECTION OF DATA …

Page 18:

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, ~~110~~ 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, ~~110~~ 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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~~3~~4. COMPUTATION OF SANITATION COMPLIANCE RATINGS …

MAKE THE FOLLOWING CHANGES TO THE 2015 PROCEDURES:

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

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., ~~F~~G. and ~~G~~H., the evaluation procedures of LEOs and SSOs.

Page 8:

d. PHS/FDA shall standardize, in accordance with Section V, ~~H~~I., 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**

A milk plant desiring a rating of their supply shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO.*

~~F~~G. **SAMPLING SURVEILLANCE PERSONNEL** …

~~G~~H. **MILK LABORATORY EVALUATION PERSONNEL** …

~~H~~I. **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., ~~I~~J.

Page 31:

~~I~~J. 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

   A milk plant desiring a listing audit of their supply shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO*.

~~6~~7. Certification Procedures for SROs Who Will Conduct HACCP Listing Audits …

Page 52:

~~7~~8. Sampling Surveillance Personnel

   Section V., ~~F~~G. shall apply as written.

Page 53:

~~8~~9. Milk Laboratory Evaluation Personnel

   Section V., ~~G~~H. 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., ~~F~~G., and Section VIII., E.~~7~~8, 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., ~~G~~H., and Section VIII., E. ~~8~~9, if applicable, of this document and those of the *EML*. …

MAKE THE FOLLOWING CHANGES TO 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

15cABCD (In two (2) locations.)

MAKE THE FOLLOWING CHANGES TO FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT (10/2013)

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

MAKE THE FOLLOWING CHANGES TO THE 2015 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS:

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

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 Proposal shall take effect on September 17, 2018.*

Name: CAPT Robert F. Hennes

Agency/Organization: FDA/CFSAN

Address: 5001 Campus Drive

City/State/Zip: College Park, MD 20740

Telephone No.: (240) 402-2175 E-mail Address: Robert.Hennes@fda.hhs.gov

36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-2
Committee:	Constitutions & Bylaws/ Liaison/ MMSR

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

A. Summary of Proposal

Building upon the work conducted at the 2015 conference through the Joint Council proposals, this proposal seeks to finalize the alignment of the Pasteurized Milk Ordinance (PMO) with the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food.

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

Since the 2015 conference was prior to FDA issuing the final rule for Preventive Controls for Human Food, which was released on September 17, 2015, the Liaison Committee drafted the following proposal working from FDA's proposed template to address those requirements under FSMA where the PMO is silent. The committee's work placed all of the FSMA requirements, under a new Appendix "T" with the exception of *Food Allergen Control* and *Holding and Distribution of Human Food By-Products for use as Animal Food* which will remain under 15p.(c) and some of the minor requirements under the new cGMP regulations under 21 CFR 117 (replacing 21 CFR part 110). Most of the additional langauge comes directly from the rule or cGMP's.

This proposal requires a separate FSMA inspection every 36 months as the other food commodities in the high risk categorization of FSMA and are to be conducted by state regulatory staff. The FSMA inspection date will be referenced on the Rating and the Check Rating documents under the long standing Section II Enforcement, item 2, where it will be prorated out of the 15 available points as the other required inspections conducted by the regulatory agency.

The proposal moves the Food Safety Plan requirements into Appendix "T" and notes that the

plant must only address those hazards not addressed by the PMO.

With the creation of an Appendix "T" the proposal also includes a Bylaw change to add Appendix "T" to Council III's responsibilities.

C. Proposed Solution			
Changes to be made on page(s):	PMO-x, xiv, xx, xxi, 1, 6, 11, 12, 15, 21, 23, 29, 62, 65, 74, 75, 76, 81, 89, 90, 98, 108, 114, 117, 122, 131, 213, 262, 340, 341, 342, 359, 396, 398, MMSR-2359, 2359j, Bylaws- 84	of the (X - one of the following):	
X	2015 PMO		2015 EML
X	2015 MMSR		2400 Forms
	2015 Procedures	X	2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

TABLE OF CONTENTS …

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ITEM 20p. PERSONNEL – CLEANLINESS <u>AND PRACTICES</u>…….

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

<u>APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE "A" MILK AND MILK PRODUCTS</u> <u>…….</u>

INDEX …….

ABBREVIATIONS AND ACRONYMS …

Page xx:

PCC (Petrifilm Colifom Count)
PCQI (Preventive Controls Qualified Individual)
PDD (Postion Detection Device) …

Page xxi:

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, ~~110~~ 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, ~~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:

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, ~~110~~ 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. …

Page 11:

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.

~~QQ~~SS. **RATING AGENCY:** ….

Note: *Re-letter remaining Definitions accordingly.*

Page 12:

~~UU~~WW. **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, ~~110~~ 113 and 117 ~~and 113~~ and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

~~VV~~XX. **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, ~~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: *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.

~~ZZ~~BBB. **TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS:** ….

Note: *Re-letter remaining Definitions accordingly.*

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

Page 15:

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….

Page 21:

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* shall be conducted by the Regulatory Agency at least once every thirty-six (36) months. Appendix T of this *Ordinance* shall take effect on September 17, 2018. Inspection for compliance by the Regulatory Agency shall occur after the completion of the Preventive Controls Regulatory Training for state regulators.

ADMINISTRATIVE PROCEDURES

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

designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for all other milk plants and receiving stations, the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due, provided that for inspections for compliance with Appendix T of this *Ordinance* the interval shall include the designated thirty-six (36) month period plus the remaining days of the month in which the inspection is due. ….

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

Page 29:

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:

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 preventive controls qualified individual (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 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 …

Page 74:

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. Storage tanks, which are used to store raw milk and/or milk products or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk and/or milk products or heat-treated milk products, shall be equipped with a seven (7) day temperature-recording device complying with the specifications of Appendix H., IV. of this *Ordinance*. Electronic records that comply with the applicable provisions of Appendix H., IV. and V. of this *Ordinance*, with or without hard copy, may be used in place of the seven (7) day temperature-recording records. Otherwise provided, evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four (44) hours, and records shall be available to verify that the operation time does not exceed forty-four (44) hours. …

Page 76:

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. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these microorganisms may be found in the milk plant environment if measures are not taken to minimize the risk of contamination by these microorganisms. Contamination of milk from the environment can result in milkborne illness. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and/or milk product or equipment with which the milk and/or milk product comes in contact; such contamination can result in adverse health consequences. Food allergens can cause mild to severe adverse reactions and sometimes may cause life threatening reactions. Thus it is important not only to declare all food allergens on milk and milk product labels, but also to prevent cross-contact of milk and milk products so they do not contain undeclared food allergens.

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 and cross-contamination from insanitary objects and from personnel to milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces and from raw milk and/or milk products to pasteurized milk and/or milk products.

~~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, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution shall be designed, constructed of appropriate materials, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution shall be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food shall be accurately identified.

b. Labeling that identifies the by-product by the common or usual name shall be affixed to and accompany 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 examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or bulk vehicle when the milk plant is responsible for transporting the human food by-products for use as animal food. …

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

Pasteurization shall be performed as defined in Section 1., Pasteurization and Item 16p of this Ordinance. Aseptic processing and packaging and retort processed after packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, ~~110~~ 113 and 117 ~~and 113~~. (Refer to Appendix L. of this Ordinance.) …

ITEM 16p.(A) BATCH PASTEURIZATION …

ADMINISTRATIVE PROCEDURES …

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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.~~

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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

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All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) 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.

1. 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*.)

~~1~~2. Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.

~~2~~3. Each employee washes their hands following a visit to the toilet room and prior to resuming work.

~~3~~4. 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.

~~4~~5. 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.

~~5~~6. 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 sources(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. Aseptically processed and packaged low-acid milk and/or milk products shall be labeled "Grade "A"" and meet Section 4. labeling requirements of this *Ordinance*. The milk plant or portion of the milk plant that is producing aseptically processed and

packaged low-acid milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher, or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings shall be equal to ninety percent (90%) or higher on the re-rating or the supply is considered in violation of this Section. In the case of HACCP/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" low-acid 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 fermented high-acid milk and/or milk products regulated under the applicable requirements of 21 CFR Parts 108 and/or ~~110~~ 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 H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT …

IV. THERMOMETER SPECIFICATIONS …

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INDICATING THERMOMETERS USED IN REFRIGERATED ROOMS WHERE MILK AND/OR MILK PRODUCTS ARE STORED

Scale Range: Shall have a span not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees), including normal storage temperatures, ± 3°C (± 5°F), with extensions of scale on either side permitted if graduated in not more than 1°C (2°F) divisions.
Temperature Scale Divisions: Spaced not less than 1.6 millimeters (0.0625 of an inch) apart between 0°C (32°F) and 13°C (55°F).
Accuracy: Within ± 1°C (± 2°F), throughout the specified scale ranges.

TEMPERATURE-RECORDING DEVICES USED IN REFRIGERATED ROOMS WHERE MILK AND/OR MILK PRODUCTS ARE STORED

Case: Moisture proof under operating conditions in milk plants.
Chart Scale: Shall have a scale span of not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees) including normal storage temperature, ± 3°C (± 5°F), graduated in not more than 1°C (2°F) divisions. Lines spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line. They shall be graduated in time scale divisions of not more than one (1) hour, having a chord of
straight-line length of not less than 3.2 millimeters (0.125 of an inch) at 5°C (41°F). These charts shall be capable of recording temperatures between 0°C (32°F) and 13°C (55°F).
Temperature Accuracy: Within ± 1°C (± 2°F), between the specified range limits.
Pen-Arm Setting Device: Easily accessible and simple to adjust.
Pen and Chart Paper: Designed to make a line not over .635 millimeters (0.025 of an inch) wide when in proper adjustment and easy to maintain.
Temperature Sensor: Protected against damage.
Stem Fittings: A pressure-tight seat or other suitable sanitary fitting with no threads exposed.
Chart Speed: The circular chart shall make one (1) revolution in not more than seven (7) days and shall be graduated for a maximum record of seven (7) days. Strip chart shall move not less than 2.54 centimeters (1 inch) per hour and may be used continuously for one (1) calendar month. …

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:

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. 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 PMO;
4. The written Supply-Chain Program, as appropriate, for hazards not addressed by PMO;
5. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by PMO;
6. The written Corrective Action Procedures, as appropriate, for hazards not addressed by PMO; and
7. The written Verification Procedures, as appropriate, for hazards not addressed by PMO.

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 of 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 facility may group types of milk or milk products or similar processes together. 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 Item 15p.(C) of this *Ordinance*;
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 analytes;
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:

a. 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; and
4. The supply-chain program.
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 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
3. 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.

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, packaging, 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;
    1. 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;
    2. Review of records; and
    3. The reanalysis of the food safety plan;

~~**NOTE:** Please refer to 21 CFR 117-Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food for additional information and requirements related to a milk plant's required food safety plan and preventive controls. …~~

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 when the 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:

a. Be scientifically valid;
b. Identify the test microorganism(s);
c. 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;
d. 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;
e. Identify the test(s) conducted, including the analytical method used;
f. Identify the laboratory conducting the testing; and
g. 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;

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 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.

c. A supply-chain program shall include:

(i) Using approved suppliers. The milk plant shall approve suppliers, and document that approval, before receiving raw materials and other ingredients;

(ii) Determine appropriate supplier verification activities to include determining the frequency of conducting the activity;

(iii) Conducting and documenting supplier verification activities. The following are appropriate supplier verification activities for raw materials and other ingredients;

A) Onsite audits shall be conducted before using the raw materials or other ingredient from the supplier and at least annual thereafter;

B) Sampling and testing of the raw material or other ingredient;

C) Review of the supplier's relevant food safety records; and

D) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(iv) When applicable, verifying a supply-chain-applied control applied by an entity other than the milk plant's supplier and documenting that verification.

(v) 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*.

MAKE THE FOLLOWING CHANGES TO FORM FDA 2359-MILK PLANT INSPECTION REPORT (11/2015)

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

15c.

Food allergen control …….. (a) ___
~~Environmental monitoring..... (b) ___~~
~~Supplier Control program ……. (c) ___~~
Human food by-products for use as animal food …… ~~(d)~~ (b) ___

MAKE THE FOLLOWING CHANGES TO FORM FDA 2359j-INTERSTATE MILK SHIPPER's REPORT (10/2013)(Page 2)

Add the following underlined text to:

Section B: REPORT of ENFORCEMENT METHODS under MILK PLANT PART II, Number 2, Ordinance Section 5, Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plant and transfer station(s) once every six (6) months, milk plant inspected once every thirty six (36) months for Appendix T requirements.

MAKE THE FOLLOWING CHANGES TO THE 2015 BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS:

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

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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 Proposal shall take effect on September 17, 2018.*

Name:	Casey McCue- Chair		
Agency/Organization:	NCIMS Liaison Committee		
Address:	New York State Dept. of Agriculture and Markets, Div. of Milk Control and Dairy Services, 10 B Airline Drive		
City/State/Zip:	Albany, NY 12235		
Telephone No.:	518-457-1772	E-mail Address:	casey.mccue@agriculture.ny.gov

36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-3 *New Procedure
Committee:	HACCP/MMSR/ Liaison

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

A. Summary of Proposal

This proposal aligns the PMO's voluntary HACCP-based Appendix K Program for Grade "A" milk and/or milk products plants with the Food Safety Modernization Act's (FSMA's) Final Rule for Preventive Controls for Human Food by incorporating requirements from the aforementioned final rule. It also aligns Appendix K with proposal being submitted by FDA.

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

The Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food requires several elements that were not fully addressed in Appendix K of the current PMO.

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) voluntary Appendix K with the requirements of FSMA's Final rule for "Preventive Controls for Human Food" and the changes to the PMO submitted by FDA.

C. Proposed Solution			
Changes to be made on page(s):	347-357 (PMO), ii-19 (Methods) & 2-59 (Procedures)	of the (X - one of the following):	
X	2015 PMO		2015 EML
X	2015 MMSR		2400 Forms
X	2015 Procedures		2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO.

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VOLUNTARY PARTICIPATION: This Appendix describes a NCIMS voluntary HACCP Program alternative to the traditional inspection system. A milk plant, receiving station or transfer station may not participate in the NCIMS voluntary HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the milk plant(s), receiving station(s) and transfer station(s) in the NCIMS voluntary HACCP Program. Both parties shall provide written commitment to each other that the necessary resources to support participation in the NCIMS voluntary HACCP Program shall be made available. Management responsible for both the Regulatory Agency and milk plant, receiving station and/or transfer station shall be willing to provide the resources required to develop and implement a successful HACCP System.
<u>A HACCP System as described in various parts of this appendix, shall at, a minimum provide compliance with all applicable sections of 21CFR117 Subparts B and C.</u>

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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; <u>Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; Part</u> ~~110, Good Manufacturing Practices (GMPs)~~ <u>117 CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD</u>; ~~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.

II. IMPLEMENTATION OF A HACCP SYSTEM

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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 21CFR117 Subpart B.

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1. **Required PPs:** The following required PPs shall have a brief written description or checklist that the PPs can be audited against to ensure compliance. PPs shall include procedures that can be monitored; records that specify what is monitored; and how often it will be monitored.
Each milk plant, receiving station or transfer station shall have and implement PPs that address conditions and practices before, during, and after processing. The PPs shall address:

~~i. An employee training program shall at a minimum address the following:~~
~~(1) All employees directly responsible for the unloading and storage of raw materials and ingredients, storage and loading of the Grade "A" milk and/or milk product as well as any processing, receive annual food safety training that includes food GMPs, Appendix K. of this *Ordinance* requirements, an overview of HACCP, and allergens.~~
~~(2) Reference log of all employees identified in (1) above and the date and type of training received.~~

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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 product~~s~~ 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~~ scientifically valid;
(2) ~~Include written procedures and records~~ Identify the test micro-organism;
(3) Identify the ~~environmental monitoring~~ locations from which samples will be collected and the number of ~~sample~~ sites to be tested during routine environmental monitoring. The number and location of the 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 environmental pathogen or appropriate indicator microorganism to be tested for;~~

~~(6)~~ (5) Identify the test(s) conducted, including the analytical method used~~, and the test result~~;

~~(7)~~ (6) Identify the laboratory conducting the testing; and

~~(8)~~ (7) Include corrective action procedures for the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring ~~test results~~ (21 CFR 117.150).

~~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.~~

c. A milk plant shall establish a written recall plan that shall include procedures ~~as~~ that 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). **(21 CFR 117.139)**

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. …

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HAZARD ANALYSIS: Each milk plant, receiving station or transfer station shall develop, or have developed for it, a written hazard analysis to determine whether there are milk and/or milk product hazards that are reasonably likely to occur for each type of milk and/or milk product processed or handled by the milk plant, receiving station or transfer station and to identify the control measures that the milk plant, receiving station or transfer station can apply to control those hazards.

The hazard analysis shall include hazards that can be introduced both within and outside the milk plant, receiving station or transfer station environment, including hazards that can occur during handling, transportation, processing and distribution.

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 21CFR117 Subpart C. (117.130 Hazard Analysis).

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CORRECTIVE ACTIONS: Whenever a deviation from a CL occurs, a milk plant, receiving station or transfer station shall take corrective action by following the procedures set forth in 1. or 2. of this Section.

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 21CFR117 Subpart C. (117.150 Corrective Actions and Corrections).

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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, ~~110~~ 113 and 117 ~~and 113~~. at a frequency determined by FDA.

(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.~~

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a. 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 21CFR117 Subpart C. (117.155 and 117.165 Verification).

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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 21CFR117 Subpart C. (117.160 Validation).

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HACCP TRAINING:

1. **Core Curriculum:** The Dairy HACCP Core Curriculum consists of:
   a. Basic HACCP training; plus
   b. An orientation to the requirements of the NCIMS voluntary HACCP Program.

Basic HACCP training consists of instruction in the application of the NACMCF Principles of HACCP to Food Safety. This training includes practical exercises in conducting a hazard analysis and evaluating potential hazards; in writing a HACCP Plan; and in the validation of the plan. It should be taught by experienced instructors.

The orientation component ideally is coupled with the basic HACCP training, but can be taught separately. The content of the orientation will be conducted under the guidance of the NCIMS. It is intended to familiarize industry and regulatory personnel with specific dairy HACCP concerns and the regulatory requirements under the NCIMS voluntary HACCP Program. It is to be taught by instructors experienced in the application of HACCP under the NCIMS voluntary HACCP Program.

The industry individual(s) responsible for the entire HACCP Program shall meet the minimum requirements of a "Preventive Controls Qualified Individual" as defined in Section 1, definition "QQ". In general, industry individuals performing the functions identified in this Appendix requiring training or listed in Part 2 of this Section shall have met the minimum requirements of a "Qualified Individual" as defined in Section 1, definition "RR" and have successfully completed appropriate training in the application of HACCP principles to milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

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3. Employee Training: An employee training program shall at a minimum address the following:

a. All employees directly responsible for the mandatory prerequisite programs (see "Prerequisites And Other Programs" section, Preventive Controls and/or CCPs shall receive annual food safety training that includes current GMPs found in 21 CFR 117 Subpart B as well as Appendix K. of this Ordinance, an overview of HACCP, food allergens and the plant's recall program.

b. Record that identifies the employees receiving training, the date of the training, a short description of the training and a "signoff" by the trainer or employee's supervisor confirming that the training was completed.

~~3.~~ 4. **Regulatory Personnel:** Regulatory personnel performing HACCP audits shall have successfully completed appropriate training in the application of HACCP principles for milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum.

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***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

MAKE THE FOLLOWING CHANGES TO THE 2015 METHODS

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~~2~~3. COLLECTION OF DATA …….

a. Recording of Inspection 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 …….
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ABBREVIATIONS AND ACRONYMS …

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PCQI (Preventive Controls Qualified Individual)
pH (Potential Hydrogen-acid/alkaline balance of a solution) …

A. DEFINITIONS …

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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. …

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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.

~~24~~25. R**ATING AGENCY: …**

NOTE: RENUMBER REMAINING DEFINITIONS ACCORDINGLY.

~~28~~29. **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 an IMS rating/listing audit or FDA check rating/audit, it is necessary to determine compliance of the milk plant with the requirements of ~~Section 7. Standards for Grade "A" Pasteurized, Aseptically Processed and Packaged Low-Acid Milk and/or Milk Products, and Retort Processed after Packaged Low-Acid Milk and/or Milk Products~~ 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. If the milk plant is not in compliance, a rating/listing audit or check rating/FDA audit is not to be completed and the Rating Agency shall immediately deny or withdraw the milk plant's IMS listing.

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 denial or withdrawal 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 Hazard Anaylsis;

B. The written Recall Plan;
C. The written Preventive Controls, as appropriate, for hazards not addressed by PMO;
D. The written Supply-Chain Program, as appropriate, for hazards not addressed by PMO;
E. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by PMO;
F. The written Corrective Action Procedures, as appropriate, for hazards not addressed by PMO; and
G. The written Verification Procedures, as appropriate, for hazards not addressed by 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.
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.
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 monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.
7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented.
8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards.
9.) The milk plant has 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.
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.
11.) A series of observations that leads to a finding of a potential food safety system failure that is likely to result in a compromise to milk and/or milk product safety.

~~2~~3. 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, ~~110~~ 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, ~~110~~ 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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~~3~~4. COMPUTATION OF SANITATION COMPLIANCE RATINGS …

MAKE THE FOLLOWING CHANGES TO THE 2015 PROCEDURES

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

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. …

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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. …

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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., ~~F~~G. and ~~G~~H., the evaluation procedures of LEOs and SSOs.

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   d. PHS/FDA shall standardize, in accordance with Section V, ~~H~~I., 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.) …

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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**

A milk plant desiring a rating of their supply shall comply with the applicable Food Safety Plan requirements cited in ~~Section 7~~ Appendix T. of the *Grade "A" PMO.*

~~F~~G. **SAMPLING SURVEILLANCE PERSONNEL** …

~~G~~H. **MILK LABORATORY EVALUATION PERSONNEL** …

~~H~~I. **SINGLE-SERVICE CONSULTANT PERSONNEL** …

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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., ~~I~~J.

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~~I~~J. **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** …

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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

   A milk plant desiring a listing audit of their supply shall comply with the applicable Food Safety Plan requirements cited in ~~Section 7~~ Appendix T. of the *Grade "A" PMO*.

~~6~~7. Certification Procedures for SROs Who Will Conduct HACCP Listing Audits …

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~~7~~8. Sampling Surveillance Personnel

   Section V., ~~F~~G. shall apply as written.

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~~8~~9. Milk Laboratory Evaluation Personnel

   Section V., ~~G~~H. 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., ~~F~~G., and Section VIII., E.~~7~~8, 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., ~~G~~H., and Section VIII., E. ~~8~~9, if applicable, of this document and those of the *EML*. …

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 effect on September 17, 2018.*

Name:	Jason Crafts		
Agency/Organization:	HACCP Implementation Committee		
Address:	1105 N. 1000 W.		
City/State/Zip:	Logan, UT 84321		
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36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-4 *New Procedure
Committee:	HACCP/Liaison/ MMSR

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

A. Summary of Proposal

Building upon the work conducted at the 2015 conference through the Joint Council proposals, this proposal seeks to finalize the alignment of the Pasteurized Milk Ordinance (PMO) Appendix K with the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food. It also aligns Appendix K with the proposal being submitted by Liaison Committee.

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

The HACCP Implementation Committee, in concert with the Liaison Committee's efforts in placing all of the FSMA requirements under a new Appendix "T" adapted Appendix K as applicable keeping in harmony the closely related ties between the FSMA requirements and HACCP. Those areas of overlap between the FSMA requirements and HACCP remain in Appendix K with slight updates to Appendix K for alignment to FSMA. This includes some of the minor requirements under the new cGMP requirements under 21 CFR 117 (replacing 21 CFR part 110). Moreover, hazard analysis, verification, validation and corrective actions have been given references to the 21 CFR 117 as applicable. The *Holding and Distribution of Human Food By-Products For Use As Animal Food* is required in Appendix K as Other Applicable NCIMS Requirements. Those requirements from FSMA that are not directly related to HACCP are captured in Appendix T.
All related inspection timeframes and regulatory management of Appendix T is outlined in the proposal submitted by the Liaison Committee.

C. Proposed Solution			
Changes to be made on page(s):	347-357 (PMO), ii-19 (Methods) & 2-59 (Procedures)	of the (X - one of the following):	
X	2015 PMO		2015 EML
X	2015 MMSR		2400 Forms
X	2015 Procedures		2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO.

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

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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; <u>Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; Part</u> ~~110, Good Manufacturing Practices (GMPs)~~ <u>117 CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD</u>; ~~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.

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PREREQUISITE AND OTHER PROGRAMS: HACCP is not a stand-alone program, but is part of a larger control system. PPs are the universal procedures used to control the conditions of the milk plant environment that contribute to the overall safety of the milk and/or milk product. They represent the sum of programs, practices and procedures that shall be applied to produce and distribute safe milk and milk products in a clean, sanitary environment. They differ from CCPs in that they are basic sanitation programs that reduce the potential occurrence of a milk and/or milk product safety hazard. Frequently, both HACCP Plan CCPs and PPs control measures are necessary to control a food safety hazard.
HACCP may be implemented only in a facility that is constructed and operated to provide a sanitary environment. Milk plant, receiving station or transfer station premises, building construction, maintenance, and housekeeping shall be maintained in a manner sufficient to

provide such an environment. These factors shall be controlled by effective milk plant, receiving station or transfer station programs or by PPs, as the milk plant, receiving station or transfer station chooses.
The exact set of PPs will vary since their application is milk and/or milk product and process specific. The existence and effectiveness of PPs should be assessed during the design and implementation of each HACCP Plan. PPs should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates how the company monitors and controls each of the PPs. PPs are established and managed separately from the HACCP Plan.
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 21CFR117 Subpart B.

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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.~~

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HAZARD ANALYSIS: Each milk plant, receiving station or transfer station shall develop, or have developed for it, a written hazard analysis to determine whether there are milk and/or milk product hazards that are reasonably likely to occur for each type of milk and/or milk product processed or handled by the milk plant, receiving station or transfer station and to identify the control measures that the milk plant, receiving station or transfer station can apply to control those hazards.
The hazard analysis shall include hazards that can be introduced both within and outside the milk plant, receiving station or transfer station environment, including hazards that can occur during handling, transportation, processing and distribution.
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.
<u>The Hazard Analysis shall at a minimum provide compliance with 21CFR117 Subpart C. (117.130 Hazard Analysis).</u>

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3. All corrective actions taken in accordance with this Section shall be fully documented in records that are subject to verification.

<u>Corrective actions and corrections shall at a minimum provide compliance with 21CFR117 Subpart C. (117.150 Corrective Actions and Corrections).</u>

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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, ~~110~~ <u>113 and 117</u> ~~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 21CFR117 Subpart C. (117.155 and 117.165 Verification).

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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 21CFR117 Subpart C. (117.160 Validation).

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***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

MAKE THE FOLLOWING CHANGES TO THE 2015 METHODS

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

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   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 ……

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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 …….
~~3~~4. 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. …

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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.

~~24~~25. R**ATING AGENCY: …**

NOTE: RENUMBER REMAINING DEFINITIONS ACCORDINGLY.

~~28~~29. **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 an IMS rating/listing audit or FDA check rating/audit, it is necessary to determine compliance of the milk plant with the requirements of ~~Section 7. Standards for Grade "A" Pasteurized, Aseptically Processed and Packaged Low-Acid Milk and/or Milk Products, and Retort Processed after Packaged Low-Acid Milk and/or Milk Products~~ 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. If the milk plant is not in compliance, a rating/listing audit or check rating/FDA audit is not to be completed and the Rating Agency shall immediately deny or withdraw the milk plant's IMS listing.

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 denial or withdrawal 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 Hazard Anaylsis;
B. The written Recall Plan;
C. The written Preventive Controls, as appropriate, for hazards not addressed by PMO;
D. The written Supply-Chain Program, as appropriate, for hazards not addressed by PMO;
E. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by PMO;
F. The written Corrective Action Procedures, as appropriate, for hazards not addressed by PMO; and
G. The written Verification Procedures, as appropriate, for hazards not addressed by 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.

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.

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 monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented.
8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards.
9.) The milk plant has 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.
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.
11.) A series of observations that leads to a finding of a potential food safety system failure that is likely to result in a compromise to milk and/or milk product safety.

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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, ~~110~~ 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, ~~110~~ 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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~~3~~4. COMPUTATION OF SANITATION COMPLIANCE RATINGS

MAKE THE FOLLOWING CHANGES TO THE 2015 PROCEDURES

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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. …

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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. …

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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., ~~F~~G. and ~~G~~H., the evaluation procedures of LEOs and SSOs.

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d. PHS/FDA shall standardize, in accordance with Section V, ~~H~~I., 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.) …

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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**

A milk plant desiring a rating of their supply shall comply with the applicable Food Safety Plan requirements cited in ~~Section 7~~ Appendix T. of the *Grade "A" PMO*.

~~F~~G. **SAMPLING SURVEILLANCE PERSONNEL** …

~~G~~H. **MILK LABORATORY EVALUATION PERSONNEL** …

~~H~~I. **SINGLE-SERVICE CONSULTANT PERSONNEL** …

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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., ~~I~~J.

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~~I~~J. **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** …

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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

   A milk plant desiring a listing audit of their supply shall comply with the applicable Food Safety Plan requirements cited in ~~Section 7~~ Appendix T. of the *Grade "A" PMO*.

~~6~~7. Certification Procedures for SROs Who Will Conduct HACCP Listing Audits …

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~~7~~8. Sampling Surveillance Personnel

   Section V., ~~F~~G. shall apply as written.

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~~8~~9. Milk Laboratory Evaluation Personnel

   Section V., ~~G~~H. 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., ~~F~~G., and Section VIII., E.~~7~~8, 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., ~~G~~H., and Section VIII., E. ~~8~~9, if applicable, of this document and those of the *EML*. …

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 effect on September 17, 2018.*

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