

5100 Paint Branch Parkway
College Park, MD 20740-3835

October 14, 2009

IMS-a-47

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Dairy and Egg Branch (HFS-316)

Subject: Actions of the 2009 National Conference on Interstate Milk Shipments

The 32nd National Conference on Interstate Milk Shipments (NCIMS) was held in Orlando, Florida, April 17-22, 2009. A total of 133 Proposals were submitted and deliberated at the Conference. During the Conference, the State delegates approved several changes to the *Grade "A" Pasteurized Milk Ordinance (PMO)* and related NCIMS documents. Following is a table showing the Actions taken by the voting delegates:

| COUNCIL | # OF PROPOSALS | NO ACTION | PASSED AS SUBMITTED | PASSED AS AMENDED | TABLED |
|----------------|-----------------------|------------------|----------------------------|--------------------------|---------------|
| I | 53 | 30 | 5 | 18 | 0 |
| II | 64 | 25 | 19 | 20 | 0 |
| III | 16 | 9 | 3 | 4 | 0 |
| TOTAL | 133 | 64 | 27 | 42 | 0 |

The following Proposals were passed and addressed changes to the PMO: 102, 110, 114, 115, 117, 119, 122, 123, 125, 126, 128, 129, 131, 132, 134, 137, 139, 141, 142, 145, 148, 150, 232, 233, 234, 236, 242, 248, 254, 255, 256, 257, 301, 302 and 304.

The following Proposals were passed and addressed changes to the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)*: 311 and 312.

The following Proposals were passed and addressed changes to the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*: 128, 236, 262, 303 and 311.

The following Proposals were passed and addressed changes to the *Constitution of the National Conference on Interstate Milk Shipments (Constitution)*: None.

The following Proposals were passed and addressed changes to the *Bylaws of the National Conference on Interstate Milk Shipments (Bylaws)*: None.

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML) or to the FDA-2400 Series Forms: 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 223, 224, 226, 227, 229 and 255.

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

- FORM FDA 2359b-MILK PLANT EQUIPMENT TEST REPORT (10/08): 125.
- FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and Closures for Milk and Milk Products) (10/08): 148.
- FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT (10/08): 311.
- A new FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATION (10/09) (PAGE 4): 262.
- A new FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATION (10/09) (PAGE 5): 262.
- FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/08): 302 and 303.
- FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (10/08): 303.
- FORM FDA 2359o-PERMISSION FOR PUBLICATION-INTERSTATE MILK SHIPPER'S LISTING (10/08): 311.

Proposal 219 was passed and addressed changes to be made to M-a-85 (Issue a New Revision #13)-Beta lactam Test Methods for use Under Appendix N and Section 6 of the Grade "A" Pasteurized Milk Ordinance (PMO) and consequently to M-I-96-10 (Issue a New Revision #7)-Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back for sheep and water buffalo milk test kits.

The following Proposal was passed and addressed the formation of an Ad-hoc Study Committee: 104.

The following Proposals were passed and did not reference any document or Form: 104, 252, 259, 260 and 307.

FDA responded in writing to the NCIMS Conference Chair on August 7, 2009 and met with the NCIMS Executive Board on September 9-10, 2009 concerning the Proposals passed during the 2009 Conference. Within FDA's letter dated August 7, 2009, FDA initially did not concur with Proposals 117, 119 and 232. During the September 9-10, 2009 NCIMS Executive Board meeting, FDA and the Executive Board mutually concurred with all of the Proposals and changes cited within this IMS-a.

All Proposals that were passed, with the exception of the ones noted below, will become effective within one (1) year of the electronic publication of the affected document(s); or by the official notification to the States through the transmittal of this IMS-a, as applicable, following

the Conference at which the changes were passed. For States that can legally enforce the new regulations based on the issuance of this IMS-a, the effective date will be October 14, 2010.

- Proposal 262 changes the calculation methods for Part I-Dairy Farms, Item 10-Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required and Item 11-Records systematically maintained and current on FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION B. REPORT OF (Page 3) (10/06), will become effective upon the issuance of this IMS-a.
- Proposal 301 extends the NCIMS Aseptic Pilot Program (APP) until December 31, 2011, unless extended by future Conference action. This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2009 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board. State regulatory and rating personnel must be trained in the implementation of the Aseptic Pilot Program prior to an aseptic milk plant being inspected and rated using the pilot program.
- Proposal 304 extends the voluntary NCIMS International Certification Pilot Program (ICPP) until December 31, 2011, unless extended by future Conference action. This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2009 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.
- Proposal 307 allows once a Third Party Certifier (TPC) under the voluntary International Certification Pilot Program has their existing 2 plants IMS Listed, the TPC may request from the ICCP Committee permission to add up to 2 additional plants for a maximum of 4 listed plants. This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2009 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.
- Proposal 311, which addressed an individual dairy farm shall only be included in one (1) IMS Listing and if the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, then the expiration date would be 12/14/2009. An effective date shall correspond to the issuance of the IMS-a addressing actions from the 2009 NCIMS Conference.

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

Proposal: 132

Document: 2007 PMO (Illustrations; and Appendixes H, I, O and R)

Pages: xiv, 217, 218, 221-223, 226-230, 232-233, 252-256, 299, 336, 340, and 349

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Figure 37. HTST Pasteurizer Utilizing Tubular Type Heat Exchangers and Homogenizer as
the Timing Pump

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Timing System Located Upstream from an Evaporator

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Figure 42. HHST Pasteurizer Utilizing Direct Culinary Steam Infusion and Vacuum Flash
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NOTE: Re-number the ILLUSTRATIONS' Section page references accordingly.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT - I. HTST PASTEURIZATION on Page 217:

~~PRESSURE RELIEF VALVE, LOCATED WITHIN HTST, HHST AND ASEPTIC PROCESSING SYSTEMS~~

1. **Between the Timing Pump and the Beginning of the Holding Tube:** Placement of a pressure relief valve between the timing pump and the beginning of the holding tube is acceptable provided it meets either OPTION I or II below:

OPTION I:

- a. Provisions are made for the cleaning of the valve vent and any return piping to the constant-level tank whenever the system is cleaned.
- b. The pasteurizer shall not be timed if the valve is leaking. Leakage may be determined by observation at the pressure relief valve vent opening to the floor or at the opening of the return piping from the pressure relief valve vent into the constant-level tank.
- c. The system is designed and operated so that loss of pressure from the pasteurized side of the regenerator cannot occur if the system flow-promoting devices stop while the FDD is in the forward-flow position. A system not protected against this potential pressure loss is considered a violation of Item 16p(D) of this *Ordinance*.

For Example: ~~In a magnetic flow meter based timing system there is a fail-safe, spring-to-close valve or check-valve that must also be located between the timing pump and the holding tube. Item 16p(D) of this Ordinance is satisfied if the pressure relief valve is located prior to this fail-safe valve or check-valve.~~

OPTION II. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator if the system flow-

promoting devices stop while the FDD is in the forward-flow position. This is considered a violation of Item 16p(D) of this Ordinance. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT- I. HTST PASTEURIZATION on Page 218:

2. Downstream from the Holding Tube in ~~HTST~~ Systems:

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT - I. HTST PASTEURIZATION on Pages 221-223:

Page 221:

NOTE: DELETE EXISTING FIGURES 31 AND 32 AND REPLACE WITH THE LEGEND AND NEW FIGURE 31.

LEGEND

| <u>LINE LEGEND</u> | |
|---------------------|-------------|
| RAW PRODUCT | ————— |
| PASTEURIZED PRODUCT | - - - - - |
| HEAT EXCHANGE MEDIA | - · - · - · |
| ELECTRICAL SIGNAL | · · · · · |

| <u>ABBREVIATIONS</u> |
|--|
| AUX STL R = AUXILIARY SAFETY THERMAL LIMIT RECORDER |
| AUX TE = AUXILIARY TEMPERATURE ELEMENT |
| CLT = CONSTANT LEVEL TANK |
| CMR = COOLING MEDIA RETURN |
| CMS = COOLING MEDIA SUPPLY |
| CTRL = CONTROLLER |
| DPLI = DIFFERENTIAL PRESSURE LIMIT INSTRUMENT |
| DRT = DIGITAL REFERENCE THERMOMETER |
| FC = FAIL CLOSED (INTERWIRED WITH FLOW DIVERSION DEVICE) |
| FRC = FLOW RECORDER / CONTROLLER |
| HMR = HEATING MEDIA RETURN |
| HMS = HEATING MEDIA SUPPLY |
| MBTS = METER BASED TIMING SYSTEM |
| P = PASTEURIZED |
| PC = PRESSURE CONTROLLER |
| PLI = PRESSURE LIMIT INSTRUMENT |
| PT = PRESSURE TRANSMITTER |
| R = RAW |
| RBPC = REGENERATOR BACK PRESSURE CONTROLLER |
| RC = RATIO CONTROLLER |
| RDPS = REGENERATOR DIFFERENTIAL PRESSURE SWITCH |
| STLR = SAFETY THERMAL LIMIT RECORDER CONTROLLER |
| T = THROTTLING (MODULATING) VALVE |
| TC = TEMPERATURE CONTROLLER |
| TE = TEMPERATURE ELEMENT |
| TT = TEMPERATURE TRANSMITTER |

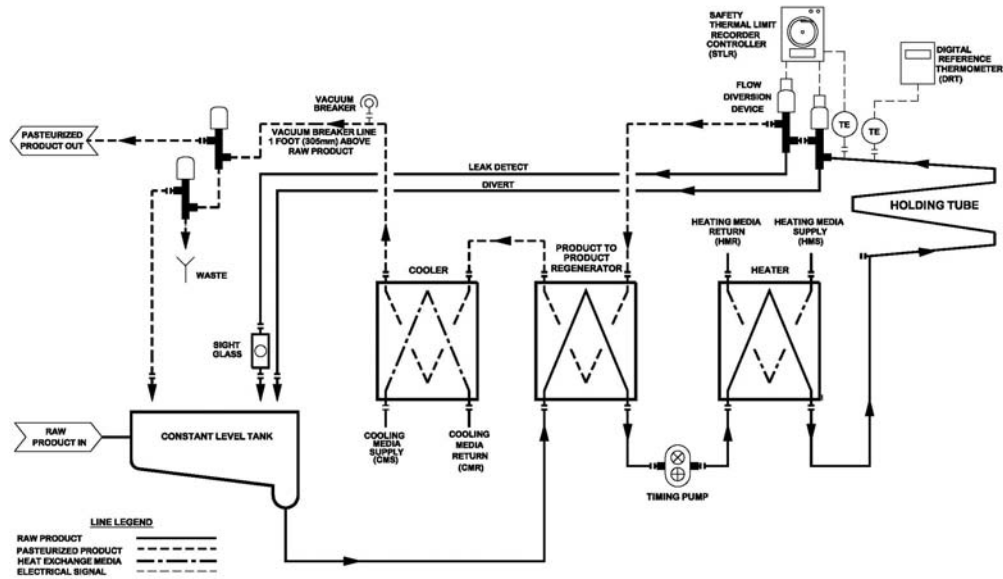


Figure 31. Milk-to-Milk Regeneration—Homogenizer Upstream from Holding Tube HTST Pasteurizer with a Positive Displacement Rotary Timing Pump

Page 222:

NOTE: DELETE EXISTING FIGURES 33 AND 34 AND REPLACE WITH THE NEW FIGURES 32 AND 33.

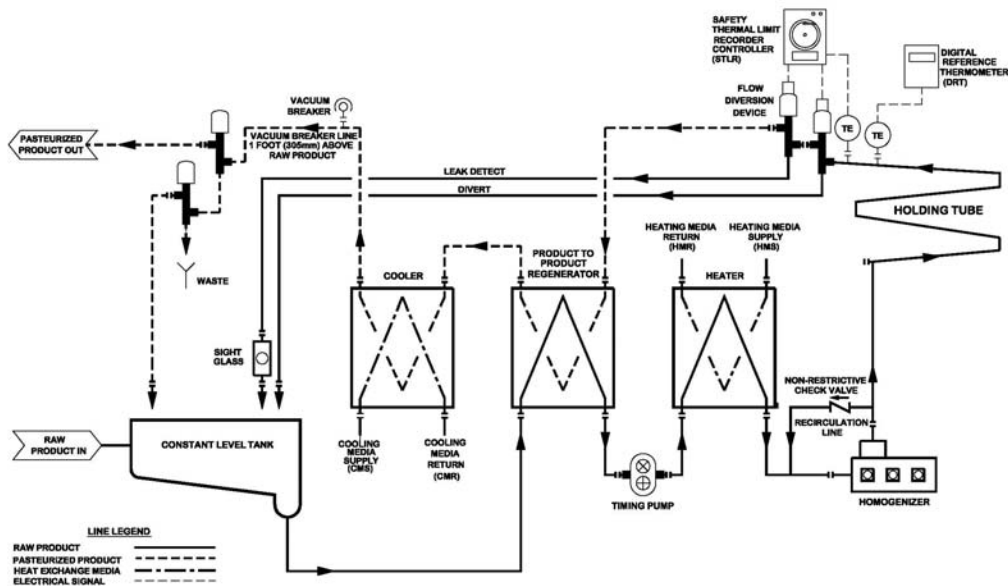


Figure 32. Milk-to-Milk Regeneration—Booster Pump HTST Pasteurizer with a Homogenizer Located at the Outlet of the Heater Section and of a Larger Capacity than the Timing Pump

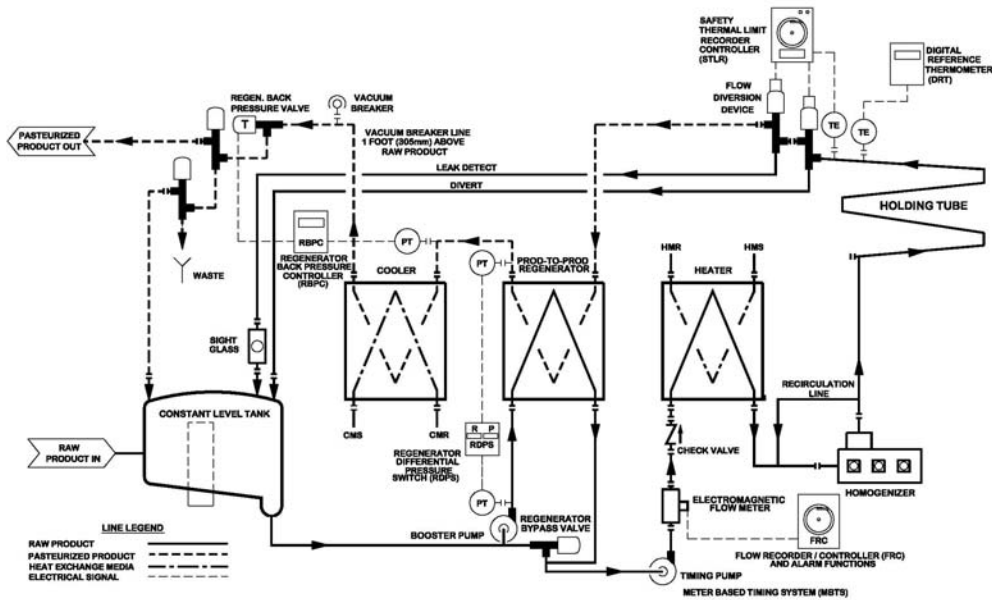


Figure 33. Milk-to-Milk Regeneration Homogenizer and Vacuum Chambers Downstream from Flow-Diversion Device HTST Pasteurizer with a Booster Pump, Meter Based Timing System and a Homogenizer with a Bypass Line

Page 223:

NOTE: DELETE EXISTING FIGURES 35 and 36 AND REPLACE WITH THE NEW FIGURES 34 AND 35.

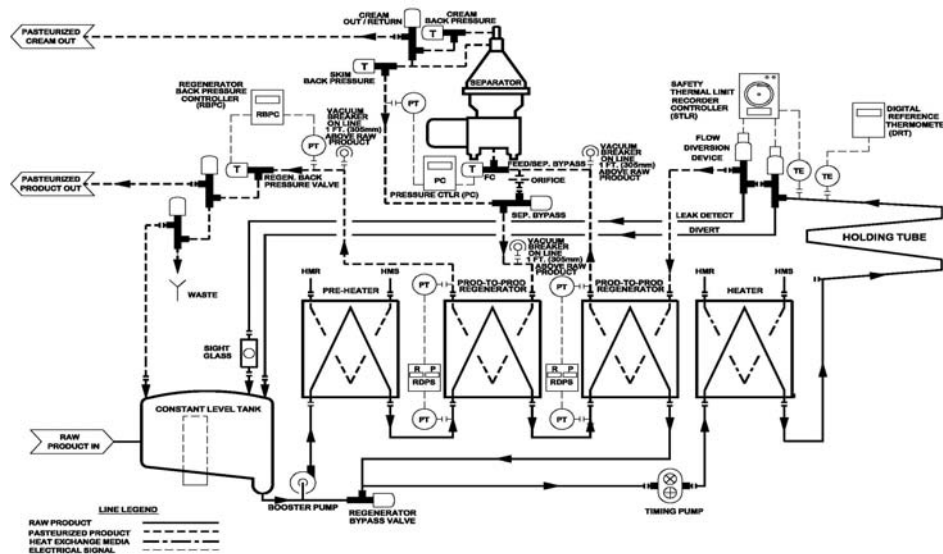


Figure 34. HTST System with a Magnetic Flow Meter Using a Constant Speed Centrifugal Pump and a Control Valve HTST Pasteurizer with a Booster Pump, Timing Pump and a CIP-Type Separator Located Between Two Pasteurized Product Regenerators with a Pre-Heater

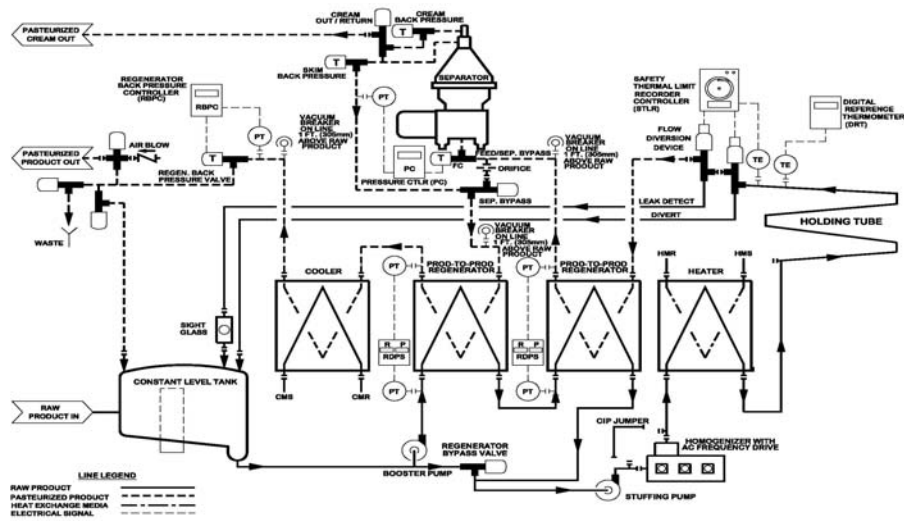


Figure 35. HTST System with a Magnetic Flow Meter Using an A-C Variable Speed Centrifugal Pump HTST Pasteurizer with a Booster Pump, Homogenizer as a Timing Pump with an AC Variable Frequency Drive, CIP-Type Separator Located Between Two Pasteurized Product Regenerators and an Air Actuated Discharge Valve with an Air Blow

NOTE: ADD ADDITIONAL NEW FIGURES 36 THROUGH 43 ON THE NEXT PAGES OF THE PMO.

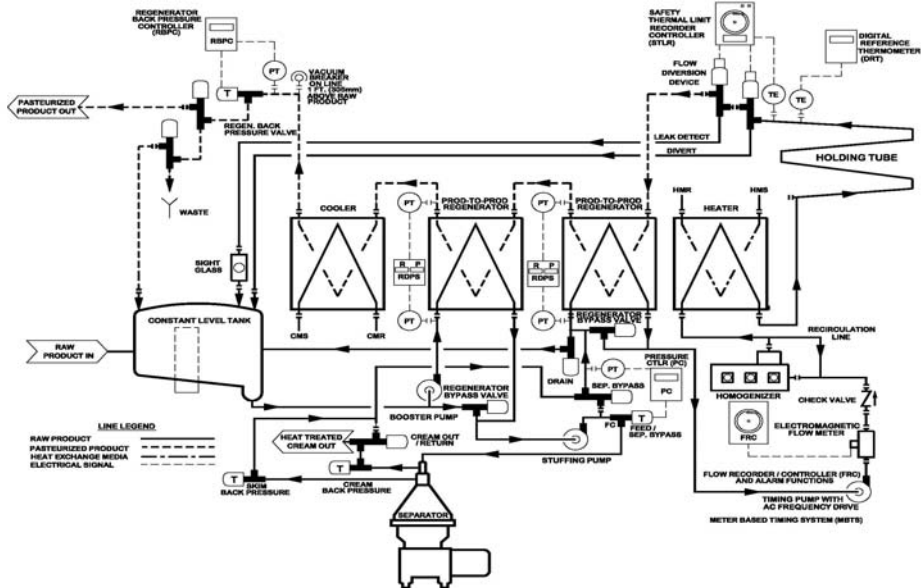


Figure 36. Controls for Steam Injection Pasteurizer HTST Pasteurizer with a Separator Between the Raw Regenerator and the Heater Section with a Meter Based Timing System and a Regenerator Bypass

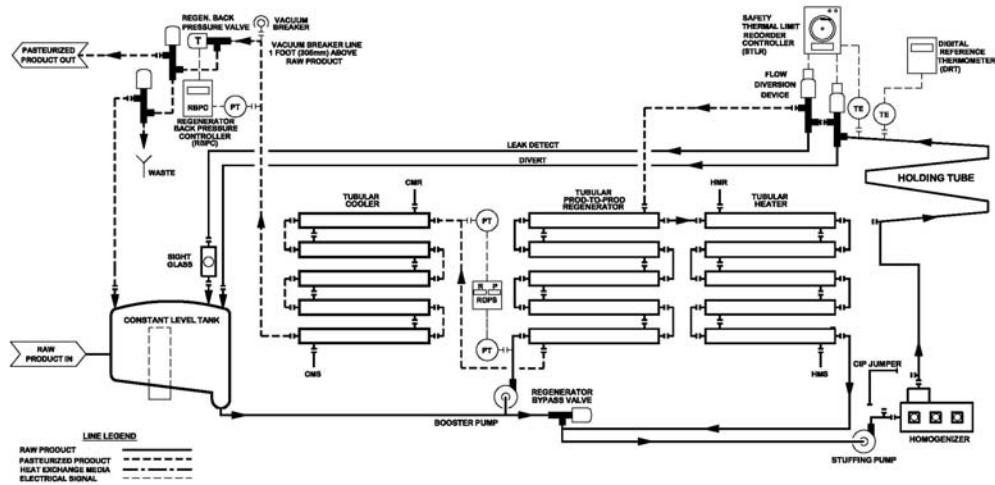


Figure 37. HTST Pasteurizer Utilizing Tubular Type Heat Exchangers and a Homogenizer as the Timing Pump

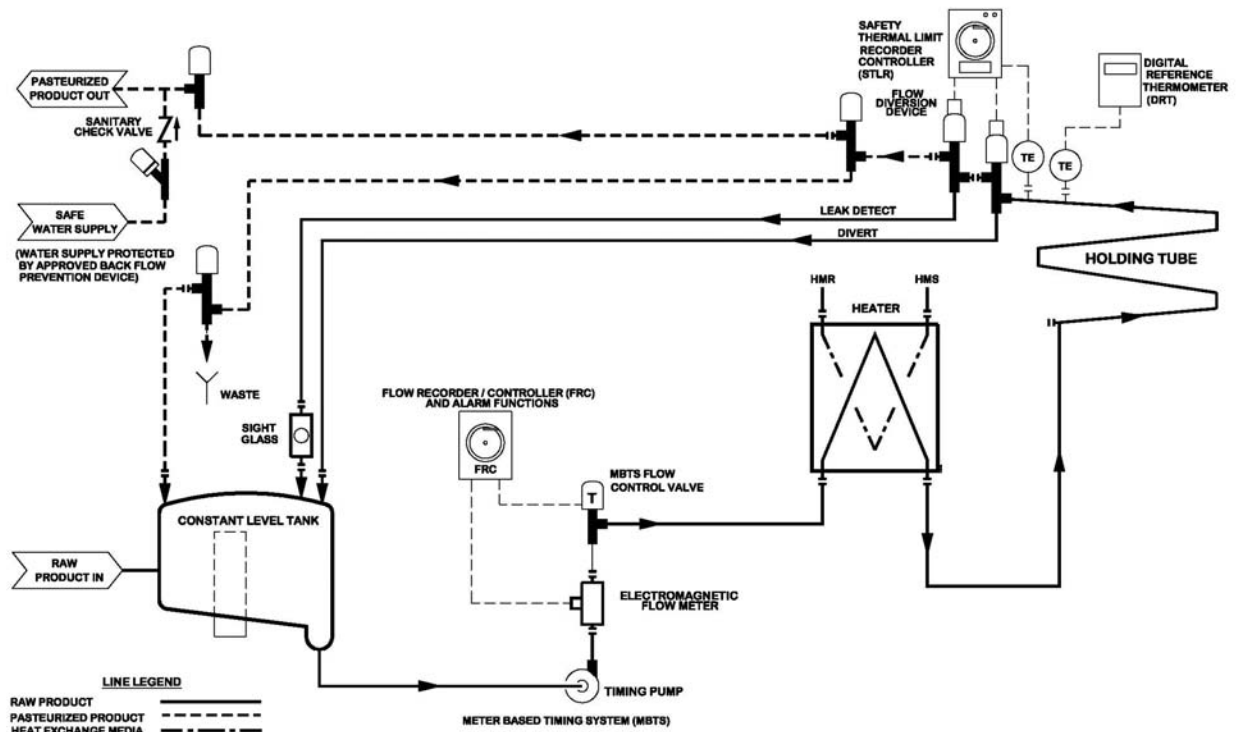


Figure 38. HTST Pasteurizer, without a Regenerator or Cooler Section, with a Meter Based Timing System Located Upstream from an Evaporator

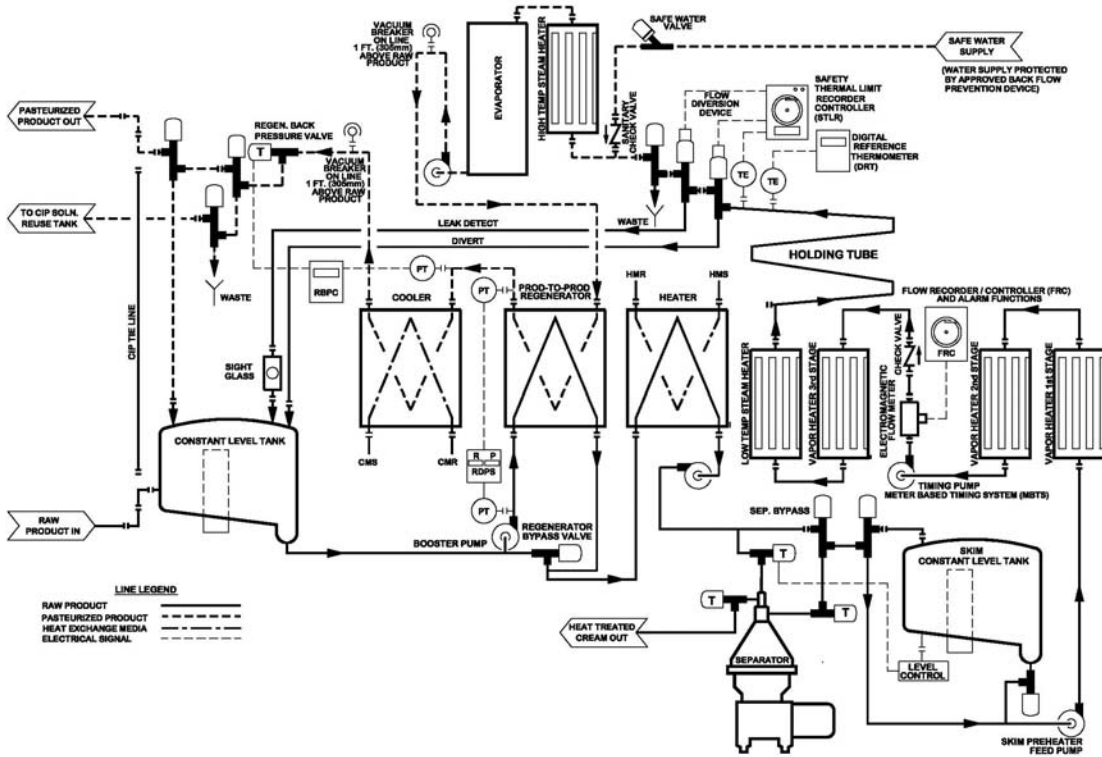


Figure 39. HTST Pasteurizer with a Regenerator, Separator, Skim Surge Tank and a Meter Based Timing System Located Upstream from an Evaporator

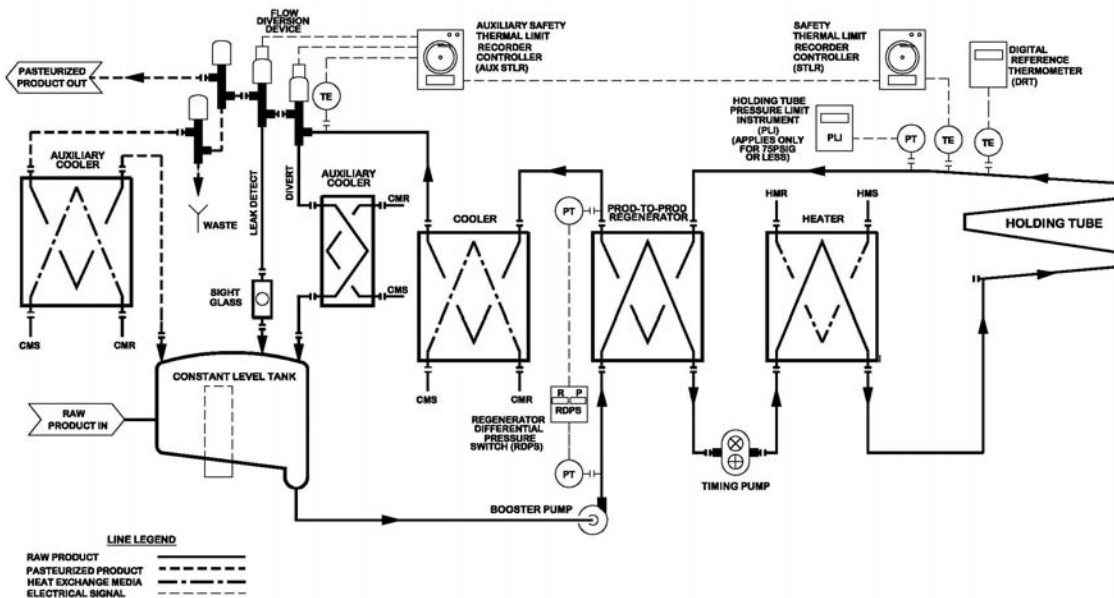


Figure 40. HHST Pasteurizer with a Flow-Diversion Device Located Downstream of the Cooling Section

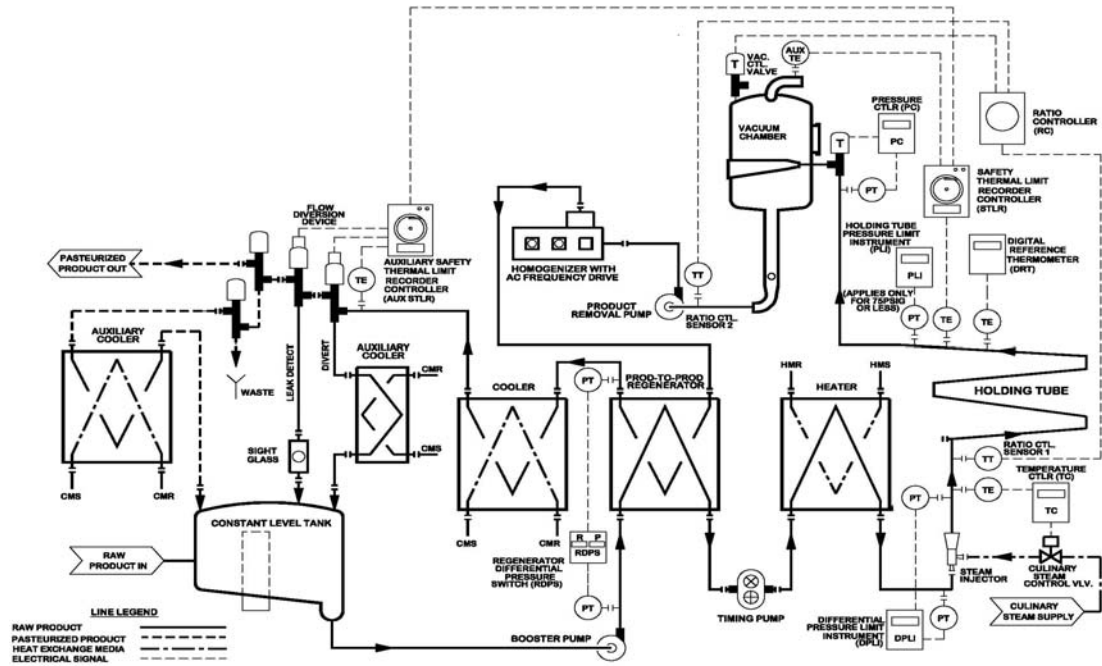


Figure 41. HHST Pasteurizer Utilizing Steam Injection Heating, Vacuum Flash Cooling and a Flow-Diversion Device Located Downstream of the Cooler Section

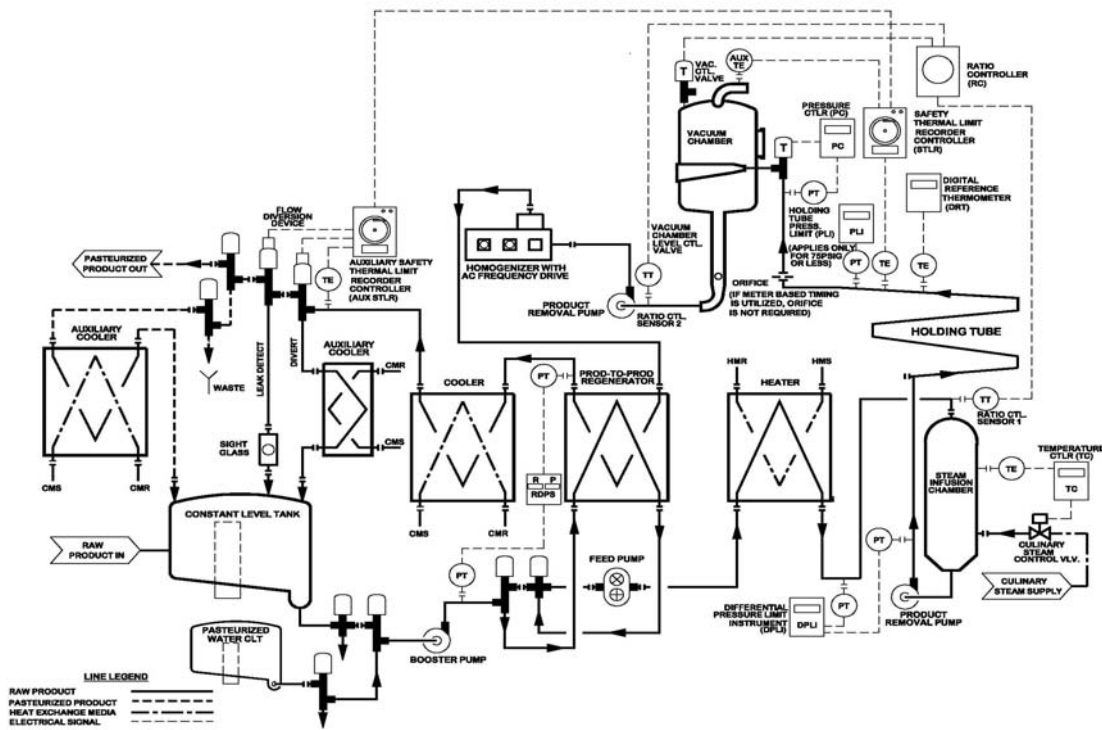


Figure 42. HHST Pasteurizer Utilizing Direct Culinary Steam Infusion and Vacuum Flash Cooling with a Homogenizer Located Downstream

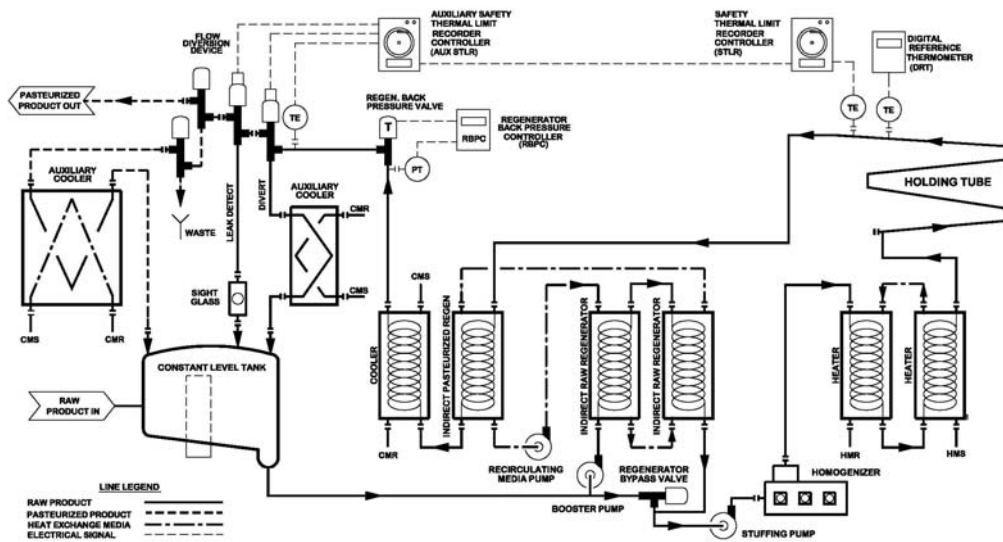


Figure 43. HHST Pasteurizer with a Homogenizer as the Timing Pump and Utilizing a Spiral Tubular Heat Exchanger with Indirect Regeneration

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT – II. AIR FOR DRYING EQUIPMENT AND AIR UNDER PRESSURE – DIRECT CONTACT WITH MILK AND MILK PRODUCTS AND MILK PRODUCT-CONTACT SURFACES on Pages 226-230:

Air Piping:

- a. When air under pressure is directed at product-contact surfaces of containers, closures and supplementary fitments, the air passage from the final filter to the point of application shall be made of a non-toxic, relatively nonabsorbent material. In this application, check-valves are not required. The final filter shall be located as close as practical to the point of application. (Refer to Figure 44 48)

Page 227:

Figure 44 37. Individual Compression-Type Air Supply

Page 228:

Figure 45 38. Central Compression-Type Air Supply

Page 229:

Figure 46 39. Individual Blower-Type Air Supply

Figure 47 40. Individual Fan-Type Air Supply

Page 230:

Figure 48 41. Rotating Mandrel Assembly

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT – III. CULINARY STEAM – MILK AND MILK PRODUCTS on Pages 232-233:

Figure 49 42. Culinary Steam Piping Assembly for Steam Infusion or Injection

Page 233:

Figure 50 43. Culinary Steam Piping Assembly for Steam Infusion or Injection (Optional Configuration)

Figure 51 44. Culinary Steam Piping Assembly for Airspace Heating or Defoaming

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT – VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE “A” PUBLIC HEALTH CONTROLS on Pages 252-256:

Figure 52 45. Logic Diagram: HTST Flow-Diversion Device, Divert Valve Stem

Page 253:

Figure 53 46. Logic Diagram: HTST Flow-Diversion Device, Leak-Detect Valve Stem

Page 254:

Figure 54 47. Logic Diagram: HTST Safety Limit Recorder-Controller

Page 255:

Figure 55 48. Logic Diagram: HTST Timing Pump

Page 256:

Figure 56 49. Logic Diagram: HTST Booster Pump

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT CONTROLS AND TESTS – II. TESTS PROCEDURES, TEST 13 on Pages 298-299:

Procedure:

1. From Figure ~~50~~ 57 determine the pressure switch setting necessary for the operating temperature, not the diversion temperature, being used in the process. Install the sanitary pressure gauge, of known accuracy, and the pressure switch sensing-element on the pneumatic testing device....

4. Determine that the cut-in pressure on the switch is equivalent to or greater than the required pressure from Figure ~~50~~ 57. If adjustment is necessary, refer to the manufacturer's instructions.

Page 299:

Figure 57 ~~50~~. Pressure Switch Setting

Make the following change to APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS - PROCESS/METHODS OF VITAMIN ADDITION on Page 336:

1. The first is a piston type metering pump with valves....

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

Separate pumps, tubing and check-valves are recommended when multiple types of vitamin concentrates are injected. (Refer to Figure ~~54~~ 58)

Make the following changes to APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS - PROCESS/METHODS OF VITAMIN ADDITION on Page 340:

NOTE: Figure ~~54~~ 58 details a two (2) speed vitamin fortification installation using two (2) pumps and two (2) vitamin concentrate sources. This enables changing from different vitamin concentrates and different speed pumps via the adjustment of three-way valves.

Figure 58 ~~54~~. Vitamin Fortification

Make the following change to APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS on Page 349:

Figure 59 ~~52~~. Decision Tree for Using pH, a_w, or the Interaction of pH and a_w to Determine if a Milk or Milk Product Requires Time/Temperature for Safety

Proposal: 234

Document: 2007 PMO (Section 1)

Page: 5

Make the following changes to **SECTION 1. DEFINITIONS** on Page 5:

S. HOOVED MAMMALS' MILK: Hooved mammals' milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals for the purpose of this Ordinance, include but are not limited to, the members of the Order Cetartiodactyla, such as: Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.). This product shall be produced according to the sanitary standards of this *Ordinance*. (Refer to the **NOTE:** on page 26)

Proposal: 232

Document: 2007 PMO (Section 1; and Footnotes)

Pages: 6 and 126

Make the following changes to **SECTION 1. DEFINITIONS** on Page 6:

~~X. **MILK PRODUCTS:** Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or loft milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low sodium milk, low sodium reduced fat or lowfat milk, low sodium nonfat (skim) milk, lactose reduced milk, lactose reduced reduced fat or lowfat milk, lactose reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.^{2,3}~~

~~Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.~~

Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR Part 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR Part 133.128) and Dry curd cottage cheese (21 CFR Part 131.129).²
3. Whey and whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, and Section 1, Definition QQ of this Ordinance.
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR Part 130.10 - requirements for foods named by use of a nutrient content claim and a standardized term.

5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form (e.g., " cottage cheese with pineapple", "fat free milk with plant sterols".)

6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products.

Safe and suitable (as defined in 21 CFR 130.3(d)) non-grade "A" dairy ingredients, can be utilized in the products defined in Items 1-6 when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices (GMPs) and are either:

- a) Prior sanctioned or otherwise approved by FDA, or
- b) GRAS (generally recognized as safe), or
- c) An approved food additive listed in the CFR.

Except that with respect to those products which have a federal standard of identity, only ingredients provided for in the standard may be utilized.

Note: When a non-grade "A" dairy ingredient is used to increase weight or volume of the product, or displace grade "A" dairy ingredients, this use is not a suitable functional or technical effect.

This Definition shall include those milk and milk products, as defined ~~herein~~ above, which have been aseptically processed and then packaged.

This Definition does not include:

1. A milk or milk product in which the milkfat of the milk or milk product has been substituted in part or in whole by any other animal or vegetable fat; provided that other fat sources may be included when they are used for purposes currently accepted in any other Grade "A" milk or milk product, such as carriers for vitamins and as an ingredient in emulsifiers and stabilizers;

2. Coffee based products where coffee or water is the primary ingredient as indicated in the ingredient statement;

3. Tea based products where tea or water is the primary ingredient as indicated in the ingredient statement;

4. Dietary products (except as defined herein);

5. Infant formula;

6. Ice cream or other frozen desserts;

7. Butter;

8. Cheese (standardized or non-standardized); or

9. Puddings.

Milk and milk products which have been retort processed after packaging, or which have been concentrated (condensed) or dried are only included in this Definition ~~only~~ if they are used as an ingredient to produce any milk or milk product defined ~~herein~~ above or if they are labeled as Grade "A" as described in Section 4.

Powdered dairy blends may be labeled Grade "A" and used as ingredients in Grade "A" ~~dairy milk and milk~~ products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade "A" cultured milk and milk products, if they meet the requirements of this *Ordinance*. If used as an ingredient in Grade "A" milk and milk products, ~~such as those~~

~~listed above~~, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy milk and milk products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade “A”. This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.....

Make the following changes to **FOOTNOTES** on Page 126:

2. Regulatory Agencies desiring to not regulate cottage cheese and dry curd cottage cheese under the terms of this *Ordinance* should ~~insert~~ delete the following definitions:
Cottage cheese is the product defined in 21 CFR 133.128.
Dry curd cottage cheese is the product defined in 21 CFR 133.129.

NOTE: FDA INITIALLY NON-CONCURRED WITH THIS PROPOSAL BASED ON A CONFLICT IDENTIFIED WITHIN THE TEXT PASSED BY THE VOTING DELEGATES, WHICH ADDRESSES “GRADE “A” MILK AND MILK PRODUCTS INCLUDES:” AND “THIS DEFINITION DOES NOT INCLUDE:”. THE FOLLOWING CHANGES WERE MUTUALLY CONCURRED WITH BY THE NCIMS EXECUTIVE BOARD AND FDA ON SEPTEMBER 9-10, 2009:

8. Cheese (standardized, ~~except cottage cheese (21 CFR Part 133.128) and dry curd cottage cheese (21 CFR Part 131.129)~~² or non-standardized); or

Make the following changes to the **FOOTNOTES** on Page 126:

2. Regulatory Agencies desiring to not regulate cottage cheese and dry curd cottage cheese under the terms of this *Ordinance* should ~~insert~~ delete the following from the definitions of Milk Products:
Cottage cheese ~~is the product defined in~~ (21 CFR Part 133.128).
Dry curd cottage cheese ~~is the product defined in~~ (21 CFR Part 133.129).

Proposal: 233
Document: 2007 PMO (Section 1)
Page: 6

Make the following changes to SECTION 1. DEFINITIONS on Page 6:

X. MILK PRODUCTS:

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” ~~dairy milk and milk~~ products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured milk and milk products, if they meet the requirements of this *Ordinance*. If used as an ingredient in Grade “A” milk and milk products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” powdered dairy blends requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 10 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade “A”.....

Proposal: 122

Document: 2007 PMO (Sections 1 and 7-Item 16p)

Pages: 7 and 81

Make the following changes to SECTION 1. DEFINITIONS on Page 7:

FF. PASTEURIZATION:

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

Make the following changes to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 81:

ADMINISTRATIVE PROCEDURES

*If the fat content of the milk product is 10 percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, ~~or is concentrated (condensed)~~, the specified temperature shall be increased by 3°C (5°F).

Proposal: 236

Document: 2007 PMO (Section 3; and Appendix E)

Pages: 13 and 198-199

Make the following changes to SECTION 3. PERMITS on Page 13:

ADMINISTRATIVE PROCEDURES

REINSTATEMENT OF PERMITS: Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit. When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the Regulatory Agency may issue a temporary permit whenever a re-sampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform, somatic cell count and temperature. and ~~†~~The Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.

Make the following changes to APPENDIX E. EXAMPLES OF 3-OUT-OF-5 COMPLIANCE ENFORCEMENT PROCEDURES on Pages 198-199:

Table 11. Example of Enforcement Procedures for Pasteurized Milk Laboratory Examinations

| Date | Bacterial Count per mL | Enforcement Action as Applied to a Standard of 20,000/mL |
|-------------|-------------------------------|--|
| 1/05/0709 | 6,000 | No Action Required |
| 1/28/0709 | 11,000 | No Action Required |
| 2/11/0709 | 12,000 | No Action Required |
| 3/15/0709 | 22,000 | Violative; No Action Required |
| 3/25/0709 | 23,000 | Violative; Written notice to the milk plant, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days. |
| 4/02/0709 | 9,000 | No Action Required |
| 4/19/0709 | 51,000 | Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend the milk plant permit; or 2. Forego permit suspension, provided the milk or milk product(s) in violation are not sold as Grade "A" milk or milk product(s); or 3. Impose monetary penalty in lieu of permit suspension, provided the milk or milk product(s) in violation are not sold as Grade "A" milk or milk product(s). |
| 4/23/0709 | | Issue temporary permit (if applicable) after a milk plant inspection. Begin accelerated sampling schedule. <u>Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i>. (Refer to Section 3)</u> |
| 4/25/0709 | 11,000 | No Action Required |
| 4/29/0709 | 3,000 | No Action Required |
| 5/4/0709 | 22,000 | Violative; No Action Required NOTE: Samples collected prior to 4/23/0709 are not used for subsequent bacterial count enforcement purposes. |
| 5/9/0709 | 5,000 | Permit Fully Reinstated |

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations

| Date | Confirmed Somatic Cell Counts per mL | Enforcement Action as Applied to a Standard of 750,000 per MI |
|------------|--------------------------------------|---|
| 7/10/0709 | 500,000 | No Action Required |
| 8/15/0709 | 600,000 | No Action Required |
| 10/1/0709 | 800,000 | Violative; No Action Required |
| 11/7/0709 | 900,000 | Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days. |
| 11/14/0709 | 1,200,000 | Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: <ol style="list-style-type: none"> 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this <i>Ordinance</i>. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i>. (Refer to Section 3) |
| 11/18/0709 | 700,000 | Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule <u>as cited under 11/14/09</u> . |
| 11/20/0709 | 800,000 | Violative; No Action Required NOTE: Samples collected prior to 11/18/0709 are not used for subsequent somatic cell count enforcement purposes. |
| 11/24/0709 | 700,000 | No Action Required |
| 11/29/0709 | 550,000 | No Action Required |
| 12/3/0709 | 400,000 | Permit Fully Reinstated |

Document: 2007 MMSR (Appendix A)
Pages: 70 and 76

Make the following changes to APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS on Page 70:

PART I. DAIRY FARMS

10. Permit issuance, suspension, revocation.....

PRODUCT COMPLIANCE

e. “Reinstating accelerated sample(s)” for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period. (PRI*)

Make the following changes to APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS on Page 76:

PART II. MILK PLANT

9. Permit issuance, suspension, revocation.....

PRODUCT COMPLIANCE

f. “Reinstating accelerated samples” for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period (~~except for drug residues~~). (PRI)*

Proposal: 242

Document: 2007 PMO (Section 5-Certified Industry Inspection)

Pages: 20-21

Make the following changes to SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS, CERTIFIED INDUSTRY INSPECTION on Pages 20-21:

Re-Certification: The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above except that a minimum of ten (10) randomly selected dairy farms and/or two (2) milk tank trucks, as applicable for the type of re-certification, shall be inspected. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency. In order to be re-certified, a certified industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree

to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant. Should the Regulatory Agency determine that a certified industry inspector has failed to demonstrate proficiency in the above re-certification procedures, the Regulatory Agency may require the certified industry inspector to perform the initial certification procedures.

Reports and Records: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate or notified of satisfactory re-certification. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume ledger of the percentage agreement on individual items, shall be retained by the Regulatory Agency.

Proposal: 102
Document: 2007 PMO (Sections 6 and 7-Table 1)
Pages: 25 and 29

Make the following changes to SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS on Page 25:

ADMINISTRATIVE PROCEDURES

LABORATORY TECHNIQUES:

6b. Goat Milk: Direct Microscopic Somatic Cell Count or Electronic Somatic Cell Count may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains ~~1,000,000/mL~~ 1,500,000/mL. Screening for official purposes must be conducted by an analyst (s) certified for that procedure. Only the Pyronine Y-Methyl Green stain or “New York modification” Single Strip Direct Microscopic Somatic Cell Count test procedures shall be used to confirm the level of somatic cells in goat milk by certified analysts.

Make the following change to SECTION 7, TABLE 1 on Page 29:

* Goat Milk ~~1,000,000 per mL~~ 1,500,000 per mL

Proposal: 248
Document: 2007 PMO (Section 6)
Page: 25

Make the following changes to SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS on Page 25:

Proposal: 115

Document: 2007 PMO (Section 7-Items 15p and 16p; and Appendix H)

Pages: 76, 87, 218, 246, 247 and 252-257

Make the following change to SECTION 7, ITEM 15p-PROTECTION FROM CONTAMINATION on Page 76:

ADMINISTRATIVE PROCEDURES

15p(B)

1. During processing, pipeline and equipment.....

b. Separation of all connection points....

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

Make the following change to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 87:

ADMINISTRATIVE PROCEDURES

2. AUTOMATIC MILK CONTROLLER:

b. **FDDs:**

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

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 218:

I. HTST PASTEURIZATION

OPERATION OF HTST SYSTEMS

POSITION DETECTION DEVICES

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

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

MAGNETIC FLOW METER BASED TIMING SYSTEM FOR HTST PASTEURIZERS

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Pages 246-247:

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

GLOSSARY

Input: Electrical signals applied to the computer and used by the computer to make logical decisions on whether or not to activate one or more outputs. Input consists of data from temperature and pressure instruments, liquid level controls, ~~micro-switches~~ position detecting devices (PDDs), and operator-controlled panel switches.

Page 247:

Output: Electrical signals from the computer that turn on or off valves, motors, lights, horns, and other devices being controlled by the computer. Outputs may also consist of messages and data to the operator.

Position Detecting Device (PDD): Mechanical limit switches (micro-switches) or electronic proximity switches capable of providing an electrical signal.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Pages 252- 256:

Revise diagrams legend:

~~MS = Microswitch~~ PDD = Position Detecting Device

Page 253-256:

Revise diagrams:

~~MS~~ with PDD

Make the following change to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 257:

VII. CRITERIA FOR STEAM-BLOCK TYPE FDD SYSTEMS

3. The Primary Divert Valve and other critical valves shall be position detectable and fail-safe and be alarmed to provide protection when needed. **NOTE:** For the detection of the FDD and valve seat positions, refer to Appendix H., I., Position Detection Devices.

Proposal: 117

Document: 2007 PMO (Section 7-Item 15p)

Page: 78

Make the following changes to SECTION 7, ITEM 15p-PROTECTION FROM CONTAMINATION on Page 78:

**ADMINISTRATIVE PROCEDURES
15p(B)**

2. Except as permitted in Item 16p, there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products ~~or water~~ not completely separated from pasteurized milk and milk products, shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in Definition FF, ~~or~~ in the case of water, shall meet at least the minimum times and temperatures provided for in Definition FF in equipment that may not meet Item 16p or has ~~have~~ undergone an equivalent process found acceptable by FDA and the Regulatory Agency or shall have undergone a hazard evaluation and safety assessment of the specific water supply and application involved and has undergone an additional treatment to destroy or remove bacterial acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product¹⁰. Supporting information shall be submitted to and approved by the Regulatory Agency. The supporting information may include, but is not limited to the following:

NOTE: FDA INITIALLY NON-CONCURRED WITH PROPOSAL 117 BASED ON THIS PROPOSAL AND PROPOSAL 119 MAKING SEPARATE BUT DISTINCT CHANGES TO THE SAME PARAGRAPH WITHIN ITEM 15p AND THE NEED TO MERGE THE TWO (2) PROPOSALS WITH APPROPRIATE EDITING TO FOLLOW THE FORMAT OF THE PMO. FOLLOWING ARE THE EDITORIAL CORRECTIONS TO PROPOSALS 117 AND 119 THAT WERE MUTUALLY CONCURRED WITH BY THE NCIMS EXECUTIVE BOARD AND FDA ON SEPTEMBER 9-10, 2009:

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

a. Meet at least the minimum times and temperatures provided for in Definition FF in equipment that may not meet Item 16p; or

- b.** Meet the requirements found in Appendix H, Section IX; or
- c.** ~~H~~ave undergone an equivalent process found acceptable by FDA and the Regulatory Agency; or
- d.** ~~H~~ave undergone a hazard evaluation and safety assessment of the specific water supply and application involved and has undergone an additional treatment to destroy or remove ~~bacterial~~ **bacteria** acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product¹⁰. Supporting information shall be submitted to and approved by the Regulatory Agency. The supporting information may include, but is not limited to the following:
- ~~a.~~**(1)** Statement of proposal;
 - ~~b.~~**(2)** Intended use;
 - ~~c.~~**(3)** Review of equipment to be used in the process;
 - ~~d.~~**(4)** Diagram of the process of interest;
 - ~~e.~~**(5)** Documentation that the source water shall meet or exceed the EPA Safe Drinking Water Bacteriological Standards. Safety Assessment comparison of samples from the facility's water source, pasteurized water, and proposed equivalent water. Water samples shall be collected daily for two (2) weeks following approval of the initial installation and every six (6) months thereafter; and
 - ~~f.~~**(6)** Protocol for the continued monitoring of criteria and procedures. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system.

Proposal: 119
Document: 2007 PMO (Section 7-Item 15p; and Appendix H)
Pages: 78 and 260

Make the following change to SECTION 7, ITEM 15p-PROTECTION FROM CONTAMINATION on Page 78:

2. Except as permitted in Item 16p, there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products or water not completely separated from pasteurized milk and milk products, shall be pasteurized at times and temperatures which meet at least the minimum times and temperatures provided for in Definition FF or in the case of water, meet the requirements found in Appendix H Section IX, or shall have undergone an equivalent process found acceptable by FDA and the Regulatory Agency or shall have undergone a hazard evaluation and safety assessment of the specific water supply and application involved and has undergone an additional treatment to destroy or remove bacterial acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product¹⁰.

NOTE: FDA INITIALLY NON-CONCURRED WITH PROPOSAL 119 BASED ON THIS PROPOPSAL AND PROPOSAL 117 MAKING SEPARATE BUT DISTINCT CHANGES TO THE SAME PARAGRAPH WITHIN ITEM 15p AND THE NEED TO MERGE THE TWO

(2) PROPOSALS WITH APPROPRIATE EDITING TO FOLLOW THE FORMAT OF THE PMO. PLEASE REFER TO PROPOSAL 117 FOR THE EDITORIAL CORRECTIONS THAT WERE MUTUALLY CONCURRED WITH BY THE NCIMS EXECUTIVE BOARD AND FDA ON SEPTEMBER 9-10, 2009.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 260:

Add a new Section IX at the end of APPENDIX H.

**IX. ACCEPTED PROCESSES FOR THE CREATION OF PASTEURIZED
EQUIVALENT WATER
ULTRAVIOLET LIGHT (UV) DISINFECTION OF WATER**

BACKGROUND

UV light between 200-400 nanometers is well known for inactivating pathogenic microorganisms in water via several mechanisms, including the formation of DNA bonds (dimers) that inhibit reproduction and infectivity. Different microbes have different responses to specific wavelengths which also can account for differences in overall dose requirements. Some microbes can use their own enzymes and mechanisms, or take advantage of host cell enzymes to repair the damaged DNA, requiring higher doses of UV to cause irrevocable damage and effective pasteurization-level disinfection.

Three critical factors determine a UV unit's ability to reliably achieve the necessary dose at any point in time: The transmissivity of the water to UV, the performance of the lamps, the hydraulics and rate of the flow in the disinfection chamber. Color, turbidity, particles and organic impurities can interfere with the transmission of UV energy and lower the disinfection efficiency below levels required to insure destruction of pathogenic organisms. Similarly, lamps can age unevenly and water can foul the protective sleeves and prevent light from reaching some pathogens. Hydraulic patterns or flow that is too high or too low can cause uneven distribution of the dose and leave some areas without adequate disinfection.

Other important factors include the geometric configuration of the reactor, the power, wavelength and physical arrangement of the UV lamps, and the UV path length. Longer path lengths provide more opportunities for UV photon-microbe interaction and inactivation.

UV lamps treat water instantaneously while it is flowing through the disinfection chamber but do not provide residual bactericidal action. Using UV for pasteurized equivalent water is not a substitute for appropriate maintenance, periodic flushing and sanitizing of the water distribution system inside the plant.

CRITERIA

The following is a list of criteria that is required to accept water treated with UV light to be considered equivalent to pasteurized water:

1. UV light shall be applied so that the entire volume of water receives at least the following dose when used as pasteurized water.

- a. Low pressure UV at 2,537 Angstrom at 186,000 microwatt-seconds per square centimeter or a 4 log adenovirus equivalent.
 - b. Medium pressure UV at 120,000 microwatt-seconds per square centimeter or a 4 log adenovirus equivalent.
 - 2. A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.
 - 3. The unit shall be designed to permit the frequent cleaning of the system without disassembly of the unit and shall be cleaned often enough to ensure that the system will provide the required dose at all times.
 - 4. An automatic flow control valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that all particles receive the minimum dose listed above.
 - 5. An accurately calibrated UV intensity sensor, properly filtered to restrict its sensitivity to the 2,500-2,800 Angstrom germicidal spectrum, shall measure the UV energy from the lamps.
 - 6. There shall be one sensor for each UV lamp.
 - 7. The light shall adjust based on water quality measured with a real time UVT analyzer to assure that the dose is always calculated accurately and provided reliably.
 - 8. A flow diversion valve or automatic shut-off valve shall be installed which will permit flow into the pasteurized product lines only when at least the required UV dosage is applied. When power is not being supplied to the unit, the valve should be in a closed (fail-safe) position which prevents the flow of water into the pasteurized product lines.
 - 9. The materials of construction shall not impart toxic materials into the water either as a result of the presence of toxic constituents in materials of construction or as a result of physical or chemical changes resulting from exposure to UV energy.
 - 10. The unit shall record the operating parameters (flow, UVT and dose) on a real time basis. These records shall be accessible to the Regulatory Agency for inspection. Electronically generated records, if used, shall meet the criteria specified in Appendix H. V.
-

Proposal: 123
Document: 2007 PMO (Section 7-Item 16p)
Page: 82

Make the following changes to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 82:

ADMINISTRATIVE PROCEDURES

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

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

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

Proposal: 125

Document: 2007 PMO (Section 7-Item 16p; Table 4; and the Index)

Pages: 91, 95, 105, and 359

Make the following change to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 91:

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

ADMINISTRATIVE PROCEDURES

2. AUTOMATIC MILK CONTROLLER:

f. Flow-Promoting Devices:

(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holding tube, shall be so controlled as to insure the holding of every particle of milk or milk product for at least the time required as defined in Definition FF of this *Ordinance*....

The ~~metering~~ or timing pump shall be of the positive-displacement type or shall comply with the specifications for magnetic flow meter based timing systems as outlined in Appendix H. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump it shall be either:

Make the following changes to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 95:

ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS

ADMINISTRATIVE PROCEDURES

2. ASEPTIC PROCESSING EQUIPMENT:

c. Timing Pump:

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

Make the following change to SECTION 7, TABLE 4-EQUIPMENT TESTS – BATCH, HTST, HHST AND ASEPTIC PROCESSING SYSTEMS on Page 105 and FORM FDA 2359b-MILK PLANT EQUIPMENT TEST REPORT (10/08):

9.3.2 HTST booster pump/~~metering~~ timing pump

Make the following change to the INDEX on Page 359:

Metering pump
 pasteurizer.....
 vitamin.....

Proposal: 126
Document: 2007 PMO (Section 7-Item 16p)
Page: 91

Make the following change to SECTION 7, ITEM 16p-PASTEURIZATION AND ASEPTIC PROCESSING on Page 91:

ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS

ADMINISTRATIVE PROCEDURES

2. ASEPTIC PROCESSING EQUIPMENT

f. Flow-Promoting Devices:

(2) The speed of pumps or other flow-promoting devices, ... stretching of the belt results in a slowdown, rather than a speedup of the pump.
 The metering or timing pump shall be of the positive-displacement type or shall comply with the specifications for magnetic flow meter based timing systems as outlined in Appendix H. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected

from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump, and both are located upstream of the holding tube, it shall be either:

Proposal: 128

Document: 2007 PMO (Section 8)

Pages: 116 and 117

*Make the following changes to **SECTION 8. ANIMAL HEALTH** on Pages 116 and 117:*

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

NOTE: Under the Federal USDA TB Eradication Program, cattle and other hooved mammals (goats, sheep, water buffalo, etc.) are covered within the USDA State TB status determination.

2. All milk for pasteurization shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:

d. Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding two (2) months.

NOTE: Under the Federal USDA Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and must comply with one of the options cited under 3 below.

Page 117:

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

d. Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test; or

e. Is determined to be free of brucellosis as provided by the development and implementation of a State administered brucellosis-free herd certification program involving a documented surveillance program, which includes records supporting the tests required in this Section, and an official annual written certification from the State Veterinarian documenting their

brucellosis-free status. The surveillance program shall be documented and the official annual written State brucellosis-free certification shall be retained on file with the State Regulatory Agency. This official annual written State brucellosis-free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, etc.) that are covered within the documented surveillance program and contained within the official annual written State brucellosis-free certification.

(Refer to the **NOTE:** on page 26.)

.....

Document: 2007 MMSR (Appendix A)

Page: 67

*Make the following changes to **APPENDIX A-GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS** on Page 67:*

PART I. DAIRY FARMS

5. Tuberculosis and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8 - ANIMAL HEALTH and APPENDIX A. - ANIMAL DISEASE CONTROL). All or nothing Item based on record verification.

a. Located in a Certified Brucellosis - Free Area as defined by USDA and enrolled in the testing program for such areas; or

3.) Have individual blood agglutination testing done annually; or

4.) For goat, sheep, water buffalo, or any other hooved mammal herds/flocks, excluding cattle and bison, they are included in an official annual written certification from the State Veterinarian documenting their brucellosis-free status.

Proposal: 304

Document: 2007 PMO (Section 11)

Page: 121

*Make the following change to **SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION** on Page 121:*

ADMINISTRATIVE PROCEDURES

9. The foreign supplies have been awarded a satisfactory listing, by an NCIMS Certified Third Party Rating Officer standardized by the FDA, under the NCIMS International Certification Pilot Program. This provision will expire December 31, ~~2009~~ 2011, unless extended by future conference action.

Proposal: 301
Document: 2007 PMO (Section 11)
Page: 121

Make the following change to SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION on Page 121:

ADMINISTRATIVE PROCEDURES

11. Aseptically processed and packaged milk and milk products in Definition X of this *Ordinance* shall be considered to be Grade "A" milk or milk products. The source of the milk and milk products shall be IMS listed and the aseptic raw milk receiving area/aseptic raw milk receiving station of the milk plant where the aseptic milk and milk products are processed and packaged shall be IMS listed. The milk plant shall be awarded a Milk Sanitation Compliance Rating of a least ninety percent (90%) and a satisfactory ASEPTIC MILK PLANT REGULATORY AGENCY REVIEW REPORT or a satisfactory HACCP listing by a SRO trained under the NCIMS Aseptic Pilot Program and label its milk and milk products "Grade "A". The NCIMS Aseptic Pilot Program will expire on December 31, ~~2009~~ 2011 unless extended by future conference action.

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

NOTE: This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2009 National Conference on Interstate Milk Shipments, following FDA's Concurrence with the NCIMS Executive Board. State regulatory and rating personnel must be trained in the implementation of the Aseptic Pilot Program prior to an aseptic milk plant being inspected and rated under the pilot program.

As part of the NCIMS Aseptic Pilot Program, an NCIMS Aseptic Pilot Program Implementation Committee (APPIC) has been formed in accordance with NCIMS *Procedures*. The APPIC is responsible for the oversight of the NCIMS Aseptic Pilot Program in consultation with FDA. This oversight includes the development of the forms, documents, guidance and training necessary to implement and evaluate the NCIMS Aseptic Pilot Program. The APPIC shall provide a report to the 2011 NCIMS.

All milk plants producing aseptically processed and packaged milk or milk products as defined by the PMO and regulated under the NCIMS program will participate in the Aseptic Pilot Program.

Proposal: 129
Document: 2007 PMO (Appendixes B and J)
Pages: 131 and 302

Make the following changes to APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION on Page 131:

I. MILK SAMPLING AND HAULING PROCEDURES

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES

2. Equipment Requirements:

- c. Sample dipper or other sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
- d. ~~Sterile~~ Single use sample containers ~~bags, tubes or bottles~~; properly stored.

Make the following change to APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS on Page 302:

A. PURPOSE AND SCOPE

These Standards shall apply to all blank fabricators, pre-form bottle manufacturers, single-service glass container manufacturers, converters, printers, closure manufacturers, plastic laminators, sheet formers, blow molders, vacuum formers, plastic extruders, injection molders, pre-formers, manufacturers of valves, tubes, dispensing devices, non-sterile sample containers and any other similar plants. These also apply to fabricating plants producing a component part(s), including fabricators of film and/or closures, which may become a product-contact surface and plants assembling components into a final assembled product. These requirements shall not apply to paper mills or resin manufacturing plants. ...

Proposal: 131
Document: 2007 PMO (Appendix D)
Pages: 170 and 171

Make the following changes to APPENDIX D. STANDARDS FOR WATER SOURCES on Page 170:

IV. CONTINUOUS WATER DISINFECTION:

A. CHEMICAL DISINFECTION OF WATER

Water supplies which are otherwise deemed satisfactory, but which prove unable to meet the bacteriological standards prescribed herein, shall be subjected to continuous disinfection...

Make the following change to APPENDIX D. STANDARDS FOR WATER SOURCES on Page 171:

Tablet Chlorinator: These hypo-chlorinators inject water into a bed of concentrated calcium hypochlorite tablets. The result is metered into the pump suction line.

B. ULTRAVIOLET LIGHT DISINFECTION OF WATER

The use of ultraviolet light (UV) to disinfect drinking water has been demonstrated to be an effective process that can inactivate microbes generally targeted by standard chemical disinfectants as well as pathogens that are resistant to other treatments such as *Cryptosporidium*. However, in the design of a water treatment system with UV light, the dairy farm, milk plant, receiving station or transfer station permit holder must exercise care to insure that all other requirements of this Ordinance relating to source, protection from contamination and, chemical and physical characteristics are met. UV disinfection does not change the chemical or physical characteristics of the water such as reducing or removing turbidity, mineral levels, or arsenic, etc., so additional treatment, if otherwise dictated, may still be required. Nor does UV treatment provide residual disinfection. Some supplies may require routine chemical disinfection, including the maintenance of a residual disinfectant throughout the distribution system, and there may continue to be a need for the periodic flushing and disinfection of the water distribution system. In addition, materials present in waters can give rise to significant transmission difficulties so that it may be necessary to pretreat some supplies to remove excessive turbidity and color. Color, turbidity, and organic impurities can interfere with the transmission of UV energy and may decrease the disinfection efficiency below levels required to insure the destruction of pathogenic organisms. In general, color and turbidity measurements do not provide an accurate measure of their impact on UV disinfection efficacy. UV transmissivity (% UVT) multiplied by time measures disinfection efficiency. As a result, an in-line ultraviolet transmissivity (UVT) analyzer is needed to assure that the proper dose is provided on a continuing basis; and it may be necessary to pretreat the water supply to assure consistent water quality. The use of UV to meet the bacteriological requirements of the PMO is acceptable provided the equipment used meets the criteria described herein. Water systems that are within the scope of the U.S. Safe Drinking Water Act as amended and 40 CFR part 141, or State programs that have adopted these requirements shall be regulated under this Act and these regulations. Individual water systems that are not regulated under this act and regulations may be continuously disinfected using UV light based technologies provided the following criteria are met.

CRITERIA FOR THE ACCEPTABILITY OF A UV DISINFECTING UNIT

1. When used to disinfect water to potable drinking water standards, UV light shall be applied so that the entire volume of water receives at least the following dose: UV at 2,537 Angstrom (254 nanometers) at 186,000 microwatt-seconds per square centimeter or equivalent to achieve an EPA log virus reduction equivalent dose.
2. A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.
3. The unit shall be designed to permit the frequent cleaning of the system without disassembly of the unit and shall be cleaned often enough to ensure that the system will provide the required dose at all times.
4. An accurately calibrated UV intensity sensor, properly filtered to restrict its sensitivity to the 2,500-2,800 Angstrom (250-280 nanometers) germicidal spectrum, shall measure the UV energy from the lamps. There shall be one (1) sensor for each UV lamp.

5. A flow-diversion valve or automatic shut-off valve shall be installed which will permit flow into the potable water lines only when at least the minimum required UV dosage is applied. When power is not being supplied to the unit, the valve shall be in a closed (fail-safe) position which will prevent the flow of water into the potable water lines.
6. An automatic flow control valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that the entire volume of water receives the minimum dose required above.
7. The materials of construction shall not impart toxic materials into the water either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes resulting from exposure to UV energy.

NOTE: Existing water supplies which otherwise comply with the applicable requirements of this Appendix may continue to use UV disinfection systems that were accepted under M-a-18. Replacement systems must comply with this Ordinance.

Proposal: 254
Document: 2007 PMO (Appendix G)
Pages: 209-212

Make the following changes to APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS on Pages 209-212:

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER - BACTERIOLOGICAL

Criteria: A Most Probable Number (MPN) of coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the ~~m~~Multiple ~~t~~Tube ~~f~~Fermentation (MTF) technique, or one of the Chromogenic Substrate techniques; a direct count of less than 1 per 100 mL using the ~~m~~Membrane ~~f~~Filter (MF) technique; or a presence/absence determination indicating less than 1 per 100 mL when one vessel containing 100 mL are tested using the MTF technique or one of the Chromogenic Substrate techniques using an MMO-MUG and XGAL-MUG technique. ~~(The MMO-MUG and XGAL-MUG Chromogenic substrate techniques is are not acceptable for recirculated cooling water). 100 ± 2.5 ml water will be used for this analysis.~~ Any sample producing a bacteriological result of Too Numerous To Count (TNTC), greater than 200 total bacteria colonies per 100 mL) or eConfluent gGrowth (CG, bacterial growth covering the entire filtration area or a portion thereof and colonies are not discrete) ~~or greater than two hundred (200) total bacteriological colonies per 100 mL by the membrane filter MF technique; or confluent growth turbidity in a presumptive test and without gas in confirmation by the MTF technique (both MPN and P/A format) by the multiple tube fermentation, MPN technique, without coliform present, shall be considered invalid and shall have a subsequent h~~Heterotrophic ~~p~~Plate ~~e~~Count (HPC) from the same sample or subsequent resample of less than ~~five hundred (500) colonies per mL in order to be deemed satisfactory. Findings by HPC shall be reported as present p~~Positive or less than 1 per 100 mL, ~~absent n~~Not-~~f~~Found for coliform organisms.

Apparatus, Method, and Procedure: Tests performed shall conform with the current edition of SMEWW or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable 2400 series laboratory forms.

II. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST

Methods: The test is based on the detection of the phosphatase enzyme, a constituent that is inactivated by pasteurization at 63°C (145°F) for thirty (30) minutes or 72°C (161°F) for fifteen (15) seconds. When pasteurization is faulty, some phosphatase remains and is ~~detected through~~ determined by the electronic detection of fluorescent or chemiluminescent by-products of its action on the approved test system's substrates phosphoricphenyl esters, releasing phenol, which is measured quantitatively by the addition of dibromo or dichloro quinonechlorimide to form an indophenol blue color.

Procedure: Refer to ~~the SMEDP~~ applicable 2400 series laboratory forms for details on phosphatase tests.

Page 210:

III. PHOSPHATASE REACTIVATION IN HTST PASTEURIZED PRODUCTS

The addition of magnesium ~~chloride~~ acetate to HTST processed milk or cream, after pasteurization but before storage, accelerates reactivation. The difference in activity between an adequately pasteurized sample, stored with and without magnesium, and an inadequately pasteurized sample, stored with and without magnesium, forms the basis of a test for differentiating reactivated from residual, inadequately pasteurized, phosphatase.

IV. DETECTION OF PESTICIDES IN MILK

Pesticide compounds gain access to milk by various routes. ~~Insecticide contamination may result from,~~ including any of the following:

2. Inhalation of toxic vapors, by the animals, following application ~~of insecticides~~ to their environment;

4. Accidental contamination of milk, feed and utensils. ~~Herbicide contamination may result from residues on the lactating animals feed and in their water supply and/or rodenticides may be present in milk as a result of accidental contamination.~~

NOTE: ~~The above testing disciplines may be applied conveniently to can milk supplies. Where Procedure 1 is used, samples of commingled milk from known sources are drawn from receiving station storage tanks. Sampling for Procedure 2 may be done directly from the weigh tank.~~

Page 211:

V. DETECTION OF DRUG RESIDUES IN MILK

Drug residues ~~should~~ shall be tested for, using tests provided for in Section 6 of this *Ordinance*. These tests are specified in memoranda from the FDA. (Refer to the latest edition of M-a-85, M-a-86, and the 2400 series forms for each specific test method.)

~~**NOTE:** *Bacillus stearothermophilus* disk assay analysis performed to fulfill the provisions of Section 7 of this *Ordinance* must be capable of detecting at least four (4) of six (6) Beta lactam drugs at or below FDA reference levels. A zone equal to or greater than 16mm will be considered positive when the *Bacillus stearothermophilus* disk assay is used, provided the 5ppb Beta lactam control zone is 16-20mm. (Refer to the most recent FDA 2400 Series Form(s) for details related to this analysis.)~~

Proposal: 255
Document: 2007 PMO (Appendix G)
Pages: 209-210

Make the following changes to APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS on Pages 209-210

II. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST

Apparatus: Fluorophos (Advanced Instruments), ~~and~~ Paslite and Fast Alkaline Phosphatase (Charm Sciences, Inc), approved/validated standards and accessories.

Methods: The test is based on the detection of the phosphatase enzyme, a constituent that is inactivated by pasteurization at 63°C (145°F) for thirty (30) minutes or 72°C (161°F) for fifteen (15) seconds. When pasteurization is faulty, some phosphatase remains and is ~~detected through~~ determined by the electronic detection of fluorescent or chemiluminescent by-products of its action on the approved test system's substrates phosphoricphenyl esters, releasing phenol, which is measured quantitatively by the addition of dibromo or dichloro quinonechlorimide to form an indophenol blue color.

Document: FDA 2400 Series Forms

Accept a new 2400 form for the Fast Alkaline Phosphatase method.

Proposal: 134
Document: 2007 PMO (Appendix H)
Page: 220

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 220:

MAGNETIC FLOW METER BASED TIMING SYSTEMS FOR HTST PASTEURIZERS

8. The magnetic flow meter shall be piped in such a manner that at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the meter, before any elbow or change of direction takes place.

THE USE OF VACUUM BREAKERS ON HTST SYSTEMS

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

1. Vacuum breakers must open to the atmosphere when subject to a negative pressure.
2. The pasteurized milk and milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw milk or milk product level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.

Spring-to-close vacuum breakers are not allowed.

Proposal: 139

Document: 2007 PMO (Appendixes H and I)

Pages: 234-242, 263 and 266

*Make the following change to **APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT** on Pages 234-242:*

IV. THERMOMETER SPECIFICATIONS

INDICATING THERMOMETERS FOR BATCH PASTEURIZERS

Pages 234-235:

Type:

2. Digital: Stand Alone:

c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

3. Digital: Combination:

- c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~
- d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

Page 236:

INDICATING THERMOMETERS LOCATED ON PASTEURIZATION PIPELINES

Type:

2. Digital:

- c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~
- d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

Pages 237-239:

AIRSPACE INDICATING THERMOMETER FOR BATCH PASTEURIZERS

Type:

2. Digital: Stand Alone:

- c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

3. Digital: Combination:

c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. ~~Vendors shall develop protocols for these tests with FDA concurrence.~~

TEMPERATURE-RECORDING DEVICES FOR BATCH PASTEURIZERS

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

Chart Scale: ...

Pen-Arm Setting Device: Easily accessible and simple to adjust for mercury-actuated recording thermometer. (Refer to Appendix I, Test 4)

Temperature Sensing Device: ~~Protected against damage at a temperature of 105°C (220°F).~~

Mercury-Actuated: Bulb, tube, and spring, protected against damage at a temperature of 105°C (220°F).

Digital:

a. No more than 0.5°C (1.0 °F) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.

b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting “open” circuits, “short” circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank, become unreadable or go visibly out of range.

c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices.

d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.

e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.

f. Calibration of the device shall be protected against unauthorized changes.

g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all application tests under Appendix I. of this Ordinance.

h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this Ordinance. ...

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

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

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

Chart Scale:

Temperature Accuracy:

Digital Temperature Sensing Device:

a. No more than 1°C (2°F) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.

Chart Speed:

RECORDER/CONTROLLERS FOR CONTINUOUS PASTEURIZERS

Pen-Arm Setting Device: Easily accessible and simple to adjust for mercury-actuated recording thermometer. (Refer to Appendix I., Test 4)

Temperature Sensing Device:

Mercury-Actuated: Bulb, tube, ~~or~~ and spring, ~~or~~ thermistor, protected against damage at a temperature of 105°C (220°F). Provided, that the recorder/controller temperature sensing devices, used on HHST systems, shall be protected against damage at temperatures of 149°C (300°F).

Digital:

a. No more than 0.5°C (1.0°F) drift over three (3) months use on a HTST system compared to a certified temperature source.

b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting “open” circuits, “short” circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank or become unreadable.

c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices.

d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.

e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.

f. Calibration of the device shall be protected against unauthorized changes.

g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all applicable tests under Appendix I. of this Ordinance.

h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this Ordinance.

i. The device must be tested from the sensing probe through the final output.

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

Page 241:

TEMPERATURE-RECORDING DEVICES USED IN STORAGE TANKS

Chart Scale:

TEMPERATURE-RECORDING DEVICES ON CLEANING SYSTEMS

Chart Scale:

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS on Pages 263-265:

II. TEST PROCEDURES

TEST 2.

RECORDING THERMOMETERS - TEMPERATURE ACCURACY

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

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

shall be above the normal operating range but below the highest temperature division on the chart.

Method: The testing of a mercury-actuated recording thermometer for temperature accuracy involves the determination of whether or not the temperature pen-arm will return to within 0.5°C (1°F), or 1°C (2°F) as provided in the **Criteria** above, of its previous setting, after exposure to high heat and melting ice.

Procedure:

1. Adjust the recording pen to read exactly as the previously tested indicating thermometer, in the temperature range for the process being used, after a stabilization period of five (5) minutes; ~~two (2) minutes for electronic recording thermometers~~, at a constant temperature. The bath shall be rapidly agitated throughout the stabilization period.
3. Immerse the recording thermometer sensing element into the boiling water, or in the case of HHST or aseptic processing systems into the media bath described above, for not less than five (5) minutes; ~~two (2) minutes for electronic recording thermometers~~.
4. Remove the recording thermometer sensing element from the boiling water or other media bath and immerse it in the media bath at a temperature within the temperature range for the process being used. Allow a five (5) minute; ~~two (2) minutes for electronic recording thermometers~~, stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recording thermometer reading should be within $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$) or $\pm 1^{\circ}\text{C}$ ($\pm 2^{\circ}\text{F}$) as provided above, of the indicating thermometer reading.
5. Remove the recording thermometer sensing element from the bath in the temperature range for the process being used, and immerse in melting ice for not less than five (5) minutes; ~~two (2) minutes for electronic recording thermometers~~.
6. Remove the recording thermometer-sensing element from the ice water and immerse in a bath at a temperature range for the process being used. Allow a five (5) minute; ~~two (2) minutes for electronic recording thermometers~~, stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recording thermometer reading should be within $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$), or $\pm 1^{\circ}\text{C}$ ($\pm 2^{\circ}\text{F}$) as provided above, of the indicating thermometer reading.

*Make the following changes to **APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS** on Page 266:*

II. TEST PROCEDURES
TEST 4.

**RECORDING THERMOMETERS - CHECK AGAINST
INDICATING THERMOMETERS**

Corrective Action: If the mercury-actuated recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by the operator.

If the digital recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the recording temperature should be adjusted to agree with the indicating thermometer. Retest the thermometer after adjustment.

Proposal: 137

Document: 2007 PMO (Appendix H)

Page: 259

*Make the following changes to **APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT** on Page 259:*

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES

**VIII MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION---
CCP Model HACCP Plan Summary**

| Critical Control Point (CCP) | Hazard(s) | Critical Limits | Monitoring | | | | Corrective Action(s)* | CCP Verification** and *** | Records |
|---|---|---|---|---|--|--|--|--|---|
| | | | What | How | Frequency | Who | | | |
| Milk and Milk Products Pasteurization (HTST and HHST) | Biological-Vegetative Pathogens (non-spore formers) | Time and Temperature NOTE: Assuring that the minimum holding times are met in systems which use a sealed timing pump would be as CCP verification during required equipment calibration. | Temperature at the exit of the holding tube <u>Residence time in the holding tube in continuous-flow Pasteurizers with magnetic flow meter based timing systems. Flow rate in forward flow in the holding tube (to verify minimum holding time) in continuous flow pasteurizers with magnetic flow meter based timing systems.</u> | Temp. Recorder Chart Flow Recorder Chart | Continuous during Operation Continuous during Operation | Pasteurizer Operator Pasteurizer Operator | Manually divert flow of product Isolate the affected product Evaluate and determine disposition of the product (reprocess or disposal) Document actions | Record Review: Pasteurizer charts verified Equipment Function Checks: Operator performs required daily tests and record on the temperature charts. Authorized plant person (supervised by regulatory when required) conducts checks listed in the <i>Milk Plant Equipment Test Report</i> (FDA Form 2359b). Seals: Verify required regulatory seals daily | Pasteurizer Charts Corrective Action Records CCP Verification - Records, including equipment testing records |

* A properly operating HTST or HHST pasteurization system will divert raw product to the constant-level tank when predetermined set points are not met.

**Every particle of milk or milk is heated, in a properly designed, calibrated and operated pasteurizer, to one of the temperature and time combinations specified in the current *Grade "A" PMO*.

*** Pressures in the regenerator of continuous-flow pasteurizers, and in the case of HHST pasteurizers as required in the holding tubes, across steam injectors, and within infusion chambers shall be addressed in the HACCP Plan and managed as CCP verification(s).

Product Description: _____ Method of Storage and Distribution: _____

INTENDED USE AND CONSUMER: _____

SIGNATURE: _____ **DATE:** _____

Proposal: 141
Document: 2007 PMO (Appendix I)
Pages: 265, 278 and 300

Make the following change to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 265:

II. TEST PROCEDURES

TEST 3.

RECORDING THERMOMETERS - TIME ACCURACY

Application: To all recording and recorder-controller thermometers used to record the time of pasteurization or aseptic processing, ~~including those used to record flow rates in magnetic flow meter based timing systems.~~

Make the following change to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 278:

II. TEST PROCEDURES

TEST 9.

9.3 ADDITIONAL HTST TESTS FOR BOOSTER PUMPS – INTERWIRING

Application: To all booster pumps used for HTST systems where the FDD is located immediately after the holding tube, except for those systems which are magnetic flow meter based timing systems, Test 9.3.2 is not required to be performed.

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 300:

II. TEST PROCEDURES

TEST 15.

ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

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

Frequency: Upon installation; any alteration of the electronic controls devices; every three (3) months thereafter; and whenever the type or wattage of the hand-held communication device(s) used in that ~~facility~~ milk plant is changed. Once a hand-held communication device has been

shown to cause a given electronic control device to react adversely, the electronic control device must be repaired and re-tested using the same type hand-held communication device. ~~Test does not have to be repeated every three (3) months using that specific hand-held communication device on the adversely affected electronic control device.~~ (Refer to the **NOTE:** below.) If the any electronic control device is altered or there is a change in the hand-held communication device(s) used, the electronic control device(s) would be required to be tested.

Criteria: The use of hand-held communication devices shall not have ~~no~~ any adverse effect on the electronic control device's public health safeguards.

Apparatus: One (1) hand-held communication device representing each make and model used in the ~~facility~~ milk plant. The device must be operating at maximum output, and be fully charged.

Method: By observing the actual effect of the hand-held communication device on an electronic control device, it can be determined if that hand-held communication device can be used near that equipment without compromising a any of the electronic control device's public health safeguard.

Procedure:

1. Position the hand-held communication device 30.5 centimeters (12 inches) in front of the electronic control device where the public health safeguard(s) resides.
2. Place the hand-held communication device in the “send” mode for five (5) seconds and observe the effect on the electronic control device's public health safeguard(s). There should not be ~~no~~ any adverse effect with the electronic control device. An adverse effect is any change that may adversely affect an electronic control device's public health safeguard(s).
3. If applicable, repeat the Test with the operator access door open.
4. Repeat the above Test for each hand-held communication device identified in the Apparatus Section.
5. Repeat the Test for each electronic control device used to regulate a pasteurization or aseptic processing system's public health safeguard(s).

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

Corrective Action: Have the ~~facility~~ milk plant check for shielding, grounding and other installation concerns with the electronic control device and retest. Until a solution, acceptable to the Regulatory Agency, can be found that does not adversely affect the electronic control device's public health safeguard(s), the hand-held communication device ~~may not~~ cannot be used in the area of the electronic control device's public health safeguard(s).

NOTE: Continuous “Hand-Held Communication Device Free” or “Radio Free” zones, etc., are not acceptable permanent solutions to hand-held communication devices which cause adverse affects to an electronic control device's public health safeguards.

Proposal: 142
Document: 2007 PMO (Appendix I)
Pages: 268-270

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 268:

II. TEST PROCEDURES

5.4 DEVICE ASSEMBLY - DUAL STEM DEVICE

Procedure:

2. Move the FDD to the diverted-flow position and turn on the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD. The timing pump and all other flow-promoting devices must be de-energized and must not run. If any pump starts momentarily and then stops, it may indicate the improper wiring of the one (1) second time delay as allowed in 16p(B)2.b.(10). Separators or downstream vacuum sources must be effectively valved-out of the system.

5.5 MANUAL DIVERSION

(Booster pump installed in the HTST system)

Procedure:

1. With the HTST system in operation and the FDD in the forward-flow position, press the manual diversion button. This should:

- a. Cause the FDD to assume the divert position;
- b. De-energize the booster pump; ~~and~~
- c. Any downstream vacuum source must be effectively valved out; and
- d. The pressure differential between raw and pasteurized milk or milk product in the regenerator should be maintained.

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 269:

II. TEST PROCEDURES

5.7 TIME DELAY INTERLOCK WITH TIMING PUMP

Procedure: With the system operating in forward-flow, move the control switch to the “Inspect” position and observe that the following events automatically occur in sequence:

1. The FDD immediately moves to the diverted-flow position and the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, are de-energized or in the case of separators or downstream vacuum sources, are effectively valved-out of the system.

2. The FDD remains in the diverted-flow position while the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD are running down or in the case of a separator or downstream vacuum sources, valving out.
3. The FDD may assume the forward-flow position only after the timing pump stops turning, and all other flow-promoting devices, which are capable of causing flow through the FDD have also stopped, or in the case of separators or downstream vacuum sources, have been effectively valved-out of the system.

Make the following change to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 270:

II. TEST PROCEDURES

5.8 CIP TIME DELAY RELAY

Procedure:

2. Move the mode switch on the FDD to the “CIP” position. The FDD should move immediately to the diverted position. Start the stopwatch when the FDD moves to the diverted position. Check all controls that are required to be in operation when the system is in the “Process” mode and in diverted-flow. For example, in HTST systems, the booster pump must stop running. Separators located between regenerator sections or on the pasteurized side of the system must be effectively valved-out and stuffer pumps for such separators must be de-energized. Any downstream vacuum source must be effectively valved out.

Proposal: 145

Document: 2007 PMO (Appendix I)

Page: 299

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 299:

II. TEST PROCEDURES

TEST 14.

SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR

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

Procedure:

Calibration of the Injector Differential Pressure Controller Probes:

1. Loosen the connection at both pressure sensors and allow for any liquid to drain through the loose connections. Both pointers, or digital displays, shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s), or the digital display(s), to read 0 kPa (0 psi).
2. Remove both sensors and mount them in a tee, or connect them to a pneumatic testing device. Record any difference in the zero (0 kPa (0 psi)) readings that may have occurred because of this change in elevation. Attach the tee and both sensors to a pneumatic testing device described in Test 9.1 and adjust the air pressure to the normal operating pressure used at the injector. Make sure that the pointer or digital display reading separation is within 6.9 kPa (1 psi) of that observed before the pressure was applied. If not, the instrument requires adjustment or repair.
3. When the results are satisfactory, record the Test results for the office record and proceed as directed below.

Setting of the Injector Differential Pressure Controller Switch:

1. Remove both pressure sensing elements from their original locations on the pasteurizer, or aseptic processor. Install a sanitary pressure gauge of known accuracy and Disconnect the sanitary pressure sensing element that is normally located after the steam injector from the pneumatic testing device and cap the resulting opening. Leave the pressure-sensing element, which is installed prior to the steam injection, on the pneumatic testing device....
-

Proposal: 148

Document: 2007 PMO (Appendix J); and FORM FDA 2359d

Page: 311

Make the following changes to APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS on Page 311:

SECTION E. CRITERIA FOR LISTING CERTIFIED SINGLE-SERVICE MANUFACTURERS IN THE IMS LIST

~~Historically, certification of manufacturers of single-service containers and related products has been for one (1) year. In addition, a ninety (90) day grace period was provided for the transmission of the *Report of Certification* through the proper channels to Milk Safety Branch (HFS-626) to provide for the lag time for printing the in *IMS List*.~~

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating and listing single-service manufacturing plants. Rating and/or Regulatory Agencies may choose from the following list of criteria for listing certified single-service manufacturers:...

- ~~2. Single-service manufacturers that operate in conjunction with an IMS Listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months, plus a ninety (90) day grace period after an evaluation.~~

4. Single-service manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months, ~~plus a ninety (90) day grace period, after an evaluation.~~
5. Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest survey date. In the case of a one (1) year certification with the earliest survey date of 6/15/2009, the expiration date would be 6/14/2010.

*Make the following changes to **FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and Closures for Milk and Milk Products)**:*

7.c. EXPIRATION DATE*
*EXPIRATION DATE

~~This date is 15 or 24 months following the survey date. Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey date. In the case of a 1 year certification, a 90 day grace period is included to provide time for transmission of the completed *Report of Certification* (Form FDA 2359d). The expiration date is one (1) or two (2) years from the earliest survey date.~~

Proposal: 302

Document: 2007 PMO (Appendix K; and FDA FORM 2359m)

Page: 322

*Make the following changes to **APPENDIX K. HACCP PROGRAM** on Page 322:*

IV. TRAINING AND STANDARDIZATION

HACCP TRAINING:

1. Core Curriculum:

The industry individual(s) performing the functions identified in this Appendix requiring training or listed in Part 2 of this Section shall have successfully completed appropriate training in the application of HACCP principles to milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

2. **Industry Personnel:** Only industry individuals who have met the requirements of Part 1 of this Section shall be responsible for the following functions:

- a. Developing PPs;

- ~~a.~~b. Developing the hazard analysis, including delineating control measures, as required;

- ~~b.~~c. Developing a HACCP Plan that is appropriate for the specific milk plant, receiving station or transfer station, in order to meet these requirements;

- e.d. Validating and modifying the HACCP Plan in accordance with the corrective action procedures and the validation activities as specified; and
- d.e. Performing required HACCP Plan records reviews.

Document: 2007 MMSR (Sections G and H; and FDA FORM 2359m)
Pages: 37 and 58

Make the following changes to SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS and SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS on Pages 37 and 58:

Correct FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/06):

Section 11: HACCP SYSTEM TRAINING (Individuals trained according to Appendix K or alternatively, have equivalent job experience)

- A. PPs developed by trained personnel. ~~Employees trained in monitoring operations.~~
- B. Hazard analysis developed by trained personnel. ~~HACCP plan reassessment performed by trained individual.~~
- C. HACCP Plan developed by trained personnel. ~~Records review performed by trained individual.~~
- D. HACCP Plan validation, modification or reassessment performed by trained personnel. ~~Employees trained in PP operations.~~
- E. HACCP Plan records review performed by trained personnel.

Proposal: 256
Document: 2007 PMO (Appendix L)
Page: 325

Make the following changes to APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE FEDERAL FOOD, DRUG AND COSMETIC ACT on Page 325

Add the following CFR citations to Appendix L where appropriate.

- 21 CFR Part 175 – INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS
- 21 CFR Part 176 – INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS
- 21 CFR Part 177 – INDIRECT FOOD ADDITIVES: POLYMERS

21 CFR Part 178 – INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

21 CFR Part 7 – ENFORCEMENT POLICY

21 CFR 184.1666 - Propylene glycol

21 CFR 182.6285 - Dipotassium phosphate

Proposal: 257

Document: 2007 PMO (Appendix N)

Page: 327

*Make the following change to **APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE** on Page 327*

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE

Industry shall screen all bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*)

Proposal: 150

Document: 2007 PMO (Appendix Q)

Page: 345

*Make the following change to **APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE “A” RAW MILK FOR PASTEURIZATION** on Page 345:*

ITEM 14r. PROTECTION FROM CONTAMINATION

AMIs are designed to automatically shift from milk to wash; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed, as referenced in Item 15p.(B), shall be located as needed to prevent cross contamination. Separation shall be provided between, milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale.....

Proposal: 311
Document: 2007 PROCEDURES (Sections III and IV)
Pages: 2-3, 7 and 30

NEW PROCEDURE

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

B. AREA RATING: An area rating, if used, shall apply to raw milk for pasteurization only. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

C. BULK TANK UNIT (BTU): A dairy farm or group of dairy farms from which raw milk for pasteurization is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

J. INDIVIDUAL RATING: An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same plant producing other Grade "A" milk or milk products, provided each listing holds a separate permit. An individual dairy farm shall only be included in one (1) IMS Listing.

*Make the following changes to **SECTION IV. OVERSIGHT AND RESPONSIBILITIES** on Page 7:*

A. PHS/FDA RESPONSIBILITIES

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at <http://www.cfsan.fda.gov/~ear/ims-toc.html>. The Sanitation Compliance and Enforcement Ratings of Regulatory Agencies and the IMS Listed shippers' expiration rating dates contained in the electronic publication are certified by the State Rating Agency to be those established by ratings conducted in accordance with the *MMSR* by certified SROs when the FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the PHS/FDA Regional Office for publication.

Transfer stations, receiving stations and dairy milk plants must achieve a Sanitation Compliance Rating of 90 percent (90%) or ~~better~~ higher in order to be eligible for a listing in the *IMS List*. Sanitation Compliance Rating scores for transfer and receiving stations and dairy milk plants will not be identified in the *IMS List*....

Make the following changes to SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS on Page 30:

C. PHS/FDA HACCP RESPONSIBILITIES

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

Section IV., A. 5. shall apply as written, except that for purposes of this Section:

a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The HACCP listings and expiration listing dates contained in the electronic publication are certified by the State Rating Agency to be those established by HACCP audits conducted in accordance with the *MMSR* by certified SROs when the FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT is signed and submitted to the PHS/FDA Regional Office for electronic publication.

Dairy Milk plants, receiving stations, and transfer stations must achieve an acceptable HACCP listing in order to be eligible for a listing in the *IMS List*.

Document: 2007 MMSR (Sections A and F; FORM FDA 2359i; and FORM FDA 2359o)
Pages: 1-2, 22-24, 33, 35, 40, 54, 56, 61, 63 and 64

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

1. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization only. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

3. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

10. **INDIVIDUAL RATING:** An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same plant producing other Grade "A" milk or milk products, provided each listing holds a separate permit. An individual dairy farm shall only be included in one (1) IMS Listing.

Make the following changes to SECTION F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT on Pages 22-24:

2. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT”

a. Individual Shipper of Raw Milk for Pasteurization

This shipper is commonly referred to as a BTU.....(Refer to Section H, #s 12 and 13 for an example).

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, then the expiration date would be 12/14/2009.

b. Receiving Station or Transfer Station

Following the computation of the Sanitation Compliance Rating.....Section F. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’S REPORT, 2., c.2) or 2., c.3).

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, then the expiration date would be 12/14/2009.

c. Milk Plant

1.) Attached Supply Only: A plant with a single source of raw milk, both under the jurisdiction of the same Regulatory Agency.

Following the computation of the Sanitation Compliance Rating whichever is earliest in time.

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, then the expiration date would be 12/14/2009.

2.) Attached Supply and Unattached Supplies: A plant with a source of raw milk for pasteurization under the jurisdiction of the same Regulatory Agency as the plant and one (1) or more sources of raw milk for pasteurization from other separate rated and listed sources.....

All unattached supplies shall have a Sanitation Compliance Rating.....shall be immediately withdrawn from the *IMS List*.

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will

have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, than the expiration date would be 12/14/2009.

3.) Unattached Supplies Only: A plant with one (1) or more sources of raw milk received from other rated and listed sources.

Following the computation of the Sanitation Compliance Rating shall be computed by one (1) of the following two (2) options:

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and will have an expiration rating date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2009, then the expiration date would be 12/14/2009.

Make the following changes to SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS and SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS on Pages 33, 35, 54, 56, and 61:

FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

| | | | | | | | | | | | |
|--|--|--|--|---|--|------------------------------|-------------------------|-----------------------------|------------------|------------------------|-----------------------|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION | | INTERSTATE MILK SHIPPER'S REPORT <i>(Submit an original and two (2) copies to the FDA Regional Office)</i> | | | | 3-A. COUNTRY | | | | | |
| 1. NAME OF SHIPPER | | | 2. CITY | | | 3. STATE | | | | | |
| 4. STREET | | 5. PLANT or BTU # | | | 6. PRODUCT CODE #s | | | | | | |
| | | | | | | | | | | | |
| 7. SURVEY DATA | | | | | | | | | | | |
| | DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL | RECEIVING OR TRANSFER STATION | MILK PLANT ¹ | | ENFORCEMENT | | | | | | |
| RATING (%) | | | | | | | | | | | |
| DATE OF RATING | | | | | | | | | | | |
| TOTAL NUMBER | | | | | APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input type="checkbox"/> YES <input type="checkbox"/> NO | | | | | | |
| NUMBER INSPECTED | | | | | | | | | | | |
| VOLUME RECEIVE DAILY (Cwt) | | | | | | | | | | | |
| RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDA <input type="checkbox"/> OTHER _____ | CERTIFIED STATE RATING OFFICER | | OFFICER'S CERTIFICATION EXPIRATION DATE | | EARLIEST RATING DATE | | | | | | |
| | | | | | MONTH | DAY | YEAR | | | | |
| | | | | | | | | | | | |
| AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY | | | | | EXPIRATION RATING DATE ² | | | | | | |
| | | | | | MONTH | DAY | YEAR | | | | |
| | | | | | | | | | | | |
| 8. LABORATORY CONTROL | | | | | | | | | | | |
| APPROVED LABORATORY NUMBER | | EXPIRATION DATE | | PROCESSED MILK TESTS APPROVED | | | RAW MILK TESTS APPROVED | | | | |
| A. _____ | | A. _____ | | SPC | COLI | PHOS | RBC | DRUG RESIDUE TESTS | VIABLE COUNTS | SOMATIC CELL COUNTS | DRUG RESIDUE TESTS |
| B. _____ | | B. _____ | | A. _____ | A. _____ | A. _____ | A. _____ | A. _____ | A. _____ | A. _____ | A. _____ |
| | | | | B. _____ | B. _____ | B. _____ | B. _____ | B. _____ | B. _____ | B. _____ | B. _____ |
| DATE OF LAST TWO SPLIT SAMPLES | | | | APPROVED WATER LABORATORY AND DATE | | | WATER TESTS APPROVED | | | | |
| A. _____ | | A. _____ | | | | | | | | | |
| B. _____ | | B. _____ | | | | | | | | | |
| 9. PUBLICATION <i>(Written permission from a shipper must be filed at a Regional Office of FDA prior to the publication of a rating/listing.)</i> | | | | | | | | | | | |
| LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? | | | | | | <input type="checkbox"/> YES | | <input type="checkbox"/> NO | | | |
| 10. SUBMISSION OF REPORT BY STATE AGENCY | | | | | | | | | | | |
| DATE OF REPORT | | | | SUBMITTED BY <i>(Signature and Title)</i> | | | | | | | |
| FOR FDA REGIONAL OFFICE USE ONLY | | | | | | | | | | | |
| Written permission from shipper dated _____ on file and publication of rating/listing recommended. | | | | | | | | | | | |
| DATE | | | | SIGNATURE <i>(FDA Milk Specialist)</i> | | | | | | | |
| | | | | | | | | | | | |

¹ Submit separate Form for each milk plant.

² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2008 with a corresponding expiration rating date of 9/30/2010, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2008 with a corresponding expiration rating date of 3/31/2009.

*Make the following changes to **SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS** and **SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS** on Pages 40, 63 and 64:*

FORM FDA 2359o-PERMISSION TO PUBLISH

PERMISSION FOR PUBLICATION

Interstate Milk Shipper's Listing

SHIPPER'S NAME

ADDRESS

You are hereby advised that on (date[s])

a State Rating or

HACCP Listing Audit was conducted with the following results:

Producer Supply (BTU)

Transfer Station

Receiving Station

Milk Plant

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings)

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating Listing is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by State and Territorial Milk Control Authorities and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, may result in immediate removal of this listing.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Mmilk Ssanitation Ceompliance Rrating of less than ninety percent (90%) shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO _____ WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

SIGNATURE OF REPRESENTATIVE

TITLE

DATE

FORM FDA 2359o (10/068)

NOTE: An effective date shall correspond to the issuance of the IMS-a addressing the actions from the 2009 NCIMS Conference.

Proposal: 312

Document: 2007 PROCEDURES (Section VIII)

Page: 41

NEW PROCEDURE

*Make the following change to **SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS** on Page 41:*

E. QUALIFICATIONS AND CERTIFICATIONS

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

c. Continuous Certification

After the initial successful Conditional HACCP Certification, subsequent certification of a SRO to make NCIMS HACCP Listing Audits will be valid for three (3) years unless revoked for cause.

1.) Milk Plant Technical Knowledge

The Candidate shall continue to meet the requirements for certification of a SRO for milk plants.

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, will complete the minimum training requirements established to maintain proficiency regarding the NCIMS HACCP Program- including having attended at least one (1) training course in the auditing of dairy plant HACCP Systems and NCIMS listing for the period of qualification. The NCIMS HACCP Implementation Committee has developed and accepted for this required training both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and an abbreviated individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Regional Milk Specialists.

Small group training with practical exercises and other appropriate training that may include written examinations will be used to evaluate the SROs technical knowledge for continuing certification.

Proposal: 303

Document: 2007 MMSR (Sections G and H; FORM FDA 2359m; and FORM FDA 2359n)

Pages: 37, 39, 58 and 60

Make the following change to SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS and SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS on Pages 37 and 58:

Correct FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/06).

Delete Section 12 C from FORM FDA 2359m (10/06), *Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report* which states, “~~STATE MILK PLANT, RECEIVING STATION OR TRANSFER STATION HACCP SYSTEM AUDIT REPORT issued and follow-up conducted as required (HACCP Listing Audits and FDA Audits Only).~~”

Re-letter the remaining Section of 12 according to this deletion.

Make the following change to SECTION G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS and SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP FORMS on Pages 39 and 60:

Correct FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (10/06):

Modify Item #2 of FORM FDA 2359n 10/06)NCIMS HACCP System Regulatory Agency Review Report to read as follow, “Milk plant, receiving station or transfer station audited by the Regulatory Agency at the minimum required frequency and follow-ups conducted as required.”

Proposal: 262

Document: 2007 MMSR (Section H; Appendix A; and FORM FDA 2359j)

Pages: 45, 49 and 69-70

Make the following changes to SECTION H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP LISTING FORMS on Pages 45 and 49:

NOTE: An effective date shall correspond to the issuance of the IMS-a addressing the actions from the 2009 NCIMS Conference.

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: BTU and Receiving Station)

SHIPPER Clear Milk Coop (BTU)-RS

DATE OF RATING June 14 - 16, 2008

ENFORCEMENT RATING 91.90

| DAIRY FARMS PART I | | | | | | | | MILK PLANT PART II | | | | | | INDIVIDUAL SHIPPER RATING PART III | | | | | | | | | | | |
|---|-------------------|--|------------------|------------------|-------------------|--------|--------|--|-------------------|---|------------------|------------------|-------------------|---|--------|--|-------------------|---|------------------|------------------|-------------------|--------|--------|--|--|
| Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | | |
| 1 | 3 | All dairy farmers hold a valid permit | 25 | 25 | 100 | 5 | 5 | 1 | 3 | All milk plants, receiving station and transfer station operators hold a valid permits | | | | 5 | 5 | 1 | | Enter Total Credit from Part I under Percent Complying | | | 88.3 | 47 | 41.5 | | |
| 2 | 5 | All dairy farms inspected at least once every six (6) months or as required in Appendix "P" | 25 | 20 | 80 | 15 | 12 | 2 | 5 | Milk plant and receiving station(s) inspected at least once every three (3) months; transfer station(s) once every six (6) months | 8 | 6 | 75 | 15 | 11.3 | 2 | | Enter Total Credit from Part II under Percent Complying | | | 90.4 | 47 | 42.5 | | |
| 3 | 5 | Inspection sheet posted or available | 25 | 25 | 100 | 5 | 5 | 3 | 5 | Inspection sheet posted or available | | | | 5 | 5 | 3 | 4 | All milk and milk products properly labeled | 1 | 1 | 100 | 6 | 6 | | |
| 5 | 8 | T B & Brucellosis certification on file as required | | | | 10 | 10 | 5 | 7 App I | Pasteurization equipment tested at required frequency | NA | NA | NA | 15 | NA | INDIVIDUAL SHIPPER ENFORCEMENT RATINGS <u>91.2</u> <u>90.2</u> Individual Shipper of Raw Milk for Pasteurization: • Without Receiving Station, Transfer Station or Plant: - Evaluate all Items Part I and record. • With Receiving Station(s) or Transfer Station(s): - Evaluate all Items Part I. - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. - Evaluate all Items Part III. Individual Shipper of Pasteurized Milk and Milk Products: • With Attached Raw Supply: - Evaluate all Items Part I. - Evaluate all Items Part II., use 47 Weight. - Evaluate all Items Part III. • With Unattached Raw Supplies: - Evaluate all Items Part II., use 94 Weight. - Evaluate all Items Part III., except Number 1. - Evaluate all Items Part III, except Number 1. | | | | | | | | | |
| | 7 | Water samples tested and reports on file as required | 25 | 25 | 100 | 5 | 5 | 6 | 7 | Individual and cooling water samples tested and reports on file as required | 8 | 6 | 75 | 5 | 3.8 | | | | | | | | | | |
| 7 | 5 | Milking time inspection program established | | | | 5 | 5 | 7 | 6 | Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examination made | NA | NA | NA | 10 | NA | | | | | | | | | | |
| 8 | 6 | At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made | 25 | 20 | 80 | 10 | 8 | 8 | 6 App B | Sampling procedures approved by PHS/FDA evaluation methods | 1 | .90 | 90 | 10 | 9.0 | | | | | | | | | | |
| 9 | 6 App B | Sampling procedures approved by PHS/FDA evaluation methods | 1 | .79 | 79 | 10 | 7.9 | 9 | 3,5, 6,16 | Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required | 1 | 1 | 100 | 15 | 15 | | | | | | | | | | |
| 10 | 3,5, 6,16 | Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required | 25 | 22 | 88 | 15 | 13.2 | 10 | | Records systematically maintained and current | 1 | 1 | 100 | 10 | 10 | | | | | | | | | | |
| 11 | | Records systematically maintained and current | 25 | 23 | 92 | 10 | 9.2 | TOTAL CREDIT, Part II | | | | | | 68.1 | | | | | | | | | | | |
| TOTAL CREDIT, Part I | | | 88.3 | | | | | (68.1/ 75 X 100 = 90.8) | | | | | | Remarks | | | | | | | | | | | |
| Remarks | | | 90.4 | | | | | Remarks | | | | | | Part II Remarks | | | | | | | | | | | |
| 2. Minimum inspection interval not met on five (5) dairy farms. (Producer #3, 7, 9, 11 and 18) | | | | | | | | 8. Insufficient number of samples from five (5) dairy farms. (Producer #2, 8, 12, 15 and 19) | | | | | | 2. Two inspection frequencies missed. (9/2007 and 2/2008) | | | | | | | | | | | |
| 4. Significant violations existing during the last inspection were not marked at five (5) dairy farms on their previous inspection sheet. (Producer #1-Item 8a; #6-Items 2a & 2b; #10-Item 9d; #14-Item 7a; and #20-Item 16a) | | | | | | | | 9. Refer to Section C. Evaluation of Sampling Procedures. | | | | | | 4. Violations of 15b(c) (5 pts) and 17d (5 pts) existed but were not marked on the last inspection. | | | | | | | | | | | |
| | | | | | | | | 10. <u>Category II-Regulatory</u> action not properly taken on three (3) dairy farms. (Producer #4-Item 6-3X; #15-Item 2a-4X; and #17-Item 8a-3X) | | | | | | 6. Recirculated cooling water sampling frequency was missed twice. (5/2007 and 1/2008) | | | | | | | | | | | |
| | | | | | | | | 11. <u>Category II-Laboratory Inspection</u> results were not up to date for two (2) dairy farms on their individual ledgers. (Producer #5 and 16) | | | | | | 8. Refer to Section C. Evaluation of Sampling Procedures. | | | | | | | | | | | |

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: BTU Only)

SHIPPER Great Cows BTU

DATE OF RATING August 10-12, 2008

ENFORCEMENT RATING 89 90

| DAIRY FARMS PART I | | | | | | | MILK PLANT PART II | | | | | | | INDIVIDUAL SHIPPER RATING PART III | | | | | | | | | | | | | | | | |
|---|-------------------|--|------------------|------------------|-------------------|--------|--------------------|--|-------------------|---|------------------|------------------|-------------------|------------------------------------|--------|---|-------------------|---|------------------|------------------|-------------------|--------|----------------|--|--|--|--|--|--|--|
| Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | Number | Ordinance Section | Item | Number Inspected | Number Complying | Percent Complying | Weight | Credit | | | | | | | |
| 1 | 3 | All dairy farmers hold a valid permit | 25 | 25 | 100 | 5 | 5 | 1 | 3 | All milk plants, receiving station and transfer station operators hold a valid permit | | | | 5 | | 1 | | Enter Total Credit from Part I under Percent Complying | | | 47 | | | | | | | | | |
| 2 | 5 | All dairy farms inspected at least once every six (6) months or as required in Appendix "P" | 25 | 20 | 80 | 15 | 12 | 2 | 5 | Milk plant and receiving station(s) inspected at least once every three (3) months; transfer station(s) once every six (6) months | | | | 15 | | 2 | | Enter Total Credit from Part II under Percent Complying | | | 47 | 94 | | | | | | | | |
| 3 | 5 | Inspection sheet posted or available | 25 | 25 | 100 | 5 | 5 | 3 | 5 | Inspection sheet posted or available | | | | 5 | | 3 | 4 | All milk and milk products properly labeled | | | 6 | | | | | | | | | |
| 5 | 8 | T B & Brucellosis certification on file as required | | | | 10 | 10 | 5 | 7 App I | Pasteurization equipment tested at required frequency | | | | 15 | | INDIVIDUAL SHIPPER ENFORCEMENT RATINGS Individual Shipper of Raw Milk for Pasteurization: • Without Receiving Station, Transfer Station or Plant: - Evaluate all Items Part I and record. • With Receiving Station(s) or Transfer Station(s): - Evaluate all Items Part I. - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. - Evaluate all Items Part III. Individual Shipper of Pasteurized Milk and Milk Products: • With Attached Raw Supply: - Evaluate all Items Part I. - Evaluate all Items Part II., use 47 Weight. - Evaluate all Items Part III. • With Unattached Raw Supplies: - Evaluate all Items Part II., use 94 Weight. - Evaluate all Items Part III., except Number 1. - Evaluate all Items Part III., except Number 1. | | | | | | | | | | | | | | |
| 6 | 7 | Water samples tested and reports on file as required | 25 | 21 | 84 | 5 | 4.2 | 6 | 7 | Individual and cooling water samples tested and reports on file as required | | | | 5 | | | | | | | | | | | | | | | | |
| 7 | 5 | Milking time inspection program established | | | | 5 | 5 | 7 | 6 | Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examination made | | | | 10 | | | | | | | | | | | | | | | | |
| 8 | 6 | At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made | 25 | 23 | 92 | 10 | 9.2 | 8 | 6 App B | Sampling procedures approved by PHS/FDA evaluation methods | | | | 10 | | | | | | | | | | | | | | | | |
| 9 | 6 App B | Sampling procedures approved by PHS/FDA evaluation methods | 1 | 79 | 79 | 10 | 7.9 | 9 | 3,5, 6,16 | Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required | | | | 15 | | | | | | | | | | | | | | | | |
| 10 | 3,5, 6,16 | Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required | 25 | 22 | 88 | 15 | 13.2 | | | | | | | | | | | | | | | | | | | | | | | |
| | | | 1 | 98 | 98 | | 14.7 | | | | | | | | | | | | | | | | | | | | | | | |
| 10 | | Records systematically maintained and current | 25 | 25 | 100 | 10 | 40 | | | | | | | | | | | | | | | | | | | | | | | |
| | | | 1 | 98 | 98 | | 9.8 | | | | | | | | | | | | | | | | | | | | | | | |
| TOTAL CREDIT, Part I | | | | | | | 89.4 | TOTAL CREDIT, Part II | | | | | | | | | | | | | | | REMARKS | | | | | | | |
| REMARKS | | | | | | | 90.4 | REMARKS | | | | | | | | 19c; #11-Item 8c; #15-Item 9b; and #18-Item 18c) | | | | | | | | | | | | | | |
| 2. Minimum inspection interval not met on four (4) dairy farms. (Producer #6, 9, 12 and 19) | | | | | | | | 6. Outdated water samples at four (4) dairy farms. (Producer #2, 5, 13 and 17) | | | | | | | | 9. Refer to Section C. Evaluation of Sampling Procedures. | | | | | | | | | | | | | | |
| 4. Violations existing on six (6) dairy farms during the last inspection and were not marked on the last inspection sheets. (Producer #1-Item 5 floors; #4-Item 7; #10-Item | | | | | | | | 8. Insufficient samples from two (2) dairy farms. (Producer #3 and 20) | | | | | | | | 10. Category II-Regulatory action not properly taken on three (3) dairy farms. (Producer #7-Item 3a-4X; #14-Item 16a-3X; and #16-Item 14b-3 X) | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | 11. Category III-Drug residue tests not recorded on ledgers for two (2) dairy farms. (Producer #10 and #22) | | | | | | | | | | | | | | |

Make the following changes to **APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS** on Pages 69-70:

PART I. DAIRY FARMS

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade “A” PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTY). ~~Prorate by number of farms in compliance.~~ **NOTE: A single farm** The BTU will be prorated by enforcement action(s) in compliance per farm. Five (5) Categories (a-e) will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance (PI);
- b. Category II: Permit Suspension (PS);
- c. Category III: Permit Revocation (PR);
- d. Category IV: Permit Reinstatement (PRI); and
- e. Category V: Hearing/Court Action (H/CA).

The Categories relate to the following Sanitation Requirements and Product Compliance, which are identified with an *. Compliance will be prorated based on **full** compliance with each of the five (5) Categories.

PRODUCT COMPLIANCE

- e. “Reinstating accelerated sample(s)” for bacterial, cooling temperature or somatic cell counts taken not more than two (2) per week on separate days within a three (3) week period. (PRI)*

For Example: FORM FDA 2359j-PART I, Item 10 Calculation:

(NOTE: Table below to be Added)

| | <u>Number Inspected</u> | <u>Number Complying</u> | <u>Percent Complying</u> | <u>Weight</u> | <u>Credit</u> |
|---------------------|-------------------------|-------------------------|--------------------------|---------------|---------------|
| <u>Category I</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>20</u> | <u>20</u> |
| <u>Category II</u> | <u>25</u> | <u>22</u> | <u>88</u> | <u>20</u> | <u>17.6</u> |
| <u>Category III</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>20</u> | <u>20</u> |
| <u>Category IV</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>20</u> | <u>20</u> |
| <u>Category V</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>20</u> | <u>20</u> |

TOTAL CREDIT ► 97.6 = 98

TOTAL CREDIT to be entered into PART I, Item 10 “Percent Complying” column of FORM FDA 2359j. (Refer to Section H, #s 4 and 8 for examples).

11. Records systematically maintained and current (*Grade “A” PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND

MILK PRODUCTS, and Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS). Make use of both general record-keeping deficiencies and record keeping by farm to determine value. ~~Prorate by number of farms in compliance.~~ **NOTE:** ~~A single farm~~ The BTU will be prorated by the number of identified record-keeping deficiencies per farm. The four (4) Categories (~~I-IV~~ a-d) listed below will be utilized for determining compliance with this Item and each will possess a value of twenty-five percent (25%) compliance. Compliance will be prorated based on **full** compliance with each of the four (4) Categories.

d. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

For Example: FORM FDA 2359j-PART I, Item 11 Calculation:

(NOTE: Table below to be Added)

| | <u>Number Inspected</u> | <u>Number Complying</u> | <u>Percent Complying</u> | <u>Weight</u> | <u>Credit</u> |
|---------------------|-------------------------|-------------------------|--------------------------|---------------|---------------|
| <u>Category I</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>25</u> | <u>25</u> |
| <u>Category II</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>25</u> | <u>25</u> |
| <u>Category III</u> | <u>25</u> | <u>23</u> | <u>92</u> | <u>25</u> | <u>23</u> |
| <u>Category IV</u> | <u>25</u> | <u>25</u> | <u>100</u> | <u>25</u> | <u>25</u> |

TOTAL CREDIT ► 98

TOTAL CREDIT to be entered into PART I, Item 11 “Percent Complying” column of FORM FDA 2359j. (Refer to Section H, #s 4 and 8 for examples).

Proposal: 201

Document: FDA 2400 Series Forms

*Make the following changes to the **FDA 2400 Series Forms**:*

CP 2400 Form (Rev. 1-09), Item 13g,

Replace with:

- a. Item 13,g ...“waste cycle procedures are validated to show sterility, must meet minimum standards for media preparation under Item 14”.

Proposal: 202

Document: EML; and FDA 2400 Series Forms

Pages: 13-15

*Make the following changes to the **EML** on Pages 13-15:*

SECTION 2: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES – MICROBIOLOGY

7.

(a) The BactoScan FC (all NCIMS approved models) shall examine a minimum of fourteen (14) samples and be operated by an approved analyst or BactoScan Industry Operator (BIO) using the procedures approved to operate the BactoScan FC and for which the analyst has been approved.

Page 14:

SPLIT SAMPLES ANALYSIS

6....

(1) The BactoScan FC Count (all NCIMS approved models) shall examine a minimum of fourteen (14) samples and be operated by an approved analyst or BIO using the procedures approved to operate the BactoScan FC Count and for which the analyst has been approved.

ANALYST PERFORMANCE LEVEL

Pages 15:

1. Analyst certified to perform the Standard Plate Count, Petrifilm Aerobic Count, Plate Loop Count, BactoScan FC (including a BIO), Spiral Plate Count Method, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase Count and Vitamin A and D3 analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 38.

Page 16:

Fully certified analyst not meeting the described performance levels shall be provisionally must pass the next on-site certification to become conditionally certified. BIO performance levels shall follow the above performance procedures criteria for fully certified analysts.

Make the following changes to the FDA 2400 Series Forms:

BACTO-SCAN INDUSTRY OPERATOR (BIO) APPROVAL PROCEDURES PROTOCOL

Training:

Two weeks of training conducted by a certified Bactoscan Operator.

Follow the most current approved BactoScan 2400 Form requirements for training

Train Log signed and Records maintained

Daily Instrument Start Up Procedure:

1. Replace Used Incubation Reagent Filter On Intake Assembly

A. Lift spring loaded disc that holds filter in position

B. Remove and discard old filter (Daily)

C. Insert new filter and release disc

D. Mark new filter with the day's date

2. Prepare Incubation Reagent (Fresh Daily)

- A. 150 Samples/hr. for 8 hr. run time
1600 ML (+/- 2%) of staining reagent and add 1 bottle
Enzyme 150. Invert container 10 times to mix before use.
- B. 100 Samples/hr. for 8 hr. run time
1100 ml (+/- 2%) of staining reagent and add 2 bottles of
Enzyme 50. Invert container 10 times to mix before use.
- C. 50 Samples/hr. for 8 hr. runtime
550 ml (+/- 2%) of staining reagent and add 1 bottle of
Enzyme 50. Invert container 10 times to mix before use.
- D. Must be used on day of preparation. Discard any left over.
- E. Label Container: Date prepared.

3. Prepare Sheath Reagent. (Ready To Use)

- A. Using a 10 liter container - pour in 8 liters (+/- 10%) of purified de-ionized
water, then add 2 liters (+/- 10%) of sheath liquid stock solution.
- B. Replace lid and invert 10 times to mix before use.
- C. Store at room temperature <25 degree C up to 7 days or 25-35 degrees C up to 2
days.
- D. Label container: Date Prepared _____ & Expiration Date _____.
 - a. Daily, Check Expiration Date. Sheath reagent must be replaced when expired.

4. Check Large Rinse Solution Container

- A. Pour 100 ml of rinse concentrate into the 50 liter container.
- B. Then add 50 liters of purified water to ensure complete mixing of the two liquids.
- C. For daily fill ups, pour 20 ml of rinse concentrate into 10 liter container - then
add 10 liters of purified water to ensure complete mixing of the 2 liquids.
- D. Label container: Date Prepared _____ and Expiration Date _____.
- E. Rinse solution must be replaced every 7 days.

5. Prepare Blank Solution

- A. Make fresh daily
- B. Mix 1 liter (+/- 10%) purified H2O and 50 ml of sheath liquid stock in a sterilized 1 liter
container
- C. Invert 10 times to mix before use
- D. Label container: Date Prepared _____

6. Prepare End of Day Solution (Ready to Use)

- A. Pour 10 liters (+/- 10%) of purified water and add 50ml (+/-10%) ammonia
25% analytical grade)
- B. Invert 10 times to mix well.
- C. Can be stored at room temperature (<25C) for a maximum of 7 days (discard
left over solution and make up fresh solution)
Date prep: _____ Exp. date _____

7. Remove The End Of Day Solution Container

- A. Transfer the rinse and incubation reagent pipettes from end of day solution to appropriate liquid containers.
- B. Rinse into the 50 liter rinse container and incubation into the incubation reagent container.

8. Turn BactoScan System On

As Instrument Warms Up:

1. Prepare Bacterial Control Sample (BCS)

- A. Using a 100 ml graduated cylinder, measure 100 ml (=/- 2%) of rehydration solution.
- B. Transfer to a suitable container with lid.
- C. Take a bacterial control sample (BCS) from the freezer.
 - a. Remove metal cap seal and loosen the lid.
 - b. Use sterile disposable 5 ml pipette to transfer 2-3 ml of rehydration solution into bacteria control sample vial.
 - c. Close BCS vial and shake to completely dissolve.
 - d. Refill the pipette with the clean rehydration solution.
 - e. Pour the dissolved BCS contents into the rehydration solution container.
 - f. Use the contents of the refilled pipette to rinse the BCS vial and pour the contents into the rehydration container.
 - g. Close lid and shake well for complete mixing.
 - h. Store the reconstituted BCS container in the refrigerator, 0 - 4.4 degrees c.
 - i. The re-constituted bacterial control sample can be stored for up to 10 hours when kept at 0-4.4 degrees C.
 - j. Label reconstituted BCS container: Prep Date _____ Prep Time _____.

2. Prepare Raft Or Float With Start-Up Control Samples (Hourly's)

- A. Place 9, 2 oz. vials in the float or raft.
- B. Vials 1 - 4 fill with your blank solution.
- C. Vial 5 label BCS - fill with Re-constituted Bacterial Control Solution.
- D. Vials 6 - 9 fill with your blank solution.
- E. Store the control samples in refrigerator 0 - 4.4 degrees C when not in use.

3. Conduct A Start-Up Control Sample Batch

- A. Enter appropriate batch type into the system (ie start-up).
- B. This will ensure the correct presentation and calculation of results.
- C. Check BCS lot number to see that it corresponds with the lot being used.

4. When The Control Sample Batch Has Been Measured

- A. Check that the blank solution counts are within acceptable limits.
All results no higher than 1 CFU.
- B. Check that the Bacterial Control Sample (BCS) results conform to the specified limits.
- C. If BCS sample or blank solution counts are outside the limits and does not correct after re-measurement - STOP - and call a BactoScan certified analyst and/or seek technical assistance. Records maintained.

D. The control samples can be re-used up to 10 hrs. with acceptable results when maintained at 0 - 4.4 degrees C.

E. Records to be maintained on all parameters each time instrument is used.

5. Measure The Control Samples

Measure the control samples at the start and end of each sample testing run.

Additionally control samples must be measured every 60 minutes, maximum, throughout the working day and records maintained.

Sample Handling:

1. Samples must first be tested for presence of growth inhibitor before testing on the BactoScan.

2. Samples kept at 0 - 4.4 degrees C until placed in racks for testing.

3. Invert samples 10 times, to mix, before placing into testing racks.

Testing Samples:

1. Enter identifying batch information into system (i.e. type, number of samples, etc.).

2. Place samples into testing rack, place on conveyor and immediately start the automatic testing procedure.

3. Samples run on BactoScan can be placed immediately into a 37 - 42 degree F water bath to be tested for somatic cells.

Results:

1. The BactoScan read out is in IBC (Individual Bacteria Counts / UL) which is converted to CFU's. (Colony Forming Units) automatically by the BactoScan and printed out on the BactoScan reports.

Records:

1. Maintain records on all results, controls and samples daily.

2. All records signed by Certified Bactoscan Operator.

End Of Day Shut Down & Cleaning:

1. Place the pipettes for incubation reagents and rinse reagents (both pipettes) into the End Of Day Solution container. Leave the sheath liquid pipette in the sheath liquid solution.

2. Start the automatic cleaning procedure - a 20 minute cycle.

3. Shut Computer System down.

Proficiency:

Initial Approval then Monthly

1. Have BactoScan Industry Operator analyze one set of 10 split milk samples.

2. Then have Certified analyst analyze the other set of 10 split milk samples.

3. Compare test results against each other to ensure results are comparable.

4. Records maintained

Evaluation:

Monthly

1. Spot check BactoScan approved operator performing different areas of the operation (i.e. start up, making BCS, check prep dates, shut downs, records, etc.).
2. Records maintained

An approved operator can run official samples for regulatory purposes without a Bacto-Scan certified operator on site or present, but available to the BIO operator.

Proposal: 203

Document: FDA 2400 Series Forms

Make the following change to the FDA 2400 Series Forms:

Cultural Procedures 2400 Form (Rev. 01-09), Section 33.a.7.b

Testing of samples to begin no longer than 48 (Delete 48) (Replace with 54) hours from the time the sample was first collected (i.e. producer bulk tank samples or plant finished product samples). If no time of collection is available, use 12:01 AM of the day of collection.

Proposal: 204

Document: FDA 2400 Series Forms

Make the following change to the FDA 2400 Series Forms:

Cultural Procedures 2400 Form (Rev. 01-09), Section 33.a.7.b

Testing of samples to begin no longer than 48 (Delete 48) (Replace with 60) hours from the time the sample was first collected (i.e. producer bulk tank samples or plant finished product samples). If no time is available, use 12:01 AM of the day of collection.

Proposals: 205, 206, 207, 208, 209, 210, 211, 213, 215, 216, 217, 224 and 226

Document: FDA 2400 Series Forms

All were referred to the Laboratory Committee to follow the 2400 Series Forms protocol.

Proposal: 212

Document: FDA 2400 Series Forms

Make the following changes to the FDA 2400 Series Forms:

Fluorophos ALP Test

3. Cuvette Heating Block
 - c. Temperature checked and recorded ~~daily~~ each day of use.
11. 12 Procedure
 - a. Perform instrument and reagent checks (item ~~14~~ 11) prior to proceeding
 1. Readings from item ~~14~~ 11 are within specification, proceed with calibration
 2. Adjustments made to bring A-D mode checks (item ~~14~~ 11) into specification
12. 13 Negative Control
13. 14 Positive Control
 - c. Test as in items ~~12~~ 13 c-f
14. 11 Check Procedures
15. Test Procedure
 - a. Perform all instrument and reagent checks (item ~~14~~ 11), negative control test (item ~~13~~ 14) prior to running analysis
16. Negative Control (see items 9c or 13)
 - a. ~~Prepare separate control for each product~~ May be prepared from suspect product or use laboratory prepared control or Phosphacheck negative control
 - b. ~~Prepare by heating sample for at least 1 min after thermometer registers 95±1C, stirring or mixing as necessary (TC used)~~ For the preparation of control using the suspect product:
 1. Prepare by heating sample for at least 1 min after thermometer registers 95±1C, stirring or mixing as necessary (TC used)
 2. Cool rapidly to 0-4.4C in an ice bath
 - c. This control must be less than 20 mU/L when tested
- 19.b.7. (items ~~21~~19b 1 & 2 above)

Proposal: 214
Document: FDA 2400 Series Forms

Make the following changes to the FDA 2400 Series Forms:

DMSCC Form

24.b.1. Slide is run through the following staining scheme

| | |
|-------------------|---------------|
| Carnoy's fixative | 5 min |
| 50% ethanol | 1 min |
| 30% ethanol | 1 min |
| H ₂ O | 1 min |
| Stain | 6 min |
| N-Butyl alcohol | flush briefly |
| Xylene | flush briefly |

a. Optionally, if smears will not adhere to slides:

1. Allow slide to dry (approx. 10 min) in the dark, after stain step but before flushing with N-Butyl alcohol OR

2. Allow slide to dry (approx. 10 min) in the dark, after Carnoy's fixative step but before the 50% ethanol step

Proposal: 218

Document: FDA 2400 Series Forms

Pages: 4, 7 and 8

Make the following changes to the FDA 2400 Series Forms:

Charm PASLITE 2400 Form

12.b. Shake vigorously or vortex (high speed or maximum speed for 10 seconds) and let settle 10 minutes at 0-4.4C for re-suspension

12.c. Shake vigorously again or vortex (high speed or maximum speed for 10 seconds) and use for test

15.a.1. For fluid white milk milks, unflavored and flavored, invert filled retail container 25 times, each inversion a full cycle down and up, shake or vortex (high speed or maximum speed for 10 seconds) negative and positive controls

15.c.1. Use a new pipet tip for each sample or control, place pipet tip in sample or prepared control (no more than 1 cm)

Proposal: 219

Document: FDA 2400 Series Forms

Make the following changes to the FDA 2400 Series Forms:

Include the Charm SL as an acceptable Appendix N test in M-a-85 for the detection of beta lactam drug residues in commingled sheep and water buffalo milk. Amend the current 2400 Form: 2400n-1 Charm SL/SL-6/SL-3 (10/07) to incorporate sheep's milk under the Charm SL.

Include the Delvotest P (mini) and Delvotest S/P as an acceptable Appendix N test in M-a-85 for the detection of beta lactam drug residues in commingled water buffalo milk. Amend the current 2400 Form: 2400d-1 Delvotest P (mini) and Delvotest S/P to incorporate water buffalo milk under the Delvotest P (mini) and Delvotest S/P.

Add test to M-a-85.

Proposal: 220

Document: FDA 2400 Series Forms

Make the following changes to the FDA 2400 Series Forms:

Cultural Procedures-General Requirements 1

24. Microbiologically Suitable (MS) Water

- a. Type _____
- b. System used _____
- c. Monthly testing criteria
 1. Standard plate count < 1,000 colonies/mL (<10,000 colonies/mL if stored)
 2. Total chlorine residual negative, recorded as less than the detection limit of test used
 3. ~~Resistance~~ Resistivity exceeds 0.5 megohm/cm or ~~conductance~~ conductivity is less than 2.0 umhos/cm (uSi/cm) (at 25C).
 - a. Brand: _____ Std. _____
 - b. Test performed in another lab _____

Proposal: 223

Document: FDA 2400 Series Forms

Page: 23

Make the following change to the FDA 2400 Series Forms:

Cultural Procedures (Rev. 1-09), Section 33.a.7.a, Page 23

1. Samples held at 13C + or - 1C for 18 hours may be tested for official ESCC.

Proposal: 227

Document: FDA 2400 Series Forms

Pages: 15 and 20

Make the following changes to the FDA 2400 Series Forms:

Easygel Aerobic Plate Count Media, Pectin Gel Method 2400 (Rev. 1-09)

Add to page 15 “27. Media”:

c. Easygel Aerobic Plate Count, Pectin Gel Method

1. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____

Re-letter c. – r., currently in Form 2400

Add to page 20 “29.Prepared Media Storage”:

e. Easygel Aerobic Plate Count plate storage

1. Store at room temperature.
2. Use before expiration date on package.
3. Store Easygel pretreated petri dishes at room temperature. Reseal unused dishes in bag.

Re-letter e. – f., currently in Form 2400

Proposal: 229

Document: FDA 2400 Series Forms

Pages: 16 and 20

Make the following changes to the FDA 2400 Series Forms:

Easygel Violet Red Bile Media, Pectin Gel Method 2400 (Rev. 1-09)

Add to “27. Media”:

f. Easygel Violet Red Bile, Coliforms in Dairy Products, Pectin Gel Method

1. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____

Re-letter e. – r., currently in Form 2400

Add to “29.Prepared Media Storage”:

f. Easygel Violet Red Bile plate storage.

1. Store frozen. Thaw at room temperature prior to use.
2. Use before expiration date on package.
3. Store Easygel pretreated petri dishes at room temperature. Reseal unused dishes in bag.

Re-letter e. – f., currently in Form 2400

Proposal: 104

Document: No Document Referenced

Suspend the requirements of the PMO Section 7 allowing only for refrigeration for the purpose of a study/pilot to be conducted following the requirements of FDA and this Ordinance to examine the benefits of using Carbon Dioxide as a processing aid in raw milk during transportation. This study/pilot will involve the incorporation of Carbon Dioxide into raw milk at the time of loading onto transport for shipment, removal of Carbon Dioxide at the final location prior to pasteurization, and be allowed to test market the product.

Proposal: 252

Document: No Document Referenced

Request FDA to issue a memorandum clarifying documentation of proper cleaning and sanitation for multiple loads.

Proposal: 259

Document: No Document Referenced

Proposal was reviewed by the Appendix N Committee and it was recommended that this proposal be sent to FDA Risk Assessment Study for review and consideration with the Appendix N Committee.

This Proposal was to modify CVM data requirements for beta-lactam screening tests to require detection of penicillin G, cephalosporin, ceftiofur and at least 1 additional beta-lactam of the six currently approved for lactating cows.

Proposal: 260

Document: No Document Referenced

Proposal was reviewed by the Appendix N Committee and it was recommended that this proposal be sent to FDA Risk Assessment Study for review and consideration with the Appendix N Committee.

This Proposal was to update CVM data requirements for milk screening tests labeled for testing milk at the bulk tank/tanker truck for drug residues.

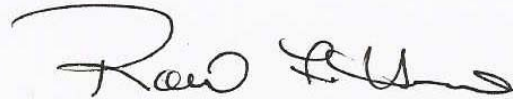
Proposal: 307

Document: No Document Referenced

Change the International Certification Pilot Program as defined in IMS-a-45 that once a TPC has their existing two (2) plants IMS listed, the TPC may request from the ICCP Committee permission to add up to two (2) additional plants for a maximum of four (4) listed plants.

All Proposals that make changes to the NCIMS documents will be incorporated into the next edition of the affected document as they are updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.



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