A. Summary of Proposal

Clarify and allow plants that are not bulk shipping milk and milk products to heat treat milk products for functional reasons (separation, hydration of powders and lipase destruction). Further, allow for dairy plants to heat treat at higher temperatures than is currently allowed for bulk shipped products to ensure complete lipase destruction.

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

Based on the current wording in Section 7 of the PMO it would appear that heat treating of milk and cream during separation is only allowed in dairy plants that are bulk shipping milk and milk products.

Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

With current requirements if a product is pasteurized there must be total (100%) physical separation between raw and pasteurized products. This means the only way to bring separated pasteurized product back to the raw system to make yogurt for example means the product must be added to the raw tank where added solid and stabilizers will be added, is with an air
break. If the air break is not properly installed and maintained the potential is for a raw product to pasteurized cross-connection.

With increased shipping distances for raw milk and more complex processing for specialty products the opportunities for rancidity to develop is increased due to enzymatic and bacterial lipase. In some cases, it is therefore important to heat treat milk as soon as practical upon receipt at the dairy plant. Research show that times and temperature needed to reduce lipase activity to 1% is in excess of pasteurization temperatures (Dairy Technology, Walstra et al.), so the current allowance to heat treat to less than pasteurization temperatures for bulk shipped products is not adequate to achieve the intended purpose.

Products made from powders such as chocolate milk may benefit hot holding of the milk – cocoa slurry at 178°F to 200°F to ensure proper wetting prior to processing. This is important on UP products as organisms survive the 280°F for 2 second process and show positive on quality tests.

It is also proposed to add a limitation that the milk and milk products that are heat treated must be pasteurized within 72 hours of heat treatment to ensure some do not attempt to utilize this allowance as a way to hold milk for extended periods of time prior to pasteurizing.

### C. Proposed Solution

<table>
<thead>
<tr>
<th>Changes to be made on page(s):</th>
<th>32</th>
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<tbody>
<tr>
<td>X  2015 PMO</td>
<td>2015 EML</td>
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<tr>
<td>2015 MMSR</td>
<td>2400 Forms</td>
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<tr>
<td>2015 Procedures</td>
<td>2015 Constitution and Bylaws</td>
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</table>

Section 7 page 32. Insert at the end of the current paragraph ending in “Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.”

In milk plants of final packaging of milk and milk products, raw milk may be heat treated for functional reasons (separation, enzymatic deactivation, powder wetting) provided all heat treated milk and/or milk products are pasteurized, ultra-pasteurized, aseptically processed, or retort processed within 72 hours of heat treatment.
Name: R. Lynn Young
Agency/Organization: Milk Regulatory Consultants, LLC
Address: 56820 Highway A
City/State/Zip: Russellville, MO 65074
Telephone No.: 573-338-1785  E-mail Address: rlynnyoung@cs.com
A. Summary of Proposal

This proposal would lower the maximum temperature of raw and pasteurized milk and dairy products to 41°F or less until processed and then maintained at 41°F (5°C) or less thereafter, excluding the exceptions already provided for in the 2015 Pasteurized Milk Ordinance.

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

The Temperature Danger Zone for potentially hazardous foods, including milk and dairy products, has been identified as those temperatures falling between 41°F and 140°F. (There is some variation with some research and documents indicating a range between 39°F and 135°F.) This Danger Zone is referenced by the USDA Food Safety Inspection Service, the U.S. Department of Agriculture, Food and Nutrition Service & Institute of Child Nutrition, and the U.S. Department of Health and Human Services Public Health Services, Food and Drug Administration, and is part of the FDA Food Code.

The current 45°F temperature used to be considered optimal but the low end of the temperature danger zone was reduced to 41°F (5°C) in 1993, because it more effectively prohibits the growth of bacteria, including pathogens. This temperature is easily attainable both at the dairy farm and dairy plant through the use of modern advancements that have been made in cooling technologies.
C. Proposed Solution

Changes to be made on page(s): 32, 34-35, 41-45, 59-60, 82, 88, 91-94, 113-117, 122-123, 129,146, 186, 231, 391, 393 of the (X - one of the following):

<table>
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<th>2015 PMO</th>
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<td>2015 Constitution and Bylaws</td>
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</tbody>
</table>

SECTION 7 including Table 1; ITEM 5r. MILKHOUSE CONSTRUCTION AND FACILITIES; 18r. RAW MILK COOLING; 15p. (A) PROTECTION FROM CONTAMINATION; ITEM 16p. PASTEURIZATION, ITEM 16p. (A) BATCH PASTEURIZATION; ITEM 17p. COOLING OF MILK AND / OR MILK PRODUCTS; 19p. CAPPING; ITEM 21p. VEHICLES; SECTION 10; APPENDIX B; APPENDIX D; APPENDIX H, APPENDIX Q, and APPENDIX R

Strike through 45°F and replace with 41°F on all pages, sections, appendices, and tables of the PMO cited above.

Name: Barb Koeltzow, Dairy Program Manager
Agency/Organization: Michigan Department of Agriculture & Rural Development
Address: 525 W. Allegan Street
City/State/Zip: Lansing, MI 48909
Telephone No.: 517-749-5846 E-mail Address: Koeltzowb@michigan.gov
and IMS listed upon FDA’s acceptance of validated Grade “A” PMO, Section 6. and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

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

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

No process or manipulation other than pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and/or milk products for the purpose of removing or deactivating microorganisms, provided that filtration and/or bactofugation processes are performed in the milk plant in which the milk and/or milk product is pasteurized, ultra-pasteurized, aseptically processed and packaged, or retort processed after packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (167°F) in a continuing heating process and immediately cooled to 7°C 5°C (41°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Milk plants, receiving stations and transfer stations participating in the NCIMS voluntary HACCP Program, shall also comply with the requirements of Appendix K. of this Ordinance.

Whey shall be from cheese made from Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging as provided in this Ordinance. Buttermilk shall be from butter made from Grade “A” cream, which has been pasteurized prior to use in accordance with Item 16p of this Ordinance. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Regulatory Agency.

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

1. Cheese made from Grade “A” raw milk for pasteurization, which has been pasteurized prior to use, in accordance with Item 16p of this Ordinance, or

2. Cheese made from Grade “A” raw milk for pasteurization, which has been heat-treated to a temperature of at least 64°C (147°F) and held continuously at that temperature for at least twenty
<table>
<thead>
<tr>
<th>GRADE “A” RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING</th>
<th>Temperature****.......</th>
<th>Cooled to 10ºC (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C 5º C (45ºF) (41ºF) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF). <strong>NOTE</strong>: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.5ºC (40ºF), where sample temperature is &gt;4.5ºC (40ºF), but ≤7°C 5ºC (45ºF) (41ºF) and less than three (3) hours after collection has not increased in temperature.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Limits ..........</td>
<td>Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization. <strong>NOTE</strong>: Tested in conjunction with the drug residue/inhibitory substance test.</td>
<td></td>
</tr>
<tr>
<td>Drugs*****..............</td>
<td>No positive results on drug residue detection methods as referenced in Section 6. - Laboratory Techniques of this Ordinance.</td>
<td></td>
</tr>
<tr>
<td>Somatic Cell Count*....</td>
<td>Individual producer milk not to exceed 750,000 per mL.</td>
<td></td>
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</tbody>
</table>

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<thead>
<tr>
<th>GRADE “A” PASTEURIZED MILK AND/OR MILK PRODUCTS</th>
<th>Temperature .............</th>
<th>Cooled to 7°C 5º C (45ºF) (41ºF) or less and maintained thereat. <strong>NOTE</strong>: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.5ºC (40ºF), where sample temperature is &gt;4.5ºC (40ºF), but ≤7°C 5ºC (45ºF) (41ºF) and less than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Limits** ......</td>
<td>Not to exceed 20,000 per mL, or gm.**** <strong>NOTE</strong>: Tested in conjunction with the drug residue/inhibitory substance test.</td>
<td></td>
</tr>
<tr>
<td>Coliform .................</td>
<td>Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. <strong>NOTE</strong>: Tested in conjunction with the drug residue/inhibitory substance test.</td>
<td></td>
</tr>
<tr>
<td>Phosphatase** ...........</td>
<td>Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.</td>
<td></td>
</tr>
<tr>
<td>Drugs**** ...............</td>
<td>No positive results on drug residue detection methods as referenced in Section 6. - Laboratory Techniques of this Ordinance which have been found to be acceptable for use with Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)</td>
<td></td>
</tr>
<tr>
<td>Product Type</td>
<td>Temperature</td>
<td>Bacterial Limits</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
</tbody>
</table>
| GRADE "A" ULTRA- PASTEURIZED (UP) MILK AND/OR MILK PRODUCTS | Cooled to $7^\circ\text{C}$ ($45^\circ\text{F}$) or less and maintained thereat. | Not to exceed 20,000 per mL, or gm. **
| | | NOTE: Tested in conjunction with the drug residue/inhibitory substance test. |
| | | Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. |
| | | No positive results on drug residue detection methods as referenced in Section 6.- Laboratory Techniques of this Ordinance which have been found to be acceptable for use with Ultra-Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.) |
| GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND/OR MILK PRODUCTS | Cooled to $7^\circ\text{C}$ ($45^\circ\text{F}$) or less and maintained thereat unless drying is commenced immediately. | Not to exceed 10 per gram. Provided, that in the case of bulk milk transport tank shipments shall not exceed 100 per gram. |
| GRADE "A" NONFAT DRY MILK AND DRY MILK AND/OR MILK PRODUCTS | Not to Exceed: 10,000 per gram 10 per gram | |
| GRADE "A" WHEY FOR CONDENSING AND/OR DRYING | Maintained at a temperature of $7^\circ\text{C}$ ($45^\circ\text{F}$) or less, or $57^\circ\text{C}$ ($135^\circ\text{F}$) or greater, except for acid-type whey with a titratable acidity of 0.40% or above. | Not to exceed 10 per gram. Provided, that in the case of bulk milk transport tank shipments shall not exceed 100 per gram. |
| GRADE "A" PASTEURIZED CONDENSED WHEY AND/OR WHEY PRODUCTS | Cooled to $10^\circ\text{C}$ ($50^\circ\text{F}$) or less during crystallization, within 72 hours of condensing. | |
| GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS | | Not to exceed 10 per gram. |

* Goat Milk 1,500,000/mL.
** Not applicable to acidified or cultured milk and/or milk products, eggnog, cottage cheese, and other milk and/or milk products as identified in the latest revision of M-a-98.
*** Results of the analysis of milk and/or milk products which are weighed in order to be analyzed shall be reported in # per gm. (Refer to the current edition of the SMEDP.)
**** Not applicable to acidified or cultured milk and/or milk products, eggnog, cottage cheese, pasteurized and ultra-pasteurized flavored (non-chocolate) milk and/or milk products and other milk and/or milk products as identified in the latest revision of M-a-98.
***** Raw sheep milk samples that have previously been frozen may be tested for Appendix N. drug residue if the samples meet the sampling requirements cited in Appendix B. of this Ordinance.

**NOTE:** It is not allowed to test frozen raw milk samples for bacteria or somatic cells.
direct opening into any barn, stable or parlor or into a room used for domestic purposes. Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.

Water under pressure shall be piped into the milkhouse.

The milkhouse shall be equipped with a two (2) compartment wash vat and adequate hot water heating facilities.

A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. In addition, the following minimum criteria shall be met:

1. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C 5ºC (45ºF) (41ºF) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this Ordinance, with or without hard copy, may be used in place of temperature-recording records. (Refer to the NOTE on page 46.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this Ordinance. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

2. Temperature-recording charts shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

3. The milk shall be sampled at the direction of the Regulatory Agency in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector.

4. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk milk tank(s) and/or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

1. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated Clean-In-Place (CIP) cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15.
2. To assure continued protection of the milk, the milk tank truck manhole shall be sealed after the truck has been cleaned and sanitized.

3. The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station, or transfer station receiving the milk, or at a permitted milk tank truck cleaning facility.

4. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 2°C 5° C (45°F) (41°F) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this Ordinance, with or without hard copy, may be used in place of temperature-recording records. (Refer to the NOTE on page 46.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this Ordinance. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

5. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

6. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

7. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

8. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15, overhead protection of the milk hose connection to the milk tank truck shall be provided.

PUBLIC HEALTH REASON

Unless a suitable, separate place is provided for the cooling, handling and storing of milk and for the washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction, which permits easy cleaning, promotes cleanliness. A well-drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness, and proper ventilation reduces the likelihood of odors and condensation. A milkhouse that is separated from the barn, stable or parlor and the living quarters provides a safeguard against the exposure of milk and milk equipment and utensils to contamination.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. A separate milkhouse of sufficient size is provided for the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils, except as provided for in Item 12r of this Section.
a. A concrete slab of adequate size, to protect the transfer hose, shall be provided under the stubbed sanitary milk and CIP cleaned lines.
b. The outside wall of the milkhouse, where the sanitary piping and concrete slab are located shall be properly maintained and kept in good repair.
c. The sanitary piping, stubbed outside the milkhouse, shall be properly sloped to assure complete drainage and the ends of the piping, which are located outside, shall be capped when the transfer hose is disconnected.
d. After the completion of milk transfer, the milk lines and transfer hose shall be properly CIP cleaned.
e. After the CIP cleaning process has been completed; the transfer hose shall be disconnected, drained and stored in the milkhouse. Proper storage of the transfer hose includes capping the ends and storing the entire hose up off the floor. The sanitary piping outside the milkhouse shall be capped at all times, except when transferring milk or being CIP cleaned. When the caps are not being used, they shall be properly cleaned and sanitized after each use and stored in the milkhouse to protect them from contamination. A transfer hose manufactured with permanent hose end fittings, attached in such a manner that will assure a crevice-free joint between the hose and the fitting, may be stored outside of the milkhouse, provided it is CIP cleaned; the stubbed piping and hose length are of sufficient design to allow complete drainage after cleaning and sanitizing; and the hose remains connected to the stubbed piping when not in use.
f. Means shall be provided to sanitize the milk-contact surfaces of the transfer hose and bulk milk pickup tanker fittings prior to the connection of the transfer hose to the bulk milk pickup tanker.
g. At all times, the bulk milk pickup tanker manhole openings(s) shall remain closed, except for brief periods for sampling and examination when environmental conditions permit.

2. A transportation tank, with or without overhead protection, may be used for cooling and/or storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck, used for cooling and/or storing milk, such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the prerequisites of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. (Refer to Appendix C. of this Ordinance for suggested plans and information on size, construction, operation and maintenance of milkhouses.)

In addition, the following minimum criteria shall be met:

a. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to $7^\circ C$ $5^\circ C$ ($45^\circ F$) ($41^\circ F$) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this Ordinance, with or without hard copy, may be used in place of temperature-recording records. (Refer to the NOTE on page 46.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this Ordinance. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.
b. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except
that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

c. The milk shall be sampled at the direction of the Regulatory Agency in a manner so as to preclude contaminating the milk tank truck or sample, by an acceptable milk sample collector.

d. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk milk tank(s) and/or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15.

b. To assure continued protection of the milk, the milk tank truck manhole shall be sealed after the truck has been cleaned and sanitized.

c. The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station or transfer station receiving the milk or at a permitted milk tank truck cleaning facility.

d. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C 5°C (45°F) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this Ordinance, with or without hard copy, may be used in place of temperature-recording records. (Refer to the NOTE on page 46.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this Ordinance. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.

e. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

f. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

g. The milk tank truck shall be parked on a self-draining concrete or equally impervious
drying devices immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these activities. Milkers and bulk milk hauler/samplers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

PUBLIC HEALTH REASON

The reasons for clean hands of the persons doing the milking are similar to those for the cleanliness of the lactating animal’s udder. The milker’s hands may have been exposed to contamination during the course of their normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing it is important that the clothes worn, during milking and the handling of milk, be clean.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Hands are washed, clean and dried with an individual sanitary towel or other approved hand-drying devices immediately before milking; before performing any milkhouse function; and immediately after the interruption of any of these activities.
2. Milkers and bulk milk hauler/samplers wear clean outer garments while milking or handling milk containers, utensils or equipment.

ITEM 18r. RAW MILK COOLING

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

PUBLIC HEALTH REASON

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

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:
1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

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

3. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.
   a. The temperature-recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this Ordinance, with or without hard copy, may be used in place of temperature-recording records.
   
   NOTE: With the above cited Criteria within Appendix H., V. of this Ordinance, the words “dairy farm” shall be substituted for “milk plant” wherever the words “milk plant” appears.

   b. The temperature-recording device shall be verified every six (6) months and documented in a manner acceptable to the Regulatory Agency using an accurate (+/- 1°C (2°F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six (6) months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.
   c. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.
   d. The temperature-recording device should be installed in an area convenient to the milk storage tank and acceptable to the Regulatory Agency.
   e. The temperature-recording device sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity.
   f. The temperature-recording device shall comply with the current technical specifications for tank recording thermometers.
bacteria, chemicals and other adulterants, as well as the potential for allergen cross-contact of such products in certain facilities, every effort should be made to provide adequate protection for the milk and milk products at all times. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these microorganisms may be found in the milk plant environment if measures are not taken to minimize the risk of contamination by these microorganisms. Contamination of milk from the environment can result in milkborne illness. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and/or milk product or equipment with which the milk and/or milk product comes in contact; such contamination can result in adverse health consequences. Food allergens can cause mild to severe adverse reactions and sometimes may cause life threatening reactions. Thus it is important not only to declare all food allergens on milk and milk product labels, but also to prevent cross-contact of milk and milk products so they do not contain undeclared food allergens.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

**15p.(A)**

1. Equipment and operations are so located within the milk plant as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. Packaged milk and/or milk products, which have physically left the premises or the processing milk plant, are not re-pasteurized for Grade “A” use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and/or milk products, provided all other aspects of this Item, including proper storage temperature and container integrity are complied with. Provided, that the re-pasteurization of milk and/or milk products shipped in milk tank trucks, which have been pasteurized at another Grade “A” milk plant and have been handled in a sanitary manner and maintained at 7°C 5° C (45°F) or less is permitted. Equipment, designated areas or rooms utilized for handling, processing and storage of returned packaged milk and/or milk products are maintained, operated, cleaned and sanitized so as to preclude the contamination of Grade “A” milk and/or milk products and equipment and the Grade “A” operations.

**NOTE:** The option for the authorizing of the reprocessing of packaged milk and/or milk products on an individual request, as cited in 2 above, shall not be applicable to a TPC authorized under the ICP.

3. All product-contact surfaces of containers, utensils and equipment are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk and milk product storage tanks and milk tank trucks, pumps, vats, etc., shall be capped or otherwise properly protected. While unloading at a milk plant, receiving station or transfer station, one of the following conditions shall be met:
   a. If the area is completely enclosed, walls and ceiling, with doors closed during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required.
In the event of a Water Control Authority issued Boil Water Order or other emergency that renders the water supply to be a public health concern, the established approved equivalency protocol shall be evaluated to determine that it will continue to produce water equivalent to pasteurized water. In addition, a Safety Assessment shall be made of the milk and milk products that may have been affected during the time that the water utilized may not have been equivalent to pasteurized water.

This Section does not require separate raw and pasteurized CIP cleaning systems.

1. Pasteurized re-circulation lines, divert lines, and leak-detect lines connecting to the constant-level tank shall be designed so that there is an air gap between the termination of these pipelines and the raw milk or milk product overflow level. This air gap shall be equivalent to at least two (2) times the diameter of the largest of these pipelines. For purposes of this Section, an overflow is defined as the flood rim of the constant-level tank or any unrestricted opening below the flood rim of the constant-level tank which is large enough that it is at least equivalent to two (2) times the diameter of the largest of these pipelines.

2. All milk and/or milk products that have overflowed, leaked, been spilled or improperly handled are discarded. Milk and/or milk products drained from processing equipment at the end of a run, collected from a defoamer system, and milk or milk product solids rinsed from equipment, containers or pipelines shall be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 72°F (22°C) or less. When the handling and/or cooling of such milk and/or milk products are not in compliance with this requirement, they shall be discarded. Milk and/or milk products from damaged, punctured or otherwise contaminated containers or product from out-of-code containers shall not be repasteurized for Grade “A” use.

3. Means are provided to prevent contamination of milk and/or milk products, containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.

4. The processing of foods and/or drinks other than Grade “A” milk and/or milk products are performed to preclude the contamination of such milk and/or milk products.

5. No product is handled in the milk plant that may create a public health hazard. Permission to handle products other than those defined in Section 1. of this Ordinance or to conduct operations in equipment or rooms, other than those for which they are designated, should be provisional and subject to revocation if found objectionable.

6. In no case shall pasteurized milk or milk products, be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.

7. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

8. Raw milk or milk product-to-water-to-pasteurized milk or milk product plate or double/triple tube type heat exchangers may be used for heat-exchange purposes, other than legal pasteurization, when constructed, installed and operated in accordance with the following:

   a. Plate or double/triple tube type heat exchangers, as described above, shall be constructed, installed and operated so that pasteurized milk or milk product in the plate or double/triple tube type heat exchanger will automatically be under greater pressure than the heat-transfer water in the plate or double/triple tube type heat exchanger at all times.

   b. The pasteurized milk or milk product, between the outlet of the last flow promoting device and the entrance to the plate or double/triple tube type heat exchanger, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest heat-transfer water level,
plant for drying without re-pasteurization, provided the following conditions are complied with:

1. The condensed, partially crystallized whey is cooled and maintained at 2°C 5º C (41ºF) or less.
2. Milk tank trucks, dedicated to hauling pasteurized product, shall be used to transport the condensed, partially crystallized whey and shall be washed and sanitized immediately prior to filling and then sealed after filling until unloading.
3. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

PUBLIC HEALTH REASON

Health officials unanimously agree upon the public health value of pasteurization. Long experience conclusively shows its value in the prevention of disease that may be transmitted through milk. Pasteurization is the only practical, commercial measure, which if properly applied to all milk, will destroy all milkborne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value can be done only at intervals and; therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by this Ordinance, if applied to every particle of milk or milk product will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the USPHS/FDA, over many years, indicate that the risk of contracting disease from raw milk is approximately fifty (50) times as great as from milk that has been “pasteurized”.

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

ADMINISTRATIVE PROCEDURES

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

1. Every particle of milk or milk product is heated in properly designed and operated equipment that meets the requirements of this Item and Appendix H. of this Ordinance, to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:
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:
   a. If the product is whey, pasteurization is not required, provided:
      (1) The product is acid whey (pH less than 4.7); or
      (2) It is processed in RO or UF equipment at temperatures at or below 7°C (45°F).
   b. If the product is raw milk for pasteurization, the product may be concentrated by the use of RO or UF membrane filtration without pasteurization, prior to the entrance into the equipment, provided the following sampling, testing, design, installation and operational criteria are met:
      (1) Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of this Ordinance;
      (2) The RO or UF filtration system is designed and operated to assure that milk 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 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;
      (3) The RO or UF system shall be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. of this Ordinance. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the system, prior to entering each stage of the modules in series that contains cooling, and the retentate stream prior to any final cooler and upon exiting the system; and
      (4) If the RO or UF system is not designed, installed and operated in accordance with the above noted criteria, the raw milk or milk product shall be pasteurized prior to entering the RO or UF system.

4. Milk and/or milk products for pasteurization may be processed by micro-filtration (MF) systems prior to pasteurization for the sole purpose of the removal of micro-organisms, provided that:
   a. Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of this Ordinance; and
   b. If there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria shall be complied with:
The MF system is designed and operated to assure that milk or milk product temperature in the circulating retentate loop is maintained at or below 18.3°C (65°F), or at or above 51.7°C (125°F) throughout the process. Provided that the product temperature may rise above 18.3°C (65°F) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1°C (70°F) or fall below 48.9°C (120°F), the product shall be either immediately diverted to the system’s balance tank until the product is again below 18.3°C (65°F) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

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

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

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

6. If condensed whey containing at least forty percent (40%) total solids, has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:
   a. The condensed, partially crystallized whey is cooled and maintained at 7°C (45°F) or less.
   b. Milk tank trucks used to transport the condensed, partially crystallized whey shall be washed and sanitized immediately prior to filling and are sealed after filling until unloading.
   c. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

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

ITEM 16p.(A) BATCH PASTEURIZATION

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

PUBLIC HEALTH REASON

Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization shall be performed in equipment, which is properly designed and operated and which insures that every particle of milk or milk product will be held continuously at the proper temperature for the specified period of time. Recording thermometers are the only known means for furnishing the Regulatory Agency with a
ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS

All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.

For a milk or milk product flavoring slurry that contains milk and/or milk products and is not intended to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H. of this Ordinance, the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7°C (45°F) or less, or at a temperature of 66°C (150°F) or greater and maintained thereat.

All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured;
2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;
6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
   a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
   b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
   c. The additional applicable critical factors*, as cited below, shall also be utilized for either
      hot fill temperature to determine the acceptability of filling at these temperatures, or
   d. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at
      13°C (55°F) or less*, or
   e. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the
      specified concentration as addressed in M-a-97, and filled at 13°C (55°F) or less*; and
7. All condensed whey and whey products shall be cooled during the crystallization process to
   10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and
   emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72)
   hour time period begins when cooling is started.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and
   temperatures, and potassium sorbate concentration or specified microbial inhibitors and/ or
   preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be
   monitored and documented by the processing facility for verification by the Regulatory
   Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and
   inaccuracies in pH measurements. Formulation or processing changes that affect critical
   factors shall be communicated to the Regulatory Agency.

NOTE: Microbial inhibitors and/or preservatives and/or all of their individual components shall
   have GRAS status; and their pathogen inhibition shall be supported by documented challenge
   study results that are acceptable to the Regulatory Agency and FDA.
All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed:

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;
4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**;
5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
   a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or
   b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or
   c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**, or
   d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Cooling temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. Every refrigerated room or tank, in which milk or milk products, whey and whey products, and condensed milk and milk products are stored, shall be equipped with an accurate indicating thermometer.
On delivery vehicles, the temperature of milk and milk products shall not exceed \(27.5^\circ C\) \((50^\circ F)\). Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.

**Electronic Data Collection, Storage and Reporting:** The electronic storage of required cleaning records and product storage temperature records, with or without hard copy printouts, shall be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency. Electronic records that comply with the applicable provisions of Appendix H., IV. and V. of this *Ordinance*, with or without hard copy, may be used in place of the cleaning records.

**PUBLIC HEALTH REASON**

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall be maintained at \(27.5^\circ C\) \((50^\circ F)\) or less until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. Provided, that all balance or surge tanks (continuous flow with a retention time not to exceed one (1) hour) for raw milk and milk products, pasteurized milk and milk products and whey and whey products may be maintained at any temperature for up to twenty-four (24) hours.
2. All whey and whey products for condensing and/or drying are maintained at a temperature of \(27.5^\circ C\) \((50^\circ F)\) or less; or \(57^\circ C\) \((135^\circ F)\) or greater until processed. Storage tanks containing whey and whey product above \(27.5^\circ C\) \((50^\circ F)\) and below \(57^\circ C\) \((135^\circ F)\) shall be emptied, cleaned and sanitized after each four (4) hours of use or less.***
3. For a milk or milk product flavoring slurry that contains milk and/or milk products and is not to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H. of this *Ordinance*, the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of \(27.5^\circ C\) \((50^\circ F)\) or less, or at a temperature of \(66^\circ C\) \((150^\circ F)\) or greater and maintained thereat.
4. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of \(27.5^\circ C\) \((50^\circ F)\) or less, unless drying is commenced immediately after condensing:
   a. Those to be cultured;
   b. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
   c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
   d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
   e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;
   f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
(1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
(2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
(3) The additional applicable critical factors*, as cited below, shall also be utilized for either hot fill temperature to determine the acceptability of filling at these temperatures, or
(4) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, or
(5) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13°C (55°F) or less*; and

g. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started.***

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

**NOTE:** Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Regulatory Agency and FDA.

5. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 2°C 5ºC (35ºF) (41ºF) or less and be maintained therat following filling or until further processed:

a. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 2°C 5ºC (35ºF) (41ºF) or less within one hundred sixty eight (168) hours of filling**;

b. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 2°C 5ºC (35ºF) (41ºF) or less within one hundred sixty eight (168) hours of filling**;

c. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 2°C 5ºC (35ºF) (41ºF) or less within ninety-six (96) hours of filling**;

d. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 2°C 5ºC (35ºF) (41ºF) or less within twenty-four (24) hours of filling**; and

e. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
(1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 2°C 5ºC (35ºF) (41ºF) or less within twenty-four (24) hours of filling**; or
(2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 2°C 5ºC (35ºF) (41ºF) or less within twenty-four (24) hours of filling**; or
(3) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7°C (45°F) (41°F) or less within seventy-two (72) hours of filling**, or
(4) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7°C (45°F) (41°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Cooling temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

6. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six (6) hours of operation or less.***
7. Each refrigerated room in which pasteurized milk and milk products are stored, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. of this Ordinance. Such thermometer shall be located in the warmest zone of the refrigerated room.
8. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H. of this Ordinance.
9. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F) (41°F).
10. All surface coolers comply with the following specifications:
   a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 of an inch) between the header sections to permit easy cleaning.
   b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.
   c. The location of supports of cooler sections shall prevent condensation and leakage from
PUBLIC HEALTH REASON

Improper closing or sealing and hand capping exposes the milk or milk product to contamination. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling, and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap, including milk or milk product that has been forced out by temperature expansion and may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the milk and milk products have not been contaminated after packaging.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The capping, closing or sealing of milk and milk product containers is done in a sanitary manner on approved mechanical capping, closing and/or sealing equipment. The term “approved mechanical capping, closing and/or sealing equipment” shall not exclude manually operated machinery. Hand capping shall be prohibited. Provided, that if suitable mechanical equipment, for the capping or closing of container(s) of 12.8 liters (3 gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Regulatory Agency.
2. All mechanical capping, closing or sealing mechanisms are designed to minimize the need for adjustment during operation.
3. Bottles and packages that have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at \(7^\circ C\) \(5^\circ F\) \(41^\circ F\) or less, except dry milk products, and subsequently repasteurized or discarded.
4. All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid milk and milk product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened.
5. All caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps that are left in the cappers at the end of an operating period, after removal from the cap tubes, shall be a violation of this Item, provided, that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the capping device shall be discarded.
6. All dry milk products are stored in a sanitary manner.

ITEM 20p. PERSONNEL - CLEANLINESS

Hands shall be thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the
toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products, containers, utensils and equipment shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products, shall wear adequate hair coverings and shall not use tobacco.

**PUBLIC HEALTH REASON**

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

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1. Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.
2. Each employee washes their hands following a visit to the toilet room and prior to resuming work.
3. All persons while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products containers, utensils, and equipment wear clean outer garments.
4. The use of tobacco products is prohibited in all rooms in which milk and milk products are handled, processed or stored, or in which milk or milk product containers, utensils and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, milk and milk product storage, cooling and dry storage ingredients, single-service article storage and container/utensil wash-up areas. Any person engaged in the processing of milk or milk products wears adequate hair coverings.
5. Specially provided clean rubbers or boot covers, clean coveralls, and white cap, clean cloth or paper, are worn whenever it is necessary to enter the drying chambers. Such articles of clothing are stored in such a manner as to be protected from contamination. Boot covers, which have come into contact with areas other than those within the dryer, are not considered clean.

**ITEM 21p. VEHICLES**

All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C 5°C 45°F (41°F) or less and are protected from contamination. Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.

**PUBLIC HEALTH REASON**

Milk and milk products, as well as empty containers, should be protected against contamination at all times.
ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All vehicles are kept clean.
2. Material that is capable of contaminating milk or milk products is not transported with milk or milk products.
3. Milk and milk products, except dry milk products, are maintained at $7^\circ C$ $5^\circ C$ ($45^\circ F$) ($41^\circ F$) or less.
4. The operation of milk tank cars and shipping bins comply with the following provisions:
   a. Milk and milk products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.
   b. Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.
   c. Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.
   d. Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks, which must make more than one trip while unloading a tank car, need not be cleaned and sanitized after each time they are emptied.
   e. Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.
5. The doors of tank cars and covers of shipping bins are sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled as prescribed in Section 4. of this Ordinance by means of a tag attached to the tank car or shipping bin.
6. Vehicles have fully enclosed bodies with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Milk plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

PUBLIC HEALTH REASON

The surroundings of a milk plant should be kept neat and clean to prevent attracting rodents, flies and other insects, which may contaminate the milk or milk products. Insecticides and rodenticides, not approved for use in milk plants, or approved insecticides and rodenticides, not used in accordance with label recommendations, may contaminate the milk or milk products processed by the milk plant.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. There is no accumulation of trash, garbage or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance.
2. Driveways, lanes and areas serving milk plant vehicular traffic are graded, drained and free
labeled “ungraded”.

**NOTE:** The option for the sale of “ungraded” milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

**SECTION 10. TRANSFERRING; DELIVERY CONTAINERS; AND COOLING**

Except as permitted in this Section, no milk producer, bulk milk hauler/sampler or distributor shall transfer milk or milk products from one (1) container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

It shall be unlawful to sell or offer for sale any pasteurized milk or milk products that have not been maintained at the temperature set forth in Section 7. of this *Ordinance*. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

**ADMINISTRATIVE PROCEDURES**

**TRANSFERRING:** The dipping or ladling of milk and fluid milk products is expressly prohibited, except for immediate cooking purposes. Milk and milk product containers, which have been filled and sealed at a milk plant, shall be used for the delivery of milk or milk products. Caps, closures or labels shall not be removed or replaced during transportation.

**BULK DISPENSERS:** Bulk dispensers, approved by the Regulatory Agency, shall satisfy the following sanitary design, construction and operation requirements:

1. All dispensers shall comply with the applicable requirements of Section 7. of this *Ordinance*.
2. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust or insects, but the delivery orifice may be exempted from this requirement.
3. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant. Provided, that dispensing valves, which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.
4. The dispensing container shall be filled at the milk plant and shall be sealed so that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).
5. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products that remain homogeneous.
6. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below \(72^\circ\text{C} 5^\circ\text{C} \left(45^\circ\text{F}\right) \left(41^\circ\text{F}\right)\) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected and shall be under adequate refrigeration during transportation and storage.
be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead. When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting Regulatory Agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted, the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency. Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of inspection as required in the PERMITTING Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.

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

1. **Samples and Sampling Equipment:** (When provided)
   a. Sample containers shall be stored to preclude contamination.
   b. The sample box shall be in good repair and kept clean.
   c. Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected.
   d. The sample transfer instrument container is provided and adequate means for maintaining sanitizer solutions is on hand.
   e. The samples are properly stored to preclude contamination.
   f. The sample storage compartment shall be clean.
   g. Samples are maintained at an acceptable temperature 0°C-4.5°C (32°F-40°F) and a temperature control sample is provided.
   h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.

2. **Product Temperature 7°C (45°F) or Less:**
   a. The product temperature shall meet all the requirements of Section 7., Items 18r-Raw Milk Cooling and 17p-Cooling of Milk and Milk Products of this Ordinance.
   b. Product that remains in external transfer systems that exceeds 10°C (50°F) is discarded. This includes pumps, hoses, air elimination equipment or metering systems.

3. **Equipment Construction, Cleaning, Sanitizing and Repair:** Items a. through l. on FORM FDA 2399b shall be evaluated according to the following criteria:
   a. Construction and Repair Requirements
      (1) The milk tank truck and all appurtenances shall meet applicable requirements of Section 7., Item 10p-Sanitary Piping and Item 11p-Construction and Repair of Containers and Equipment of this Ordinance. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this Ordinance.
cleaned at the same required frequency as the equipment generating the reclaimed water.

**NOTE:** Water reclaimed from raw milk membrane processes shall not be used for Category I purposes unless it has been heat-treated at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of Pasteurization of this Ordinance or undergone an equivalent process found to be acceptable to FDA and the Regulatory Agency.

**CATEGORY II. USED FOR LIMITED PURPOSES**

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

1. Production of culinary steam.
2. Pre-rinsing of the product surfaces where pre-rinses will not be used in milk or milk products.
3. Cleaning solution make-up water.
4. Non-recirculated heat exchange media used against unpasteurized milk or milk products or acid whey provided it complies with Item 1. as cited below.
5. Non-recirculated heat exchange media used against pasteurized milk and milk products with the plate or double/triple tube type heat exchanger designed and operated in accordance with Item 15p.(B)10.

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

1. There is no carry-over of water from one (1) day to the next, and any water collected is used promptly; or
   a. The temperature of all water in the storage and distribution system is maintained either at $\leq 5^\circ C$ ($41^\circ F$) or below, or at $63^\circ C$ ($145^\circ F$) or higher by automatic means; or
   b. The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, or UV disinfection that complies with the criteria in Appendix D. of this Ordinance, prior to the water entering the storage tank; or
   c. The water shall comply with the Bacteriological Standards of Appendix G. of this Ordinance and, in addition, shall not exceed a total plate count of 500 per milliliter (500/mL). Samples shall be collected daily for two (2) weeks following initial approval of the installation and semi-annually thereafter. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. All physical, chemical and microbiological tests shall be conducted in accordance with the latest edition of SMEWW; and that,
2. Distribution lines and hose stations are clearly identified as “limited use reclaimed water”; and
3. Water handling practices and guidelines are clearly described and prominently displayed at appropriate locations within the milk plant; and
4. These water lines are not permanently connected to product vessels, without a break to the atmosphere and sufficient automatic controls, to prevent the inadvertent addition of this water to product streams.
pump and the slurry injection valve(s) described in 2 below.

1. All valves shall be inter-wired to assure they fully isolate the slurry pump from the pasteurization system when the FDD is not in the forward-flow position or whenever any flow-promoting device(s), which is (are) upstream of the FDD and (are) capable of generating flow through the FDD, is (are) not in operation.

2. The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, and are “block-and-bleed” design with a full port open to the atmosphere between the HTST isolation seat and the slurry pump when slurry is not being injected.

3. The slurry piping between the slurry pump and the injection point may rise to a height that is higher than the overflow level of the slurry supply tank(s) but is at least 30.5 centimeters (12 inches) lower than the required opening to the atmosphere on the pasteurized side.

4. The slurry supply tank has an overflow that is at least twice the diameter of the largest inlet pipe, or all inlet pipes are disconnected and the openings capped during operation of the slurry pump.

5. There is a check-valve in the flow stream of the milk or milk product line from the last regenerator, typically after the separator, upstream of the injection point valve.

6. For a milk or milk product flavoring slurry that contains milk and/or milk products the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of \( 7^\circ C \) \( 5^\circ C \) (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat until the time of injection.

7. If computers or programmable controllers are used to provide any of these required functions, they shall meet the applicable portion of Appendix H., VI. of this Ordinance.

8. Appropriate test procedures shall be provided to evaluate the required inter-wiring and function.

**NOTE:**

1. This Section describes one (1) method that has been reviewed and accepted for this purpose. It does not preclude other methods that may be reviewed and found acceptable.

2. In order to help assure compliance with Section 2, Adulteration of this Ordinance, a Regulatory Agency may require that the milk plant close the slurry valve and de-energize the slurry pump during times when the system is recycling milk or milk product, such as in recycle mode, diverted-flow, or the first ten (10) minutes of the CIP cycle. If a computer is used to accomplish this, it does not need to meet Appendix H., VI. of this Ordinance.

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

The pressures in the pasteurized side of the regenerator shall be protected from falling within 6.9 kPa (1 psi) of the pressures in the raw side of the regenerator at all times, including during shut down. A pressure relief valve on the pasteurized side of the FDD will meet this criterion if the pressure relief valve is fail-safe, A leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator during a shut down and is considered a violation of Item 16p(C) of this Ordinance. Any leakage from this pressure relief valve shall be readily visible. This may be accomplished by opening the pressure relief valve vent directly to
contamination. Separation shall be provided between milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale. Each dairy producer shall keep a copy of the AMI manufacturer’s testing verification procedures for the fail-safe valve systems on file at the dairy farm. AMIs, which have a wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving arrangement that provides for an air break equal to the diameter of the wash line.

ITEM 18r. RAW MILK COOLING

For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7°C (45°F). The milk in the farm bulk milk tank/silo shall not exceed 7°C 5°C (45°F) (41°F) after that time. Farm bulk milk tank/silo recording thermometers are recommended if not already required by this Ordinance.
important in determining if the item is a TCS milk or milk product. Appropriate evidence acceptable to FDA; such as other published scientific research and/ or an inoculation study should be used to determine whether a food can be held without time/temperature control when:

1. Combination products are prepared; or
2. Other extrinsic factors (packaging/atmospheres) or intrinsic factors (redox potential, salt content, antimicrobials, etc.) found in the food are used to control or eliminate pathogen growth.

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

1. Is the intent to hold the milk or milk product without using time or temperature control? If the answer is “No”, no further action is required. The decision tree is not needed to determine if the item is a TCS milk or milk product.
2. Is the milk or milk product raw or heat-treated, or is the milk or milk product pasteurized?
3. Does the Grade “A” PMO already require TCS for the milk or milk product?
4. Does a product history with good scientific rationale exist indicating a safe history of use?
5. Is the milk and/or milk product processed and packaged so that it does not require TCS; such as, aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products?
6. What is the \( a_w \) and pH of the milk or milk product in question using laboratory results accepted by FDA.

A milk or milk product designated PA (further product assessment required) in either Table A or B should be considered TCS until sufficient information is provided to demonstrate the safety of the product. The PA shall be an evaluation of the milk or milk product group’s ability to not support pathogenic growth. Means to evaluate this assessment include (but are not limited to): literature review of similar milk products, inoculation studies, expert risk assessment, and/or Regulatory Agency assessment.

A milk or milk product designated PA (further product assessment required) in either Table A or B should be considered TCS until sufficient information is provided to demonstrate the safety of the product. The PA will be an evaluation of the product or product group’s ability to not support pathogenic growth. Means to evaluate this assessment include (but are not limited to): literature review of similar products, inoculation studies, expert risk assessment, and/or state regulatory assessment.

**INSTRUCTION FOR USING TABLES A AND B**

1. Does the operator want to hold the milk or milk product without using time or temperature control?
   a. No: Continue holding the milk or milk product at \( 7^\circ C, 5^\circ C (45^\circ F, 41^\circ F) \) or less as required in the Grade “A” PMO.
   b. Yes: Continue using the decision tree to identify which table to use to determine whether TCS is required.
A. Summary of Proposal

Lower the PMO somatic cell count requirement for bovine milk from 750,000/mL to 400,000/mL.

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

Lowering the somatic cell count (SCC) requirement to 400,000/mL will result in improved human health by improving raw milk quality. And, since SCC is a direct indicator of dairy cow health, lowering the SCC requirement will have a positive impact on dairy cow health.

According to the USDA Economic Research Service, "Since the mid-2000s, the value of U.S. dairy product commercial exports has grown tremendously.” Much of this product is exported to the European Union (EU) and other countries that have adopted the EU standard for maximum SCC of 400,000/mL. U.S. exporters are therefore required to certify that all milk utilized in the exported products meets the 400,000/mL standard, placing a significant and unnecessary regulatory burden on those companies.

Lowering the PMO somatic cell count standard will improve raw milk quality, resulting in improved human and dairy cow health, reduced regulatory burden on exporters and increased exports of US dairy products.
C. Proposed Solution

Changes to be made on page(s): xvii, Section 7 p34-35, Appendix E p.212, Appendix P p.380 of the (X - one of the following):

<table>
<thead>
<tr>
<th></th>
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<th>2015 EML</th>
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<tbody>
<tr>
<td></td>
<td>2015 MMSR</td>
<td>2400 Forms</td>
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<tr>
<td></td>
<td>2015 Procedures</td>
<td>2015 Constitution and Bylaws</td>
</tr>
</tbody>
</table>

Make the following changes to the 2015 PMO:

2015 PMO

TABLES, PAGE xvii

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examination for Cattle (Effective January 1, 2018)

Table 13. Sieve Sizes and Designations

2015 PMO

SECTION 7-TABLE 1, PAGES 33-34

Somatic Cell Count*... Individual producer milk not to exceed 750,000 per mL, 400,000 per mL (effective January 1, 2018).

2015 PMO

APPENDIX E, PAGE 211

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations for Cattle (Effective January 1, 2018)

<table>
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<tr>
<th>Date</th>
<th>Confirmed Somatic Cell Counts per mL</th>
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NOTE: Authorize FDA editorial license to delete the Table cited above in future revisions of the PMO when they have reached their expiration date and the next lower SCC level has reached its effective date.

2015 PMO
APPENDIX P, PAGES 385-386

MINIMUM ONE (1) YEAR INSPECTION INTERVAL (ONE (1) INSPECTION EACH TWELVE (12) MONTHS):

All criteria below shall have been met for the previous twelve (12) months:

1. No more than one (1) sample with SPC >25,000, but less than 100,000;
2. All Somatic Cell Count (SCC) samples ≤ 400,000 (effective January 1, 2018)

NOTE: Farms in this category who are re-categorized to a six (6) month inspection interval for a single violation of one (1) milk quality parameter (SCC > 500,000 or cooling temperature violation) may be re-categorized to the one (1) year inspection interval if all ten (10) criteria listed above are met for the next six (6) months.

MINIMUM SIX (6) MONTH INSPECTION INTERVAL (ONE (1) INSPECTION EACH SIX (6) MONTHS):

All criteria below shall have been met for the previous twelve (12) months:

1. May have more than one (1) sample with SPC >25,000;
2. May have one (1) or more SCC sample > 400,000 (effective January 1, 2018)

Name: C. Peter Cole
Agency/Organization: Holstein Association USA, Inc.
Address: PO Box 808
City/State/Zip: Brattleboro
Telephone No.: (800)952-5200 x 4127 E-mail Address: pcole@holstein.com
A. Summary of Proposal

This Proposal clarifies within Item 5r-Milkhouse – Construction and Facilities of the PMO that shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided where milk is handled or stored; or where containers, utensils and/or equipment are washed and/or stored in a milkhouse on a dairy farm.

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

Light bulbs and other lights that are not shatter-resistant or otherwise protected against breakage have the potential to contaminate exposed milk and containers, utensils and/or equipment located in the milkhouse from the physical hazard of broken glass and/or other foreign materials. By requiring that light bulbs and other lights be shatter-resistant or otherwise protected against breakage where milk is handled or stored; or where containers, utensils and/or equipment are washed and/or stored in a milkhouse on a dairy farm this physical hazard should be adequately controlled to prevent this potential contamination from occurring. The proposed text is from 21 CFR 117 (Subpart B)-CGMP.
C. Proposed Solution

Changes to be made on page(s): 43 of the (X - one of the following):

- X 2015 PMO
- 2015 MMSR
- 2015 Procedures
- 2015 EML
- 2400 Forms
- 2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

ITEM 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES …

ADMINISTRATIVE PROCEDURES …

Page 43:

6. A minimum of twenty (20) foot-candles (220 lux) of light is provided at all working areas from natural and/or artificial light for milkhouse operations. Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass breakage shall be provided where milk is handled or stored; or where containers, utensils and/or equipment are washed and/or stored. …

Name: CAPT Robert F. Hennes
Agency/Organization: FDA/CFSAN
Address: 5001 Campus Drive
City/State/Zip: College Park, MD 20740
Telephone No.: (240) 402-2175  E-mail Address: Robert.Hennes@fda.hhs.gov
A. Summary of Proposal

To require Grade A dairy farms to have, maintain, and use approved indicating thermometers to confirm the minimum CIP return temperatures required for adequate cleaning in raw milk piping systems.

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

Adequate cleaning can only be achieved if there are adequate temperatures to provide proper cleaning. In particular, raw milk butterfat must be adequately liquefied to be removed from piping systems. This requires CIP return temperatures in excess of 120°F. Since there is now no requirement for observation or indication of on farm cleaning systems, improper cleaning can result in high bacteria counts in the raw milk, which can compromise an entire co-mingled load, raw silo tank, or processing plant’s entire production day.
C. Proposed Solution

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Modify the 2015 PMO page 43, ITEM 13. MILKHOUSE – CONSTRUCTION AND FACILITIES, ADMINISTRATIVE PROCEDURES

13. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils. (Refer to Appendix C.) Temperature of CIP cycles are to be verified with an approved return-temperature indicating thermometer.

Name:          Warren Taylor
Agency/Organization:  Snowville Creamery, LLC
Address:        32623 OH-143
City/State/Zip:  Pomeroy, Ohio 45769
Telephone No.:  740-698-2340   E-mail Address:  info@snowvillecreamery.com
### A. Summary of Proposal

To require seven day temperature-recording charts, for all Grade A dairy farms, to record the CIP cleaning return temperature.

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

Only when there is the combination of bulk tank temperature and CIP return temperature recording chart available for review by the licensed weigher-hauler, can adequate assurance of raw milk quality be confirmed.

Since dairy farm bulk tanks are required to have a chart recorder, it will be a relatively small and low cost improvement to add a second CIP return temperature recording function.
C. Proposed Solution

Changes to be made on page(s): 43 of the (X - one of the following):

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Modify the 2015 PMO page 43, ITEM 13. MILKHOUSE – CONSTRUCTION AND FACILITIES, ADMINISTRATIVE PROCEDURES

13. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils. (Refer to Appendix C.) Temperature of CIP cycles are to be verified with an approved return-temperature seven day temperature-recording chart.

Name: Warren Taylor

Agency/Organization: Snowville Creamery, LLC

Address: 32623 OH-143

City/State/Zip: Pomeroy, Ohio 45769

Telephone No.: 740-698-2340 E-mail Address: info@snowvillecreamery.com
### A. Summary of Proposal

Require testing for glyphosate residues in the feed and forage used as a feed ingredient for any portion of the total ration of the lactating dairy animal. Confirm: that feed and forage do not contain levels of glyphosate which result in glyphosate being secreted in the milk at any level, which may be deleterious to human health.

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

Increasing use of pesticides on dairy cattle feed and forage, including spraying for killing and desiccation of plants before harvest, are raising glyphosate levels in dairy cattle feed and forage, with resultant likelihood of higher glyphosate levels in the American milk supply. This proposal is to require new testing protocols to ensure that no measurable residue of those toxic chemicals are present in the milk supply.

The most commonly used pesticide in America, glyphosate, is nearly the only one not tested for residues in the human food supply. The dairy industry should not allow the integrity, purity, and safety of their products to be compromised by this lapse in cautionary testing of human foods.
C. Proposed Solution

Changes to be made on page(s): _______ 1 and 37 _______ of the (X - one of the following):

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A-3. Contaminated Milk: Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA), or from residual pesticides from animal feed.

Modify the 2015 PMO, page 37, STANDARDS FOR GRADE ‘A’ RAW MILK FOR PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, Item 1r. Abnormal Milk, Administrative Procedures.

7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:
a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and
b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances, which are secreted in the milk at any level, which may be deleterious to human health.
8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.
9. Feed and forage used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall be tested for glyphosate residues.
Name: Warren Taylor
Agency/Organization: Snowville Creamery, LLC
Address: 32623 OH-143
City/State/Zip: Pomeroy, Ohio 45769
Telephone No.: 740-698-2340  E-mail Address: info@snowvillecreamery.com
A. Summary of Proposal

To ensure bulk tank and DLO tanker hoses are sloped to drain, to or from the tanker attach point while filling.

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

The reason is that my state and IMS Inspector agree that hoses must be sloped to drain, not “drainable”. This change would be consistent with their interpretation and save them the ink from writing this as an infraction on every single inspection due to our “U” shaped hose or pipeline.
C. Proposed Solution

Changes to be made on page(s): 50 of the (X - one of the following):

- X 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms
- 2015 Procedures
- 2015 Constitution and Bylaws

Modify the 2015 PMO, page 50, Section __, __________, item 9r.

12. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, milk tank truck (direct load), when needed for functional purposes. Such hoses shall be drainable sloped to drain, be as short as practical, have sanitary fittings, and be permanently attached in such a manner that will assure a crevice.

Name: Chad Rucks
Agency/Organization: C & M Rucks Dairy, Inc.
Address: 22420 N.W. 144th Avenue
City/State/Zip: Okeechobee, FL 34972
Telephone No.: 863-610-1616 E-mail Address: chadrucks@hotmail.com
A. Summary of Proposal

To restrict the use of flexible plastic/rubber hoses during the filling process.

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

To reduce alternative interpretations that have arisen, coinciding with the interpretation from the southeastern division of the FDA and the State of Florida. This would also exclude the flexible hose from being used anywhere else within a system including but not limited to with dual receivers and plate coolers, also consistent with FDA interpretations. This would not apply to bulk tank transfer operations.
C. Proposed Solution

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Modify the 2015 PMO, page 50, Section __, __________, item 9r.

12. During filling, flexible plastic/rubber hoses may only be used between the fill valves of bottom fill and top fill bulk milk storage tanks only, when needed for functional purposes.

Name: Chad Rucks
Agency/Organization: C & M Rucks Dairy, Inc.
Address: 22420 N.W. 144th Avenue
City/State/Zip: Okeechobee, FL 34972
Telephone No.: 863-610-1616  E-mail Address: chadrucks@hotmail.com
A. Summary of Proposal

To clarify ambiguous language with respect to hand washing facilities proximity to the milkhouse, milking barn stable, parlor and flush toilet.

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

To allow for a more consistent implementation and enforcement of the PMO free from the subjectivity of the word “convenient” with respect to hand washing facilities. Alternatively, an agreed upon number other than 200 feet or 90 seconds would satisfy the intent of this proposal.
C. Proposed Solution

Changes to be made on page(s): 58 of the (X - one of the following):

X 2015 PMO 2015 EML

2015 MMSR 2400 Forms

2015 Procedures 2015 Constitution and Bylaws

Modify the 2015 PMO, page 58, Section __, __________, item 16r.

1. Handwashing facilities are located convenient to, and within 200 feet of and a maximum 90 second walk, to or from the milkhouse, milking barn stable, parlor and flush toilet.

Name: Chad Rucks

Agency/Organization: C & M Rucks Dairy, Inc.

Address: 22420 N.W. 144th Avenue

City/State/Zip: Okeechobee, FL 34972

Telephone No.: 863-610-1616 E-mail Address: chadrucks@hotmail.com
A. Summary of Proposal

To ensure milk pipelines and flexible hoses are sloped to drain at all times.

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

There is no clear language that milk hoses must be sloped to drain during milking and CIP position. This change is consistent with the interpretation of the State of Florida and IMS Inspectors.
C. Proposed Solution

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Modify the 2015 PMO, page 71, Section __, __________, item 10p.

All CIP cleaned milk pipelines and return-solution lines are rigid, self-draining and so supported to maintain uniform slope and alignment. Milk hoses larger than one inch diameter are sloped to drain. Return solution lines shall be constructed of material meeting the specifications of Item 2 above.

Name: Chad Rucks
Agency/Organization: C & M Rucks Dairy, Inc.
Address: 22420 N.W. 144th Avenue
City/State/Zip: Okeechobee, FL 34972
Telephone No.: 863-610-1616 E-mail Address: chadrucks@hotmail.com
A. Summary of Proposal

To require approved seven day temperature-recording charts for all Grade A dairy farm bulk tanks, removing the “grandfather clause” for the implementation of raw milk bulk tank temperature-recording charts.

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

Recorders have been required for new bulk tanks for 15 years. The time and temperature progression required for raw milk after milking is important and carefully described in the PMO. Compliance can only be verified with a recorder.

A milk processor incurs risk utilizing raw milk from multiple farms. Each day’s production is co-mingled, and often pasteurized, processed, and packaged through a Grade A facility before microbiological tests have been completed.

As America moves to strengthen food safety with the Food Safety Modernization Act, we believe that dairy farms need to practice stronger product quality assurance and sanitation standards. To ignore evolving technologies and “Good Manufacturing Practices” is such an unacceptable risk.
C. Proposed Solution

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Modify the 2015 PMO page 60, ITEM 1. RAW MILK COOLING

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). Proper cooling times and temperatures shall be confirmed, before milk collection by a licensed weigher-hauler, by checking the approved seven day temperature-recording chart.

Modify the 2015 PMO page 60, ITEM 3. RAW MILK COOLING

3. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved seven day temperature-recording chart.

Name: Warren Taylor

Agency/Organization: Snowville Creamery, LLC

Address: 32623 OH-143

City/State/Zip: Pomeroy, Ohio 45769

Telephone No.: 740-698-2340 E-mail Address: info@snowvillecreamery.com
A. Summary of Proposal

To clarify the ninety-six (96) hour deadline for a direct load tanker with respect to cleaning and sampling and the start time for sample usage on a direct load farm. This proposal would make these times consistent with those for a farm with bulk tanks.

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

The PMO requires equipment, including direct load tankers, to be properly cleaned and sanitized. Depending on how the time for first use and the time for collection are calculated and how long it takes to load the tanker, there can be strain on use of the tanker and/or availability of the sample for bacteria testing.

This proposal clarifies the start time and sample collection time for direct load tankers.
## C. Proposed Solution

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**Page 76:**
All milk tank trucks that transport Grade “A” milk and/or milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank shall be re-sanitized. First use shall be defined as when the first milk goes into the tanker.

**Page 141:**

### 3. Milk Quality Checks:

... 

c. Record milk temperature, collection time (optionally, in military time (24 hour clock)) Note: The collection time for a direct load farm shall be defined as when the tanker is picked up from the farm), date of pick-up and bulk milk hauler/sampler’s name and license or permit number on the farm weight ticket; monthly the hauler/sampler shall check the accuracy of the thermometer on each bulk tank and record results when used as a test thermometer. Accuracy of required recording thermometers shall be checked monthly against a standardized thermometer and recorded. Pocket thermometer shall be sanitized before use.

---

Name:  
NMPF NCIMS Committee

Agency/Organization:  
National Milk Producers Federation

Address:  
2107 Wilson Blvd, Suite 600

City/State/Zip:  
Arlington, VA  22201

Telephone No.: 703-243-6111  
E-mail Address: bbriczinski@nmpf.org
A. Summary of Proposal

Modify the requirement for state regulatory agencies to test the caustic strength in soaker-type bottle washers from a monthly to a quarterly frequency.

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

Item 12p. includes Table 2, entitled Combination of Causticity, Time and Temperature, of Equal Bactericidal Value, for the Soaker Tank of Soaker-Type Bottle Washers. The note found at the base of Table 2 requires state regulatory agencies to test the caustic strength of soaker type bottle washers on a monthly basis. Although this testing is very important, changing the requirement to each (3) months makes it compatible with the plant inspections and pasteurization equipment inspections that the regulatory agency must also perform. This testing frequency will be more achievable for state regulatory agencies while still requiring the causticity testing at the same (3) month frequency that the milk plant and associated pasteurization equipment require inspection.
C. Proposed Solution

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Modify the 2015 PMO, page 77, Item 12p., Table 2., NOTE.

**NOTE:** The NSDA, Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly **each (3) months** by the Regulatory Agency.

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<thead>
<tr>
<th>Name:</th>
<th>Paul M. Hoge</th>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Pennsylvania Department of Agriculture, Bureau of Food Safety and Laboratory Services</td>
</tr>
<tr>
<td>Address:</td>
<td>2301 North Cameron Street</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>Harrisburg, PA 17110-9408</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>717-329-8803</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:phoge@pa.gov">phoge@pa.gov</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

Remove the requirement to sanitize single service glass containers at dairy plant filling single service glass containers.

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

Currently Single Service Glass Containers are the only items manufactured at an IMS Listed Single Service Manufacturer that requires sanitizing at the dairy plant filling the container. All other single service packaging material used in the Grade A program may be used without sanitizing at the filling plant, even the lid going on these single service glass containers are not required to be sanitized.
C. Proposed Solution

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Section 7 Item 12p 8.

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

Re-Letter the remaining items.

<table>
<thead>
<tr>
<th>Name:</th>
<th>R. Lynn Young</th>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Milk Regulatory Consultants, LLC</td>
</tr>
<tr>
<td>Address:</td>
<td>56820 Highway A</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>Russellville</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>573-338-1785</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:rlynnyoung@cs.com">rlynnyoung@cs.com</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

ITEM 16p.(A) BATCH PASTEURIZATION, 3. g.

Add “plug” to the definition prior to ‘valve’

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

Revise to read:

  g. “Leak-Protector Valve” shall mean a properly constructed stainless steel plug valve provided with a leak-diverting device, which when the valve is in any closed position, shall prevent leakage of milk or milk product past the valve.

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

Other types of block/bleed valves have been suggested as meeting the PMO requirements. However, the only valves currently available that meet the requirements of this section are Leak-Detector Plug Valves fabricated with stainless steel plugs. The purpose of this revision is to ensure that no other type of valve are used as Leak-Detector Valves until they have been determined by the regulatory authority to satisfy the requirements of this section.
C. Proposed Solution

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g. “Leak-Protector Valve” shall mean a properly constructed stainless steel plug valve provided with a leak-diverting device, which when the valve is in any closed position, shall prevent leakage of milk or milk product past the valve.

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<thead>
<tr>
<th>Name:</th>
<th>Gabe Miller</th>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Process Innovation – Food Safety, LLC</td>
</tr>
<tr>
<td>Address:</td>
<td>N 1299 O’Connor Rd.</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>Lodi, WI 53555</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>608-332-3471</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Gabe.miller@pi-fs.com">Gabe.miller@pi-fs.com</a></td>
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</table>
A. Summary of Proposal

This proposal details criteria for allowing a double-seat mixproof valve with automated controls as a leak detection valve on vat pasteurizers.

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

There have been no significant changes made to the manually operated leak detect outlet valve of a vat pasteurizer for decades. The manual operation of these types of valves on large vertical vats often poses a safety risk for the operator. Manual operation and maintenance of these important valves are only as reliable as the operator. The plug style valve is prone to damage by galling, nicks and dents every time it is operated or removed for cleaning. The leak detection grooves may become compromised by the improper use of lubricants or product accumulation.

The allowance for automated double-seat mixproof valves for use on vat pasteurization equipment would give facilities new means to control product safety factors and improve the efficiencies of vat pasteurization. The automated leak detect valve may be controlled such that it will only open when all time and temperature parameters have been satisfied while concurrently the system would allow for accurate recording of time and temperature, including recording the operation of the leak detect valve. The mixproof valve design and operation would eliminate cold pockets of milk or milk products held in a traditional system with a plug style outlet valve which could allow unpasteurized product to leak and would be a significant public health concern. Valve automation on a vat pasteurization system could greatly reduce or eliminate operator error and/or reduce the potential for improperly pasteurized milk or adulterants to enter into the pasteurized supply.
C. Proposed Solution

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

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Modify the 2015 PMO, page 98, Item 16p(A) BATCH PASTEURIZATION, ADMINISTRATIVE PROCEDURES, Section 4. DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS

k. The use of an automated double-seat mixproof valve used as a leak detect valve shall comply with item 4. a, b, e, f, h, i above as well as the following requirements:

1. The valve shall be fail safe to the closed position.
2. The valve Leak Detect port must be self-draining.
3. The valve control system shall verify the valve is in the closed position prior to beginning time and temperature monitoring.
4. The valve control system shall ensure that the proper time and temperature for pasteurization has been met prior to opening the valve.
5. The valve control system shall record the valve’s opened and closed position to the temperature recorder.
6. The valve control system shall be sealed by the Regulatory Agency.
7. The valve control system shall comply with VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE “A” PUBLIC HEALTH CONTROLS
8. The valve shall be tested in accordance with Appendix I, Test 6 and other tests as specified by the FDA under the specific manufacturer’s accepted M-b

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A. Summary of Proposal

To make minor editorial changes and to remove confusing and/or unnecessary wording from various portions of the PMO.

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

Paragraphs 1 and 2 of the Administrative Procedures of ITEM 16p.(B) refer to instruments that are used in all continuous-flow pasteurizers, not just HTST systems. Limiting these paragraphs to HTST applications is incorrect and misleading.

The beginning of the second sentence in the PUBLIC HEALTH REASON paragraph of ITEM 16p.(C) is missing words and is confusing. Elimination of the first part of the sentence will not change the meaning or intent of the paragraph and will remove the confusion.

The title of section 1 of Appendix H refers to HTST Pasteurization, but some parts of this section are applicable to other types of pasteurizers besides HTST’s.

Paragraph 9 under Magnetic Flow Meter Based Timing Systems in Appendix H refers to the CIP time delay of the FDD. This has nothing to do with MFMBTS, and is more appropriate to the discussion of FDD’s in 16p.(B).
C. Proposed Solution

Changes to be made on page(s): 98, 105, 227, 234 of the (X - one of the following):

X  2015 PMO  2015 EML
______  2015 MMSR  2400 Forms
______  2015 Procedures  2015 Constitution and Bylaws

Page 98  Modify paragraph 1 and 2 of ITEM 16p.(B) as follows:

1. INDICATING THERMOMETERS AND RECORDER/CONTROLLER INSTRUMENTS
All indicating thermometers and recorder/controller instruments and devices used in connection with the HTST, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H. of this Ordinance.

2. AUTOMATIC MILK CONTROLLER
Each HTST, continuous-flow pasteurization system shall be equipped with an automatic milkflow control of the diversion type, which complies with the following definition, specifications and performance requirements:

Page 105  Modify the PUBLIC HEALTH REASON of ITEM 16p.(C) as follows:

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

Page 227  Modify the title of Section 1 of Appendix H as follows:

I. HTST PASTEURIZATION
9. When switching to the “CIP” position, the FDD shall move to the divert position and shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST pasteurization systems the booster pump cannot run during this ten (10) minute time delay. *(renumber as necessary)*
A. Summary of Proposal

Remove wording that limits the application of downstream FDD systems to pasteurizers producing UP milk and/or milk products.

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

The wording in paragraph (12) of ITEM 16p(B),2,b. limits the application of pasteurization systems with the FDD located downstream of the regenerator and/or cooler, while paragraph (2) of ITEM 16p(B),2,c defines the required control interlocks for these systems. The express purpose of paragraph 12 should only be to provide the allowance for “Steam-Block Type” FDD’s. The purpose of paragraph 2 is to restate the requirements of Thermal Logic Sequence Control that was defined in paragraph (7) of the FDD section above. The use of and control of a downstream FDD should be applicable to any HHST system, not just those operating in the UP time/temperature range.
C. Proposed Solution

Changes to be made on page(s): 100 and 101 of the (X - one of the following):

X 2015 PMO  2015 EML

2015 MMSR  2400 Forms

2015 Procedures  2015 Constitution and Bylaws

Modify paragraph (12) of ITEM 16p.(B),2,b. as follows:

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

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

(2) ………Provided, that for systems used for the processing of milk or milk products labeled as UP, it is not necessary to set and seal the thermal-limit controller at or above 138°C (280°F). Also, provided that these systems shall meet all the public health control requirements for HHST systems, and that the recorder-controller chart shows that the UP milk or milk product has been processed at a minimum temperature of 138°C (280°F), and has been verified by the Regulatory Agency to have a calculated holding time of at least two (2) seconds. The seal, if required, shall be applied by the Regulatory Agency after the equipment has been tested, and shall not be re- moved without immediately notifying the Regulatory Agency. ……….

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A. Summary of Proposal

Correct inaccurate language in ITEM 16p(B),2,c in which the description of the control for flow promoting devices references flow through the “holder” instead of the “FDD”.

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

Wording in paragraph paragraph (3) of ITEM 16p(B),2,c describes the interwiring requirements for manual switches of flow promoting devices in the case of low pasteurization temperature or a FDD that is out of position. The paragraph references devices which produce flow through the holder, when the real concern should be limiting flow through the FDD. In the case of an HHST system with the FDD located downstream of the regenerator and/or cooler, the present wording would allow flow promoting devices located after the holding tube to continue to run with the FDD out of position.
C. Proposed Solution

Changes to be made on page(s): 101 of the (X - one of the following):

X 2015 PMO  2015 EML

2015 MMSR  2400 Forms

2015 Procedures  2015 Constitution and Bylaws

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

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

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A. Summary of Proposal

This Proposal eliminates language in three (3) NOTEs in Appendix I-Pasteurization Equipment and Controls – Tests of the PMO, which allow for an HHST indicating temperature sensing element (indicating thermometer) to be located at the beginning of a holding tube if the entire length of the holding tube is insulated. This allowance does not appear anywhere else in the PMO. It also makes a correction to the text in the three (3) NOTEs related to the slope of the holding tube to be consistent with the text in Item 16p(B)-High-Temperature-Short-Time (HTST) Continuous-Flow Pasteurization of the PMO related to holding tube slope and makes an editorial adjustment to Item 16p(B).

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

In “Product” mode, the flow-diversion device (FDD) in a continuous flow pasteurization system shall not move to the forward flow position until every particle of milk or milk product in the holding tube has been held at or above the required legal pasteurization temperature. This critical pasteurization temperature is measured and recorded by the recorder/controller. The sensor for the recorder/controller is required to be located at the downstream end of the holding tube. Item 16p(B)2.e.-Indicating and Recording Thermometers (1) of the PMO states: “An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk or milk product between the two thermometers does not differ significantly in temperature.” In order to meet this requirement, the indicating thermometer sensing element shall also be located at the downstream end of the holding tube.
The older note in the Appendix I testing procedures of the PMO mentioning an alternate location for the indicating temperature sensing element within an HHST at the beginning of an insulated holding tube is inconsistent with this required indicating thermometer location as cited above within Item 16p(B) of the PMO.

The elimination of this alternate location for the indicating temperature sensing element within an HHST pasteurization system will not affect the acceptance of insulated holding tubes which have both the indicating and recording temperature sensing elements located at the downstream end of the holding tube.

### Changes to be made on page(s): 101, 323, 325 and 328 of the (X - one of the following):

- X 2015 PMO
- 2015 MMSR
- 2015 Procedures
- 2015 Constitution and Bylaws

**MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:**

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

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

2. **AUTOMATIC MILK CONTROLLER …**

Page 101:

d. **Holding Tube …**

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

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

**II. TESTING PROCEDURES …**

11.3 **CALCULATED PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING INDIRECT HEATING …**
5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water—…

### 11.4 CALCULATED PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING DIRECT HEATING …

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

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water—…

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

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

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water—…
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A. Summary of Proposal

The requirement for measuring the HHST holding tube length and for the calculation of the holding time based on that length is outlined in the 2015 PMO Appendix 1. The formula provided in section 11.4 is based on direct heating and includes a thermal/volume expansion factor of 12% (page 326). If this formula is utilized in the design of the holding tube and the legal flow transmitter is located UPSTREAM the direct heating, this formula allows the flow transmitter to have a 12% correction factor in to measure accurately the product/steam/condensate that is passing through the flow transmitter at that point. However, if the flow transmitter is located DOWNSTREAM the direct heating, as in the case of a steam infusion system, the flow transmitter does not need to be corrected by 12% because it is measuring the actual product/steam/condensate volume represented in the formula.

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

The double application of the 12% expansion factor in steam infusion systems requires additional holding tube length and longer holding times. For processors, this negatively impacts operations due to several factors including: higher energy use; greater potential for soils to be deposited; shortened runs between cleanings due to soils; higher chemical usage to remove soils; negative flavor consequences in dairy products – especially white milks.
C. Proposed Solution

Changes to be made on page(s): 102 and 326 of the (X - one of the following):

- X 2015 PMO
- 2015 MMSR
- 2015 Procedures
- 2015 EML
- 2400 Forms
- 2015 Constitution and Bylaws

PAGE 102
(8) With the direct steam heating processes, the holding time is reduced because the milk or milk product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized milk or milk product is cooled in the vacuum chamber. For example, with a 66ºC (120ºF) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) will occur in the holding tube. The measurement of the average flow rate, at the discharge of the pasteurizer, does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, shall be considered in the calculations. If the measurement of the average flow rate occurs after the direct heating process (as in the case of steam infusion), the volume increase, i.e., holding time decrease is not to be considered in the calculations.

PAGE 326
Alternate Procedures for the Determination of the Holding Tube Length for Non-Standard Pipe Size: The holding tube length may also be accurately calculated from the following equation:

\[ L = \frac{588 \text{ Qt} \times 1.12}{D^2} \]

Where:

- \( L \) = Holding tube length (inches)
- \( Q \) = Pumping rate (gallons per second) measured upstream the direct heating process
- \( t \) = Pasteurization holding time standard (seconds)
- 1.12 = 12% expansion for steam
- \( D \) = Internal diameter of the holding tube (inches)

PROPOSAL TO ADD -
NOTE: If in the design of the HHST, the direct heating occurs upstream (ahead of) the legal flow transmitting device, the measured flow therefore contains the steam and condensate and the 12% expansion factor may be removed from the Holding Tube Length formula.

NOTE: Table 15 provides the internal pipe diameters for piping in a HHST pasteurization system’s holding tube with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches. Internal diameters, for pasteurization system’s holding tubes designed for high pressure and for holding tubes with external piping sizes not listed in Table 15, shall be individually determined and the minimum holding tube length calculated using the above formula.
<table>
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<tr>
<th>Name:</th>
<th>Steve Smith</th>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Fairlife LLC</td>
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<tr>
<td>Address:</td>
<td>999 W Randall Street</td>
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<tr>
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<tr>
<td>E-mail Address:</td>
<td><a href="mailto:steves@fairlife.com">steves@fairlife.com</a></td>
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A. Summary of Proposal

Remove redundant, unnecessary and possibly confusing language from the description of FDD operation related to regenerators. Paragraph 12 of ITEM 16p.(C) should be eliminated.

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

Paragraph 5 of ITEM 16p.(C) discusses the controls and interlocks required on a booster pump to maintain proper differential pressures, including the need for the timing pump to be in operation.

5. No pump shall be located between the raw milk or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk or milk product is flowing through the pasteurized milk or milk product side of the regenerator and when the pressure of the pasteurized milk or milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:
a. The timing pump is in operation;
Paragraph 10, however, specifies that paragraph 5 may be eliminated in the case of pasteurization systems with the FDD located downstream.

10. In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, the requirements of paragraphs (2), (3), (5), (7) and (8) of this Section may be eliminated.

Paragraph 12 is simply an attempt to restate this elimination of paragraph 5. It is not needed, and because it is stated in isolation, it has been, at times, taken to apply to all booster pump applications.

C. Proposed Solution

Changes to be made on page(s): 105-106 of the (X - one of the following):

- [x] 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms
- 2015 Procedures
- 2015 Constitution and Bylaws

Eliminate paragraph 12 of ITEM 16p.(C) in its entirety.

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

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A. Summary of Proposal

To remove confusing and inaccurate wording from paragraph 8 of ITEM 16p.(C).

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

This paragraph describes the requirement that the raw side of regenerators be free draining when a pasteurization system is shut down. However, the final wording which indicates that the raw milk product connections at the regenerator are to be disconnected to accomplish this draining are not correct. It shouldn’t be necessary to disconnect piping for the regenerator to drain, and if it is actually a requirement for the piping to be disconnected, there is no need for a low overflow level on the constant level tank.
C. Proposed Solution

Changes to be made on page(s): 106 of the (X - one of the following):

X 2015 PMO 2015 EML
_____ 2015 MMSR 2400 Forms
_____ 2015 Procedures 2015 Constitution and Bylaws

Modify paragraph 8 of ITEM 16p.(C) as follows:

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

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A. Summary of Proposal

Update the reference for a “flow control valve” in Appendix D and Appendix H for controlling performance in UV light systems used to treat water and add a “flow control system”.

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

There are various ways to ensure proper treatment of water using Ultra-Violet light technologies. The PMO uses a performance/criteria approach and does not require systems to be third party validated. In compliance with the current criteria and technology, PMO compliant UV systems ensure system performance and the correct dose based on current real time data from lamp, flow and water quality information.

Since the dose is a function of real time data rather than flow restriction or manufacturer design parameters, the section has been updated to clarify focus on criteria that sure the water is adequately treated with the proper dosage of UV light.

Automatic software control system based on the flow data is the most reliable way to achieve this.

This is very similar to advances in magnetic flow control system used on pasteurizers. The first acceptable systems could only use a constant speed centrifugal timing pump with a control valve or A-C variable frequency motor speed control, today the PMO does not reference a specific pump as the timing pump but rather looks at all flow promoters and the meter as a timing system.
## C. Proposed Solution

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2015 PMO Appendix D page 183:

6. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that the entire volume of water receives the minimum dose required above.

2015 PMO Appendix D page 184

5. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that the entire volume of water receives the minimum dose required above.

2015 PMO Appendix H page 282-283

4. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that all particles receive the minimum dose listed above.

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**E-mail Address:** phyllisp@atlantium.com
A. Summary of Proposal

Allow for the use of UV light treatment, meeting Appendix H criteria, of water reclaimed from raw milk membranes to allow the reclaimed water to be used as Category I water.

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

This will allow alternative treatment of the water in a more cost effective manner than heat pasteurization.

Appendix H criteria for the use of UV light treatment uses USEPA Ultraviolet Disinfection Guidance Manual (November 2006). This manual points out the maximum turbidity for surface water is 5 units (page 3-20) the same as the PMO standards for reclaimed water. Through the use of appropriately designed (on line UVT sensors as required in PMO Appendix H) UV light treatment systems can overcome 10 units of turbidity.
C. Proposed Solution

Changes to be made on page(s): 186 of the (X - one of the following):

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<td>2015 Procedures</td>
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</table>

PMO Appendix D page 186:

NOTE: Water reclaimed from raw milk membrane processes shall not be used for Category I purposes unless it has been heat-treated at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of Pasteurization of this Ordinance or been treated with UV light in a system meeting all criteria found in Appendix H IX. Disinfection of Water of this Ordinance or undergone an equivalent process found to be acceptable to FDA and the Regulatory Agency.

<table>
<thead>
<tr>
<th>Name:</th>
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<tbody>
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</tr>
</tbody>
</table>
A. Summary of Proposal

To remove an unnecessary restriction on the location of flow promoting devices in systems using meter based timing systems.

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

Paragraph 11 in the description of Magnetic Flow Meter Based Timing Systems in Appendix H describes the placement of components within a MFMBTS. Item 1. of that description states that the timing system’s flow promoting devices(s) shall be located upstream from the magnetic flow meter. However, as long as item 2. of that description specifies that there can be no flow promoting components between the flow meter and the holding tube, it doesn’t matter where else the flow promoting devices are located. Whatever flow rate the flow meter sees will be what the holding tube sees. There is no need for the restriction stated in item 1.
C. Proposed Solution

Changes to be made on page(s): 234 of the (X - one of the following):

- X 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms
- 2015 Procedures
- 2015 Constitution and Bylaws

Modify paragraph 11 of the MFMBTS description in Appendix H as follows:

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

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

1. The timing system’s flow promoting device(s) shall be located upstream from the magnetic flow meter.
2. The magnetic flow meter shall be placed after the last raw product regenerator outlet and upstream of the holding tube. There shall be no intervening flow-promoting components between the magnetic flow meter and the holding tube.

*(Editorial note: Renumbered items 2-7 of paragraph 11. should be indented alpha tagged paragraphs (a. – e.))*

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A. Summary of Proposal

Air under pressure in contact with raw milk in ‘Dairy Farm – Construction and Operation – Milking Barn, Stable, or Parlor’ to be referenced with an appropriate air quality engineering value for the milk producing farm industry to specify commercial air filtration requirement.

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

On-farm raw milk interpretation and application of Appendix H reference is inconsistent. Concerns are:

- Micron rating comes under question
- Terminology: ‘Point of use filter’ vs. ‘final filter’ vs. Appendix C ‘terminal filter’ interpretations
- Which filters, and where located for removal of oil, dust, rust, moisture, etc.
- Distance between effective filter(s) and point of use in milk transport systems
- Purpose of ‘point of use’ filter media – effective filtration? Vs. filtration efficacy indication?

Requirements of air under pressure per the applications of ‘Pasteurization Equipment and Procedures and Other Equipment’ per Appendix H vs. ‘Dairy Farm Construction Standards and Milk Production’ per Appendix C, and 14r. of the ordinance, are not equivalent in outcome with regard to public health risk. Air compression systems as installed in Grade A Milking Barns, Stables, or Parlors have commercial water, oil and particulate removal equipment as necessary for operation of non-lubricated valves and equipment. These systems are typically installed in accordance with Appendix H schematics.

Furthermore, in milking installations, the amount of pressurized air directed against milk to
clear a milk transport pipe is a small fraction of the amount of air incorporated into milk flow
via air admission methods, necessary to move milk away from the teats and into milk
conducting pipelines. This air admission is typically drawn from directly below the cow and is
entirely unprotected.

Appendix H cites the following reference: Method of Testing Air Cleaning Devices, ASHRAE
Standard 52, in which the minimum filtration efficiency reporting value of MERV 12 achieves
all of the following:
MERV 9 – 12: 1.0 to 3.0 microns, effective for:
   Legionella, lead dust, milled flour, coal dust, auto emissions, nebulizer drops, welding
   fumes (equivalent with superior residential and commercial buildings, and hospital
   laboratories)
MERV 5 – 8: 3.0 to 10 microns, effective for:
   Mold, spores, hair spray, cement dust, powdered milk (equivalent with commercial
   buildings, better residential, industrial workplace, and paint booth inlets)
MERV 1 – 4: Larger than 10.0 microns, effective for:
   Pollen, Spanish moss, dust mites, sanding dust, paint spray, dust, textile fibers, carpet
   fibers (equivalent with residential filtration, window air conditioners)

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Make Changes to:
The 2015 Pasteurized Milk Ordinance – APPEDIX H. Pasteurization Equipment And
Procedures And Other Equipment, SECTION II. Air For Drying Equipment And Air Under
Pressure – Direct Contact With Milk And Milk Products and Milk Product-Contact Surfaces,
pages 243-246

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

AIR FOR DRYING EQUIPMENT

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

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

**AIR UNDER PRESSURE – MILK PRODUCT-CONTACT SURFACES**

**Filter Media:** Air intake and pipeline filters shall consist of fiberglass with a downstream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, spun metal, electrostatic material or other equally acceptable filtering media, which are non-shedding and which do not release to the air, toxic volatiles or volatiles which may impart any flavor or odor to the milk or milk product.

**Filter Performance:** Intake air filter efficiency shall be at least 98% SAE J726², June 1987³ using Air Cleaner (AC) coarse test dust. Final filter efficiency shall be at least 99% as measured by the Diocetylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns).⁴ When commercially sterile air is required, the final filter efficiency shall be at least 99.999% as measured by the DOP test. When used in Milking Barn, Stable, or Parlor Construction and Operation per Appendix C, and 14r. of this ordinance, the final filter efficiency shall be at least MERV 12.¹

**FABRICATION AND INSTALLATION**

**Air Supply Equipment:** The compressing equipment shall be designed to preclude contamination of the air with lubricant vapors and fumes. Oil-free air may be produced by one (1) of the following methods or their equivalent:

a. Use of a carbon ring piston compressor;

b. Use of oil-lubricated compressor with effective provision for removal of any oil vapor by cooling the compressed air; or

c. Water-lubricated or non-lubricated blowers.

The air supply shall be taken from a clean space or from relatively clean outer air and shall pass through a filter upstream from the compressing equipment. This filter shall be located and constructed so that it is easily accessible for examination and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage, water, product spillage and physical damage.

---

¹ The method of making these tests will be found in the following reference: Method of Testing Air Cleaning Devices, ASHRAE Standard 52. Available from The American Society of Heating, Refrigerating and Air-Conditioning Engineers.


Moisture Removal Equipment: Air under pressure systems in excess of one (1) bar, i.e., 103.5 kPa (15psi), shall be provided with methods of moisture removal. The removal of moisture may be achieved by condensation and coalescing filtration or absorption, or equivalent, to prevent free water in the system. If it is necessary to cool the compressed air, an after-cooler shall be installed between the compressor and the air storage tank for the purpose of removing moisture from the compressed air.

Filters and Moisture Traps: Filters shall be constructed so as to assure effective passage of air through the filter media only. The coalescing filter and associated traps shall be located in the air pipeline downstream from the compressing equipment, and from the air tank, if one is used. The filter shall be readily accessible for examination, cleaning, and for replacing the filter media. The moisture trap shall be equipped with a petcock or other means for draining accumulated water. (Refer to Figures 44, 45 and 48.)

When coalescing filters are used, a means shall be provided to measure the differential pressure across the filter. The differential pressure device is required to indicate the need for filter media replacement. All coalescing filter housings shall be provided with a means of removing the condensed liquid from the filtration device. This can be accomplished by an automatic or manual drain installed on the base of the filter housing.

The final filter media shall be disposable. The filter media shall be located in the air line upstream from, and as close as possible practical to, the point of application. (Refer to Figures 44, 45 and 48.) Except that a final filter shall not be required where the compressing equipment is of a fan or blower type and operating at a pressure of less than one (1) bar, i.e., 103.5 kPa (15psi). (Refer to Figures 46 and 47.)

Electronic air cleaners utilizing electrostatic precipitation principles to collect particulate matter may be used.

Disposable filter media shall not be cleaned and reused.

Air Piping: The air piping from the compressing equipment to the filter and moisture trap shall be readily drainable.

A milk or milk product check-valve of sanitary design shall be installed in the air piping, downstream from the disposable media filter, to prevent backflow of milk or milk product into the air pipeline, except that a check-valve shall not be required if the air piping enters the milk or milk product zone from a point higher than the milk or milk product overflow level, which is open to the atmosphere, or is for dry product applications, or for other dry application where liquids are not present.

When a check-valve is not required, plastic or rubber or rubber-like tubing and suitable compatible fittings and connections made of plastic or stainless steel may be used between the final filter and the point of application.

Air distribution piping and fittings after the final filter shall be of corrosion-resistant materials. Air distribution piping, fittings and gaskets between the discharge of the sanitary check-valve to the processing equipment shall be sanitary piping that conforms to the requirements of Item 10p, Section 7. of this Ordinance, except that:

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 48.)

When used for air agitation, tubing used to introduce air into the product and/or product zone shall be sanitary piping that conforms to the requirements of Item 10p, Section 7. of this Ordinance. There shall be no threads on product-contact surfaces. When drilled or perforated pipe is used, internal drilling burrs shall be removed and the orifices shall be chamfered on the outer surface of the pipe. If the volume of the air from the compressing equipment is in excess of that required for satisfactory agitation, suitable means shall be employed to eliminate the excess volume.
NOTE: For additional details, refer to the 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product-Contact Surfaces 604-## and 3-A Accepted Practices for Spray Drying Systems 607-##.

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<th>Name:</th>
<th>William Bernhard</th>
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A. Summary of Proposal

To allow a centralized filtered air manifold system that distributes air under pressure to multiple locations where this centralized air manifold system is cleaned in place.

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

It is common for manufacturers to use a single use, disposable disk filter for air under pressure that is used to push raw milk from silo transfer lines to the balance tank of a pasteurizer. We want to clarify that a system that uses a centralized filtered air manifold system that distributes air under pressure to multiple locations and where this centralized air manifold system is cleaned in place is acceptable.
C. Proposed Solution

Changes to be made on page(s): 245 and 248 of the (X - one of the following):

- X 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms
- 2015 Procedures
- 2015 Constitution and Bylaws

Modify the 2015 PMO, page 245, 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, Fabrication and Installation

**Filters and Moisture Traps:** Filters shall be constructed so as to assure effective passage of air through the filter media only. The coalescing filter and associated traps shall be located in the air pipeline downstream from the compressing equipment, and from the air tank, if one is used. The filter shall be readily accessible for examination, cleaning, and for replacing the filter media. The moisture trap shall be equipped with a petcock or other means for draining accumulated water. (Refer to Figures 44, 45 and 48.)

When coalescing filters are used, a means shall be provided to measure the differential pressure across the filter. The differential pressure device is required to indicate the need for filter media replacement.

All coalescing filter housings shall be provided with a means of removing the condensed liquid from the filtration device. This can be accomplished by an automatic or manual drain installed on the base of the filter housing.

The final filter media shall be disposable. The filter media shall be located in the air line upstream from, and as close as possible to, the point of application. (Refer to Figures 44, 45 and 48.) In the case of a cleaned in place (CIP) centralized air manifold distribution system that is constructed in a sanitary manner, the final filter media may be located just prior to a product check valve of sanitary design at the entrance to the air manifold distribution system. (Refer to Figure 45a.) Except that a final filter shall not be required where the compressing equipment is of a fan or blower type and operating at a pressure of less than one (1) bar, i.e., 103.5 kPa (15psi). (Refer to Figures 46 and 47.)

Electronic air cleaners utilizing electrostatic precipitation principles to collect particulate matter may be used.

Disposable filter media shall not be cleaned and reused.
Modify the 2015 PMO, page 248, 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, Fabrication and Installation

Figure 45a

1. Compressing Equipment
2. Intake Air Filter
3. After-cooler
4. Sanitary Relief Valve
5. Air Pipe Line Coalescing Filter and Moisture Trap
6. Pressure Gauge (Optional)
7. Dryer
8. Sanitary Piping Downstream From This Point
9. Product Check-Valve (Where Required)
10. Final Filter
11. To Point of Application
12. Drain Valve
13. Moisture Leg or Trap
14. Air Storage Tank
15. Air Gap
16. Trap and Drain Valve
17. Condensate Pipe
18. CIP Supply
19. Double Block and Bleed Valves

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A. Summary of Proposal

This Proposal provides a technology update to the PMO. Control of the public health controls for continuous flow pasteurization systems using programmable logic controller (PLC) has been allowed for nearly twenty years, and to date requires all signals to be hardwired to prevent connection to the programming. However, technology has progressed, and there are compelling reasons to allow other connectivity to this FDD PLC. However, guidance is needed for the people building these systems so milk plant staff still cannot access program settings such as temperature and flow set points, or CIP and other timers. Also, Regulatory Agency personnel, Milk Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) need criteria to evaluate that the systems preserve the intention of the PMO to protect the public.

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

Technology has improved, and many devices that create signals for HTST and HHST pasteurization systems are being offered as Ethernet or serial connectivity as the primary method of transmission. Several states have allowed devices such as small operator interfaces to replace the hardwired switches, or flow meters transmitting a digit signal instead of the traditional analog signal. These devices are communicating directly with the communication port.

While these are currently being allowed on a case-by-case basis, there currently is not any guidance that exists for the regulatory personnel, SROs or RMSs to evaluate that this communication doesn’t allow other access, or that the operator interface only allows the proper signal interface.
This Proposal adds language to the PMO to provide guidance for this new technology.

C. Proposed Solution

Changes to be made on page(s): 267 - 269 of the (X - one of the following):

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MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES FOR OTHER EQUIPMENT …

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

Page 267:

GLOSSARY

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

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

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

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

Page 268:

CRITERIA …

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

a. Any other non-public health computer or Human Machine Interface human machine interface may request a function of a device (valve, pump, etc.) within the HTST or HHST pasteurization system through a hard-wired input; however, this request would be granted or denied by the logic in the public health computer depending on the current status of the public health computer program and the Ordinance’s public health (Ordinance)
requirements.
b. The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems.
c. Digital outputs from another other computer systems may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer.
d. The wiring connections shall be provided with isolation protection such as relays, diodes, or optical-coupling devices to prevent the public health outputs from being driven by the other non-public health computer systems.

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

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

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A. Summary of Proposal

Allow “Read-Only” hardware communication devices (such as ROpport™) in a sealed sterilization process PLC panel, connecting to the communications port of the PLC, such that the PLC RAM memory information can be accessed “Read-Only” from a port external to the sealed area. This allows the plant operator to access diagnostic and production information available in the PLC without allowing the modification of the legally certified program.

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

When troubleshooting legally sealed PLCs, operators are often faced with having to break the seal to complete a diagnosis of a system. This requires the PLC to be officially re-sealed, wasting time for all parties involved.

A read-only hardware communications device could pass data from PLC RAM to a communication port external to the sealed panel, and would be programmed with a white list of acceptable commands such as “View Running Program Online” and “Retrieve Program”. Any commands other than the approved list (that could alter the certified PLC program) would be denied in the hardware communications device, and an error code would be returned to the PLC’s software user interface.

Given the ability to view the live data in RAM, an operator could use that information to effectively troubleshoot, and could rule out issues with the PLC hardware. Having read-only
access to the PLC RAM data would also allow for production cycle information to be collected, aiding in an operator’s efforts to increase plant efficiency through statistical process control.

C. Proposed Solution

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9. The public health computer program access shall be sealed, except for certified Read-Only hardware communications devices.

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A. Summary of Proposal

This proposal adds alternative criteria for conducting Test 8 of Appendix I using electronic recording controller-devices that are paperless or use a self-printing chart.

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

The current thermometric response test procedure assumes that the temperature recorder-controller uses a preprinted paper chart with a pen drive. Recent PMO Appendix H section VI changes have added the ability to electronically record the operating temperatures for HTST systems leading to difficulties in conducting these test procedures. The current Appendix I Test 8 procedure measures the response time on a rapid rising temperature to the selected cut-in temperature of the system, thus requiring the tester to establish multiple temperature points in conducting this test. The new proposed procedure simplifies the test to verify the system’s rapid response to a temperature decline at each cut-out set point applicable to the HTST system. The intent of this proposal is to address the ability of the HTST system to instantly divert in response to a drop in temperature below the legal cut-out set point.
C. Proposed Solution

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TEST 8.
TEMPERATURE RECORDER-CONTROLLER
THERMOMETERS - THERMOMETRIC RESPONSE
Reference: Item 16p.(B) and (D)
Application: To all HTST continuous-flow pasteurization systems, except for those in which the FDD is located downstream of the pasteurized regenerator section(s) and/or the final cooler section.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever the temperature recorder-controller thermometer has been repaired and/or replaced; or whenever the regulatory seal has been broken.
Criteria 1: Five (5) seconds or less.
Criteria 2: Less than One (1) second.
Apparatus for temperature recorder-controller using Criteria 1:
1. Accurate time measuring device;
2. The indicating thermometer, which was previously tested against a known accurate test thermometer;
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the media bath.
Method: Measure the time interval between the instant when the temperature recorder-controller thermometer reads 7ºC (12ºF) below the cut-in temperature and the moment of cut-in by the temperature recorder-controller. This time interval measurement is made when the temperature recorder-controller sensing element is immersed in a rapidly agitated media bath maintained at 4ºC (7ºF) above the cut-in temperature.
Procedure:
1. Check and, if necessary, adjust the pen-arm setting of the temperature recorder-controller thermometer to read the same as the indicating thermometer at pasteurization temperature.
2. Allow the temperature recorder-controller sensing element to cool to room temperature.
3. Heat the media bath to 4ºC (7ºF) above the cut-in temperature, while continuously agitating the media bath to insure a uniform temperature.
4. Immerse the temperature recorder-controller sensing element in the media bath. Continue agitation during Procedures 5 and 6 below.
5. Start the accurate time measuring device when the temperature recorder-controller thermometer reaches a temperature of 7ºC (12ºF) below the cut-in temperature.
6. Stop the accurate time measuring device when the temperature recorder-controller cuts in.
7. Record the results of the Test on the appropriate Form.
8. Repeat Procedures 1 through 7 for each temperature cut-in set point.

Apparatus for Electronic Recording and Self-printing Chart Temperature Recorder-Controller
Thermometers: Using Criteria 2 Less than One (1) second.
1. Accurate time measuring device;
2. The indicating thermometer, which was previously tested against a known accurate test thermometer;
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the media bath.
Method: Measure the time interval between the removing of the temperature probe from the agitated media bath to the controller’s diversion output. Identify the Electronic Recorder-Controller cut-out set point output, this may include an output light on a PLC.
Procedure:
1. With the HTST system in forward flow, adjust the agitated heating media to less than 1 degree above selected cut-out temperature and stabilize heating media.
2. Start the accurate time measuring device when temperature probe is removed from heating media.
3. Stop the accurate time measuring device when the Electronic Temperature Recording Controller energizes the cut-out set point output.
4. If HTST has multiple cut-out set points repeat for each cut-out set point.

Action: If the response time exceeds five (5) seconds for Criteria 1 or one (1) second for Criteria 2, the temperature recorder-controller shall be repaired or replaced by milk plant personnel. If the temperature recorder-controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.(D); or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.(D).

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A. Summary of Proposal

Remove the requirement to label single service glass containers as “Single Service Use Only”

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

Currently no other single service container or closure is required to as “single service use only”. This can create some difficulties in utilizing the same container molds for producing containers for a US facility and for facilities located outside the US.

C. Proposed Solution

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Section 7 Item 12p Page 80 sub-item 8;
e. Single-service glass containers shall be labeled with wording to designate “single-service use only”.

Appendix J D. FABRICATION PLANT STANDARDS Page 345 Item 20;

b. Single-service glass containers shall be labeled with wording to designate “single-service use only”.

Re-letter the remain items under sub-item 20
A. Summary of Proposal

This Proposal updates Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO to align it with the Federal Register (FR) announcement on page 46578, issued July 18, 2016, that amended 21 CFR 172.380 to allow manufacturers to fortify milk with vitamin D₃ at a level not to exceed 84 international units (IU) per 100 g (800 IU (20 mcg)/quart) when named with a nutrient content claim for vitamin D₃ and a standardized term in accordance with 21 CFR 130.10. The minimum allowable limit for a fortified milk with vitamin D remains unchanged at 42 IU per 100 g (400 IU (10 mcg)/quart) as cited in 21 CFR 131.110(b)(2). This Proposal also changes the acceptable range for vitamins A and D in standardized milk and/or milk products from 100% - 150% to 100% - 120% of the labeled claim, but in no case may exceed 800 IU (20 mcg) vitamin D₃ per quart as the upper limit in accordance with 21 CFR 172.380.

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

On July 18, 2016, a final rule was published in the Federal Register (81 FR 46578) announcing that FDA has amended the food additive regulations to permit the use of vitamin D₃ as a nutrient supplement in milk at levels higher than those currently permitted in 21 CFR 172.380 and referenced in the Standard of Identity (SOI) for “milk” in 21 CFR 131.110(b)(2).

Under the law, FDA may approve the use of a food additive only after conducting a scientific safety review of information to ensure that the use of the substance is safe for the general population. In this case, the FDA evaluated the projected human dietary exposure to vitamin D from foods and dietary supplements, safety data, and other relevant information and found the higher fortification levels of vitamin D₃ for milk to be safe.
NOTE: Vitamin D without a subscript represents either vitamin D₂ or vitamin D₃ or both.

This approval, which amends existing 21 CFR 172.380, will allow manufacturers to fortify milk with vitamin D₃ at a level not to exceed 84 international units (IU) per 100 g (800 IU (20 mcg)/quart) so that it meets the requirements for foods named by the use of a nutrient content claim and a standardized term in accordance with 21 CFR 130.10. The minimum allowable limit for a fortified milk remains unchanged at 42 IU per 100 g (400 IU (10 mcg)/quart) as cited in 21 CFR 131.110(b)(2).

Manufacturers were permitted to begin using the new amount on July 18, 2016.

The new 800 IU (20 mcg)/quart level conflicts with the text contained in Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO that states “* 100% - 150% of label claims = 400 IU (10 mcg) – 600 IU (15 mcg) per quart for vitamin D and …”

FDA has been informed by industry that some manufacturers have updated their labels for foods in the marketplace in order to comply with new regulations for nutrition facts information already. The Institute of Medicine (IOM) of the National Academies updated the recommended amount of vitamin D to be consumed from 400 IU (10 mcg) to 800 IU (20 mcg) per day for adults and children greater than or equal to 4 years of age. This will be reflected in updated % Daily Values (% DV) on labels to comply with the revision of the nutrition and supplement facts label final rule published in May, 2016. As a result of the amended food additive regulation some milk processor may voluntarily choose to increase vitamin D₃ fortification of milk to this higher level.

The approval for permitting 800 IU (20 mcg)/quart milk of vitamin D₃ in fluid milk was based on safety information provided by the petitioner. Our exposure estimates demonstrated that, for all U.S. populations, cumulative exposure to vitamin D from all sources, which included fortification of fluid milk at the proposed level, did not exceed the Institute of Medicine (IOM) Tolerable Upper Intake Level (UL) for vitamin D. (Note that the IOM increased the ULs in 2010.)

The addition of 21 CFR 172.380(c)(8) establishes a maximum level for vitamin D₃ not to exceed 84 IU/100 g in milk that contains more than 42 IU vitamin D per 100 g (400 IU (10 mcg)/quart. In addition, the product and labeling must meet the requirement for foods named with a nutrient content claim for vitamin D₃ and a standardized term in accordance with 21 CFR 130.10.

The existing general range for vitamins of 100-150% of labeled claim as cited in Appendix O is excessive based on stability data provided by the petitioner that supported the amendment of 21 CFR 172.380. The proposed range of 100-120% of the label declaration is in line with NLEA compliance targets and accurate label declaration of added nutrients. CFSAN’s Office of Food Additive Safety (OFAS) and Office of Nutrition and Food Labeling (ONFL) accept overages up to 20% of the targeted fortification for vitamin A and D.

The following information was utilized by FDA to determine a level of vitamin D in milk above which should be referred to FDA for a health hazard review. This level was determined
by using dietary intake data for milk from the 2009-2012 National Health and Nutrition Examination Survey (NHANES) and the tolerable upper intake levels (ULs) for vitamin D established by the IOM. The IOM has established ULs for 10 population groups ranging from 0 to 6 month old infants to adults aged 71 and above. Of the 10 population groups, the lowest IOM UL (1,000 IU/day) is for 0 to 6 month old infants; however, infants in this age range typically do not consume milk. The next lowest UL is for 6 to 12 month old infants (1,500 IU/day), and approximately 19% of this population group was reported to consume milk in the 2009-12 NHANES survey. Consumers of milk in the 6 to 12 month old population group at the 90th percentile were reported to consume 910 grams of milk per day. A vitamin D level of 1570 IU/quart in milk would result in a 6 to 12 month old 90th percentile consumer of milk exceeding the UL for vitamin D.

Table 1. 90th percentile milk intake from the 2009-12 NHANES survey and levels of vitamin D in milk needed to exceed the IOM UL for vitamin D for infants aged 6 to 12 months who consume milk

<table>
<thead>
<tr>
<th>Percent of Infants Aged 6 to 12 Months Reported Consuming Milk</th>
<th>90th Percentile Milk Intake (g)</th>
<th>IOM UL for Vitamin D (IU/day)</th>
<th>Vitamin D Level in Milk Needed to Exceed UL</th>
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<tbody>
<tr>
<td>19%</td>
<td>910</td>
<td>1500</td>
<td>1.65 165 1570</td>
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From Table 1, a 6 to 12 month old consumer of milk at the 90th percentile has an intake of almost a quart of milk per day. To allow for a more direct reference to the IOM UL established for vitamin D for 6 to 12 month olds, we recommend that the level of vitamin D in milk for which products need to be referred to FDA for a health hazard review be set at 1500 IU/quart.

C. Proposed Solution

Changes to be made on page(s): xix and 380-384 of the (X - one of the following):

- X 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms
- 2015 Procedures
- 2015 Constitution and Bylaws

**MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:**

Strike through text to be deleted and **underlined** text to be added.
ABBREVIATIONS AND ACRONYMS

Page xix:

IU, IU (International Units) …

MC (Milk Company)
mcg (micrograms) …

Pages 380-384:

APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS

PROCESS/METHODS OF VITAMIN ADDITION

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

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

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

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

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

These positive-displacement pumps have a history of reproducibility and reliability. All metering pumps should be designed to conform with this Ordinance. The recommended injection point for the vitamins is after separation and prior to homogenization. This allows the homogenization process to distribute the vitamins throughout the milk. A check-valve is recommended to prevent milk from contaminating the vitamin concentrate. Separate pumps, tubing and check-valves are recommended when multiple types of vitamin concentrates are injected. (Refer to Figure 58.) Pumps should be calibrated based on the pasteurization system flow rate. If flow rates change for different milk or milk products, additional vitamin pumps may be needed. Re-calibration of the metering pumps is not recommended without verifying the accuracy. Routine calibration of metering pumps is recommended. The following are recommended to achieve desired vitamin fortification levels:

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

**BATCH ADDITION**

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

**METERING PUMPS**

Use an accurate, sanitary, positive-displacement metering pump with a scheduled cleaning procedure after each use. For batch addition, use only accurate, calibrated measuring devices, such as plastic graduated cylinders, or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e., if 8 mL is added, a 10 mL graduated cylinder would be appropriate. Measuring devices should be rinsed with the milk or milk product being fortified
to insure no residual concentrate is left. Use a check-valve on the injection line to prevent milk or milk product from being pushed back into the injection line. This depends on the pump displacement. Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows. Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace the tubing regularly. Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis. A regular systematic cleaning and sanitizing schedule shall be maintained for these vessels, pumps and tubing. Vitamin concentrates should be stored and held in accordance with the manufacturer's recommendations for maximum shelf life. Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows. Analyze finished milk and/or milk products regularly. Results should be reported in International Units (I.U. IU)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory; one that is familiar with the handling and testing of vitamin fortified dairy milk and milk products. Care shall be taken when reprocessing reclaimed milk and/or milk products so vitamin A and/or D levels do not exceed the label claims by more than 150 120%.  

GOOD MANUFACTURING PRACTICES

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

For the purpose of label claims, compliance for nutritional labeling of food 21 CFR 101.9 c(14)(g) applies, and states:

“(3) (i) Class I. Added nutrients in fortified or fabricated foods; and (4) (i) Class I vitamins, mineral, protein, dietary fiber, or potassium. When a vitamin, mineral, protein or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.”

Therefore, if added, the acceptable range for vitamins A and D, in the standardized milk or milk products listed in 21 CFR, 131.110 Milk, 131.111 Acidified Milk, 131.112 Cultured Milk, 131.127 Nonfat Dry Milk Fortified with Vitamin A and D (vitamin addition not optional), 131.200 Yogurt, 131.203 Lowfat Yogurt, and 131.206 Nonfat Yogurt are as follows:

* 100% - 150 120% of label claims = (400 - 600 IU, 800 IU per quart for vitamin D and 2000 - 3000 IU, IU per quart for vitamin A) 2000 – 2400 IU (600-720 mcg) per quart for vitamin A
and 400 – 480 IU (10-12 mcg) per quart for vitamin D.

*Within method variability*

The acceptable range for vitamin D₃ in milk that contains more than 400 IU (10 mcg) per quart and is named by use of a nutrient content claim for vitamin D₃ and a standardized term in accordance 21 CFR 130.10 is:

100-120% of the labeled claim, but in no case may exceed 800 IU (20 mcg) vitamin D₃ per quart as the upper limit in accordance with 21 CFR 172.380.

Fluid milk and/or milk products found below 100% or above 120% of the required values or label claims, or any fluid milk and/or milk products found above 800 IU (20 mcg)* vitamin D₃ per quart should shall be resampled and the cause of the problem determined.

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

Additionally, 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term (b)-Nutrient addition states: "That nutrients Nutrients must shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter, for products which combine a nutrient content claim, i.e., lowfat, non-fat, or reduced fat, with a standardized term, i.e., milk, sour cream, eggnog. The addition of nutrients shall be reflected in the ingredient statement." Therefore, vitamins A and D shall be added to dairy milk and milk products from which fat has been removed; such as, reduced fat, lowfat, and nonfat dairy milk and milk products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat.

**TESTING METHODS**

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

**TYPE OF VITAMIN CONCENTRATES AVAILABLE**

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

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

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

Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of fresh milk with Vitamin D is acknowledged to have virtually eliminated rickets in milk drinking children. It is also known that these levels are required as one the requirement for vitamin D increases with age up to the age of 70. Adequate levels of vitamin D has been associated with reducing the incidence of osteoporosis in premenopausal women.

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

Excessive levels of Vitamin A and D in fluid milk and/or milk products can be a potential threat to public health. Over fortification with levels of Vitamin A over 6,000 IU (1800 mcg) per quart and Vitamin D over 800 IU (1,500 mcg) per quart in fluid milk and/or milk products should be referred to FDA for a health hazard review.

PROBLEMS INVOLVED WITH FORTIFICATION

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

In general, when lactating animals are transferred from pasture to winter rations in the fall, a decline in the Vitamin A and D levels can be expected in the raw milk. This occurs slowly through the winter season until the animals are once more on pasture in the spring. With the proper selection of feed and diet concentrates this effect can be kept to a minimum. Natural levels of Vitamin A range from 400 IU (12 mcg)/quart in winter to 1200 IU (360 mcg) /quart in summer, and Vitamin D, 5 IU (0.125 mcg)/quart in summer. These are approximate ranges to indicate possible seasonal variations. Because of seasonal and other variations in natural vitamin levels it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices. Vitamin concentrate potency degrades with time. Concentrates should be stored in accordance with manufacturer's recommendation to maintain label potency. Vitamin concentrate potency should be verified by the vitamin supplier.

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

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

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

**Recommendations:**

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

![Figure 58. Vitamin Fortification](image-url)
<table>
<thead>
<tr>
<th>Name:</th>
<th>CAPT Robert F. Hennes</th>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>FDA/CFSAN</td>
</tr>
<tr>
<td>Address:</td>
<td>5001 Campus Drive</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>College Park, MD 20740</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>(240) 402-2175</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Robert.Hennes@fda.hhs.gov">Robert.Hennes@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

This Proposal corrects an oversight in the amendment to Proposal 134 from the 2015 Conference that was passed to update Appendix Q—Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed After Packaging, Item 14r—Protection from Contamination of the PMO to clarify that all computer system’s controlled functions responsible for the fail-safe valve system(s) providing separation between milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale must be verified and documented at the commissioning of the computer system.

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

Appendix Q, General Requirements for AMI Computer Systems of the PMO requires a manufacturer’s written or electronic documentation addressing the computer system’s monitoring and controlling functions related to Items 1r, 13r, and 14r to explain the devices controlled, the sensors or instruments monitored, and testing procedures. It also requires all computer system’s controlled functions to be verified and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency.

This Proposal corrects an oversight with the amendment to Proposal 134 from the 2015 Conference that was passed to clarify that the manufacturer’s written or electronic documentation addressing the verification of all computer system’s monitoring and controlling functions only also applies to Item-14r. From Proposal 134 from the 2015 Conference, Items...
1r and 13r currently specify what control function(s) are required to be verified and documented; however, because of an oversight to the amendment to Proposal 134 form the 2015 Conference, Item 14r does not cite the same verification requirements that are warranted. This Proposal identifies the specific protection from contamination computer system’s monitoring and control function(s) that must be verified and documented.

C. Proposed Solution

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<td>_____ 2015 Procedures</td>
<td>2015 Constitution and Bylaws</td>
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MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

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

Pages 390 – 391:

ITEM 14r. PROTECTION FROM CONTAMINATION

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

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

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

A verification of all computer system’s controlled functions responsible for the fail-safe valve
system(s) providing separation between milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by an AMI manufacturer’s designated representative; or other means accepted by the Regulatory Agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA. AMIs, which have a wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving arrangement that provides for an air break equal to the diameter of the wash line.

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A. Summary of Proposal

To allow for the continuous use of CIP cleaning devices, such as cleaning cups commonly referred to as ‘jetters’, for the purpose of providing additional protection to milking equipment, such as milking teat cups, which are evaluated in the appropriate ordinance Sections for protection from contamination.

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

Pipeline milking and cleaning equipment which are designed for CIP cleaning may be sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed, and operated to protect the product and solution-contact surfaces. Criteria which may be considered in determining proper protection includes a method to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

In a typical AMI operation, milking teat cups (inflations) are positioned and/or protected during the teat prepping process to assure that contaminants do not enter through the teat cups and get into the milk. There are a variety of solutions:

1. teat cup flushing
2. teat cup shell and/or milk hose spraying
3. shielding by mechanical means, typically engagement with CIP cleaning devices

With CIP cleaning device engagement, these are used in the process between each cow milking, and therefore are not amenable for being ‘stored’ permanently until such time that milking has ceased for a complete system CIP cleaning. To allow the advantages of this additional level of protection would require that it be evaluated vs. the traditional ‘storage’ requirement for equipment not in use.
C. Proposed Solution

Changes to be made on page(s): 390

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Modify the 2015 PMO, page 390, Appendix Q, Item 12r., Storage

AMI’s are designed to automatically shift from milking to cleaning/sanitizing positions; therefore the devices for cleaning and sanitizing the automatic milking unit shall be positioned to assure complete drainage and shall be protected from contamination prior to use, or variations may be individually evaluated and found to also be acceptable by FDA and the Regulatory Agency.

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

Name: William Bernhard
Agency/Organization: Association of Equipment Manufacturers – Dairy Equipment Engineering Committee
Address: 6737 West Washington Street, Suite 2400
City/State/Zip: Milwaukee, WI 53214-5647
Telephone No.: 414-298-4106  E-mail Address: wbernhard@aem.org
**A. Summary of Proposal**

Establish when ventilation shall be energized.

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

Distinguish when ventilation is required to be energized. Standardize the interpretation for equipment manufacturers, installers, and regulatory agencies.
C. Proposed Solution

Modify Appendix Q ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

AMIs shall have positive air ventilation systems in operation whenever milking has shut down and full system CIP cleaning and sanitizing is taking place and the milking system is being cleaned and/or sanitized. The air for this ventilation system shall come from outside the cattle housing area and shall be as clean and dry as practical and sufficient to establish air movement around milking equipment. This positive air ventilation system shall also run during milking if needed to minimize odors, moisture and/or for pest control.

Name: William Bernhard
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A. Summary of Proposal

This proposal provides the required level of separation when AMIs flush milking teat cups, and/or milk receiver and milk lines with potable water.

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

At the end of a milking cycle for an individual dairy animal, AMIs may flush the milking teat cups, or in another operation the milk receiver and milk lines with potable water. The required separation between the milk receiver jar and the water for flushing is not specified. This proposal specifies the requirement for the use of a fail-safe type valve for separation of potable water from milking equipment or milk conveying hoses or pipes.
Appendix Q ITEM 14r. PROTECTION FROM CONTAMINATION

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

During the flushing of milking teat cup(s), milk hose(s), or line(s) and vessel(s) with potable water, the water piping may be separated from these milk contact surfaces by one (1) fail-safe valve(s) that upon loss of air or power will move to a position that will close and block the water line(s).

AMIs are designed to automatically shift from milking to cleaning/sanitizing positions; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item 14r of this Ordinance, shall be located as needed to prevent cross contamination. Separation shall be provided between milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale. Each dairy producer shall keep a copy of the AMI manufacturer’s testing verification procedures for the fail-safe valve systems on file at the dairy farm.

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

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