33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	101
Committee:	Tech/Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): Page 28 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

SUBSTITUTE SOLUTION TO PROPOSAL 101:

RECOMMEND THAT THE NCIMS CHAIR ESTABLISH A STUDY COMMITTEE TO ADDRESS THE USE OF UV ILLUMINATION AS AN ADJUNCT TO PASTEURIZATION. THE STUDY MUST BE CONSISTENT WITH FEDERAL REGULATIONS AND REVIEWED AND ACCEPTED BY FDA PRIOR TO IMPLEMENTATION. RESULTS WILL BE REPORTED BACK TO THE 2013 NCIMS CONFERENCE.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	103
Committee:	Lab

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

C. Proposed Solution

Changes to be made on page(s): 30 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

SECTION 7. STANDARD FOR GRADE "A'" MILK AND MILK PRODUCTS

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

Page 30:

GRADE "A" NONFAT DRY MILK AND DRY MILK AND MILK PRODUCTS	~~Butterfat……~~	~~No More Than~~ Not to Exceed: ~~1.25%~~
	~~Moisture……~~	~~4.00%~~
	~~Titratable Acidity……~~	~~0.15%~~
	~~Solubility Index……~~	~~1.25 mL~~
	Bacterial Limit…….	~~30,0000~~ 10,000 per gram
	Coliform……..	10 per gram
	~~Scorched Particles disc B……..~~	~~15.0 per gram~~

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	106
Committee:	Hauling

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

C. Proposed Solution

Changes to be made on page(s): 36-40 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

2009 PMO, Pages36-37:

- **Double underlined text is new proposed wording in the original proposed solution.**

- **~~Double struck through~~ text is wording in the original proposed solution that is proposed to be deleted.**

2009 PMO
SECTION 7, ITEM 5r, PAGES 36-37

5r. MILKHOUSE - CONSTRUCTION AND 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: ….

~~1a~~1. An accurate, accessible temperature-recording device …..
~~2b~~2. Temperature-recording charts shall be maintained …..
~~3c~~3. The milk shall be sampled at the direction of …..
~~4d~~4. The milk tank truck shall be effectively agitated …..

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 tank(s) or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

~~1a~~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. ~~In the case of direct loading of milk from the milkhouse to the transportation tank it shall be done in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15.~~ 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.
~~2b~~2. To assure continued protection of the milk, …..
~~3c~~3. The milk tank truck shall be washed and sanitized …..
~~4d~~4. An accurate, accessible temperature-recording device shall be installed …..
~~5e~~5. Temperature-recording records shall be maintained …..
~~6f~~6. The milk shall be sampled at the direction of the Regulatory Agency, …..
~~7g~~7. The milk tank truck shall be parked …..
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. ….

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

~~13~~12. Water under pressure is piped into the milkhouse.
~~14~~13. Each milkhouse is provided with facilities for heating …..
~~15~~14. The milkhouse is equipped with a wash-and-rinse vat …..
~~12~~15**.** The transfer of milk from a bulk milk tank ~~or the direct loading of milk from the milkhouse~~ to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The hose port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the hose port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination.
Provided, milk can be transferred from a bulk milk tank ~~or directly loaded from the milkhouse~~ to a bulk milk pickup tanker by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall, provided: ….
16. A transportation tank, with or without, …

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 tank(s) 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. ~~In the case of direct loading of milk from the milkhouse to the transportation tank it shall be done in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15.~~ 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. ....

h. 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.

2009 PMO
APPENDIX M-REPORTS AND RECORDS, PAGE 337

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS, the following changes to FORM FDA 2359a-DAIRY FARM INSPECTION REPORT shall be made:

MILKHOUSE OR ROOM

5. **Construction and Facilities:**

Miscellaneous Requirements

….

Suitable shelter or direct load for transport truck as required …(f) □

….

FORM FDA 2359a (~~10/08~~ 10/12) Edition

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	**DAIRY FARM INSPECTION REPORT**	INSPECTING AGENCY
NAME AND LOCATION OF DAIRY FARM		POUNDS SOLD DAILY PLANT PERMIT NO.

Inspection of your dairy farm today showed violations existing in the Items checked below. You are further notified that this inspection report serves as notification of the intent to suspend f the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the **Grade "A" Pasteurized Milk Ordinance**.)

COWS

1. Abnormal Milk:

Cows secreting abnormal milk milked last or in separate .....

Abnormal milk properly handled and disposed of.....

Proper care of abnormal milk handling equipment.....

MILKING BARN, STABLE, OR PARLOR

2. Construction:

Floors, gutters, and feed troughs of concrete or equally aterials; in good repair .....

Walls and ceilings smooth, painted or finished adequately; in .....good repair; ceiling dus

Separate stalls or pens for horses, calves, and bulls; no .....

Adequate natural and/or artificial light; well distributed .....

Properly ventilated .....

3. Cleanliness:

Clean and free of litter .....

No swine or fowl .....

4. Cowyard:

Graded to drain; no pooled water or wastes.....

Cowyard clean; cattle housing areas and manure packs ained .....

No swine .....

Manure stored inaccessible to cows.....

MILKHOUSE OR ROOM

5. Construction and Facilities:

Floors

Smooth; concrete or other impervious material; in good repair ...

Graded to drain.....

Drains trapped, if connected to sanitary system.....

Walls and Ceilings

Approved material and finish.....

Good repair (windows, doors, and hoseport included).....

Lighting and Ventilation

Adequate natural and/or artificial light; properly distributed .....

Adequate ventilation.....

Doors and windows closed during dusty weather .....

Vents and lighting fixtures properly installed .....

Miscellaneous Requirements

Used for milkhouse operations only; sufficient size.....

No direct opening into living quarters or barn, except as rdinance .....

Liquid wastes properly disposed of.....

Proper hoseport where required .....

Acceptable surface under hoseport .....

Suitable shelter or direct load for transport truck as f) ☐

Cleaning Facilities

Two-compartment wash and rinse vat of adequate size .....(a) ☐

Suitable water heating facilities .....(b) ☐

Water under pressure piped to milkhouse .....(c) ☐

6. Cleanliness:

Floors, walls, windows, tables and similar non-product .....contact surfaces clean (

No trash, unnecessary articles, animals or fowl.....(b) ☐

TOILET AND WATER SUPPLY

7. Toilet:

Provided; conveniently located.....(a) ☐

Constructed and operated according to *Ordinance* .....(b) ☐

No evidence of human wastes about premises .....(c) ☐

Toilet room in compliance with *Ordinance* .....(d) ☐

8. Water Supply:

Constructed and operated according to *Ordinance* .....(a) ☐

Complies with bacteriological standards .....(b) ☐

No connection between safe and unsafe supplies; no merged inlets .....(c) ☐

UTENSILS AND EQUIPMENT

9. Construction:

Smooth, impervious, nonabsorbent, safe materials; able.....(a) ☐

In good repair; accessible for inspection.....(b) ☐

Approved single-service articles; not reused .....(c) ☐

Utensils and equipment of proper design.....(d) ☐

Approved CIP cleaned milk pipeline system.....(e) ☐

10. Cleaning:

Utensils and equipment clean .....(a) ☐

11. Sanitization:

All multi-use containers and equipment subjected to approved rocess (Refer to *Ordinance*).....(a) ☐

12. Storage:

All multi-use containers and equipment properly stored.....(a) ☐

Stored to assure complete drainage, where applicable.....(b) ☐

Single-service articles properly stored .....(c) ☐

MILKING

13. Flanks, Udders, and Teats:

Milking done in barn, stable, or parlor .....(a) ☐

Brushing completed before milking begun .....(b) ☐

Flanks, bellies, udders, and tails of cows clean at time of ed when required .....(c) ☐

Teats cleaned, treated with sanitizing solution (if required) and ior to milking.....(d) ☐

No wet hand milking.....(e) ☐

TRANSFER/PROTECTION OF MILK

14. Protection From Contamination:

No overcrowding.....(a) ☐

Product and CIP cleaning circuits separated.....(b) ☐

Improperly handled milk discarded .....(c) ☐

Immediate removal of milk.....(d) ☐

Milk and equipment properly protected.....(e) ☐

Sanitized milk surfaces not exposed to contamination.....(f) ☐

Air under pressure of proper quality.....(g) ☐

15. Drug and Chemical Control:

Cleaners and sanitizers properly identified.....(a) ☐

Drug administration equipment properly handled and stored.....(b) ☐

Drugs properly labeled (name and address) and stored .....(c) ☐

Drugs properly labeled (directions for use, cautionary state e ingredient(s)) .....(d) ☐

Drugs properly used and stored to preclude contamination .....of milk or milk product-contact surfaces (

PERSONNEL

16. Handwashing Facilities:

Proper handwashing facilities convenient to milking .....(a) ☐

Wash and rinse vats not used as handwashing facilities .....(b) ☐

17. Personnel Cleanliness:

Hands washed clean and dried before milking, or performing nctions; rewashed when contaminated .....(a) ☐

Clean outer garments worn .....(b) ☐

COOLING

18. Cooling:

Milk cooled to 45°F (7°C) or less within 2 hours after milking, rmitted by *Ordinance*.....(a) ☐

Recirculated cooling water from a safe source and properly mplies with bacteriological standards .....(b) ☐

An acceptable recording device shall be installed and when required .....(c) ☐

PEST CONTROL

19. Insect and Rodent Control:

Fly breeding minimized by approved manure disposal efer to *Ordinance)*.....(a) ☐

Manure packs properly maintained.....(b) ☐

All milkhouse openings effectively screened or otherwise ors tight and self-closing; screen doors open .....(c) ☐

Milkhouse free of insects and rodents .....(d) ☐

Approved pesticides; used properly .....(e) ☐

Equipment and utensils not exposed to pesticide n.....(f) ☐

Surroundings neat and clean; free of harborages and as.....(g) ☐

Feed storage not attraction for birds, rodents or insects .....(h) ☐

REMARKS

DATE	SANITARIAN

NOTE: Item numbers correspond to required sanitation Items for Grade "A" raw milk for pasteurization in the **Grade "A" Pasteurized Milk Ordinance**.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	113
Committee:	Tech

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

C. Proposed Solution

Changes to be made on page(s): 77 and 78 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

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

*Make the following changes to the **2009 PMO**.*

ITEM 15p. PROTECTION FROM CONTAMINATION

Page 77:

15p.(B)

1. During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

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

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

(1) The <u>drainable</u> opening to the atmosphere (vent) is equal to the largest pipeline ~~feeding the valve(s)~~ <u>connected to the mixproof valve or one (1) of the following exceptions:</u>

<u>i) If the cross sectional area of the vent opening is less than that of the largest pipe</u>

diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines); or

ii) In low pressure, gravity drain applications, i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

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

….

(6) The vent is not cleaned until milk and milk products have been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent may be cleaned while milk or milk products are present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve will incorporate the following:

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

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

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a proximity switch that is interlocked with the cleaning pump …

Page 78:

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

~~**For Example:** In low pressure, gravity drain applications where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. If a common drain line is used to connect vent lines from more than one (1) block-and-bleed vent, such as in the case of drain lines from a series of cheese vats with a common drain for the block-and-bleed vent lines, the cross sectional area of the common drain line must be at least equal to the total cross sectional area of the lines connected to the header. Or, a common drain line of the same size as the vent may be used, if provisions are included in a fail-safe control system to sequence the use and cleaning of the vats to assure that no more than one (1) vat attached to that drain can be~~

~~washed at the same time. All other criteria still apply. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.~~

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	114
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 81 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

SUBSTITUTE SOLUTION TO PROPOSAL 114

2009 PMO
SECTION 7, ITEM 15p, PAGE 81

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

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, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

c. The pasteurized milk or milk product, between its outlet from the plate or double/triple tube type heat exchanger and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

d. The overflow of the top rim of the water supply tank shall always be lower than the lowest heat-transfer water level in the plate or double/triple tube type heat exchanger.

e. A pump(s) or flow-promoting device(s), which can affect the proper pressure relationships within the plate or double/triple tube type heat exchanger, shall not be located between the pasteurized milk or milk product outlet from the plate or double/triple tube type heat exchanger and the nearest downstream point open to the atmosphere.

f. A pump(s) shall not be located between the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the water supply tank, unless it is designed and installed to operate only when pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger and when the pressure of the pasteurized milk or milk product is higher than the maximum pressure produced by the pump(s). This may be accomplished by wiring the heat-transfer water pump(s) so that it cannot operate unless:

(1) Pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger; and

(2) The pasteurized milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the heat-transfer water pump. A pressure differential controller shall be installed with a sensor located at the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the pasteurized milk or milk product outlet of the plate or double/triple tube type heat exchanger. The differential set point of this pressure differential controller shall be tested by the Regulatory Agency upon installation; at least once every three (3) months thereafter; whenever the regulatory seal has been broken; and following any repair or replacement. Accuracy shall be determined by utilizing testing procedures as outlined in Appendix I, Test 9.2.1 to assure that the pressure differential controller probes are accurately calibrated. Also, the applicable procedures cited in Appendix I, Test 9.2.2 shall be utilized to assure that the pressure differential controller is accurately calibrated and will de-energize the heat-transfer water pump at the required differential pressure set point.

g. All heat-transfer water in the plate or double/triple tube type heat exchanger will automatically drain freely back to the water supply tank or to the floor when the heat transfer water pump(s) are shut down and the heat-transfer water connection(s) at the plate or double/triple tube type heat exchanger is disconnected.

NOTE: INCORPORATE THE PROPOSED SOLUTION FROM PROPOSAL 122, WITH PROPOSED AMENDMENTS BELOW, INTO THIS SUBSTITUTE SOLUTION.

2009 PMO
APPENDIX D-STANDARDS FOR WATER SOURCES, PAGE 176

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.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	115
Committee:	Tech/Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 84 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Grade "A" Pasteurized Milk Ordinance.

~~Strike out~~ text to be deleted and underlined text to be added

Add to Item 16p, ADMINISTRATIVE PROCEDURES:

~~6~~**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. ~~p~~**P**rior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N.;

b. ~~i~~**I**f there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria ~~must be met~~ **shall be complied with**:

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

18.3ºC (65ºF) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

(2) The MF system must 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 circulating pump**.

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

~~4~~**5**. All condensed milk and milk products transported to a milk plant for drying shall be repasteurized at the milk plant where it is dried.

(Renumber the remaining items accordingly.)

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	116
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

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

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Substitute Solution for Proposal 116

ITEM 16p.(E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION AND ASEPTIC PROCESSING RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA, in place of charts shall be preserved for a period of three (3) months. Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

a. **Batch Pasteurizers**:

(1) Date;

(2) Number or location of recording thermometer when more than one is used;

(3) A continuous record of the product temperature;

(4) Extent of holding period, including filling and emptying times when required;

(5) Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; **Provided, if the airspace thermometer is a digital combination airspace/recording thermometer; which provides a continuous**

recording of the airspace temperature; and ~~which~~ has been calibrated by the ~~state regulatory agency~~ State Regulatory Agency in accordance with Appendix I, Test 4; the recording of the airspace temperature on the chart shall only be required at the start of the holding period.

(6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
(7) Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to the Regulatory Agency;
(8) Amount and name of the pasteurized milk or milk product, represented by each batch or run on the chart;
(9) Record of unusual occurrences;
(10) Signature or initials of the operator; and
(11) Name of the milk plant.

TEST 4.
RECORDING THERMOMETERS - CHECK AGAINST INDICATING THERMOMETERS
Reference: Item 16p.(A), (B), (C) and (E)
Application: To all recording and recorder-controller thermometers used to record milk or milk product temperatures during pasteurization or aseptic processing**, and for batch pasteurizer digital combination airspace/recording thermometers with a continuous recording of the airspace temperature and where the airspace temperature is read and recorded on the recording chart only at the start of the holding period.**
Frequency: Upon installation and at least once each three (3) months by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(E)2; **whenever the regulatory seal is broken**; and daily by the milk plant ~~**operator**~~ **personnel for HTST and HHST pasteurization systems.**
Criteria: The recording thermometer and recorder-controller thermometer shall not read higher than the indicating **or airspace** thermometer.
Apparatus: No supplementary materials required.
Method: This Test requires only that the reading of the recording thermometer**,** ~~**or the**~~ recorder controller thermometer **or airspace recording thermometer** be compared with the indicating thermometer at a time when both are exposed to ~~**milk or milk product**~~ ~~**at**~~ a stabilized **temperature at or above the minimum legal** pasteurization or aseptic processing temperature.
Procedure:
1. While the indicating and recording temperatures are stabilized at or above the minimum legal pasteurization or aseptic processing temperature, read the indicating thermometer.

2. For batch pasteurizers, while the airspace indicating and recording temperatures are stabilized at or above the minimum legal pasteurization temperature, read the airspace thermometer.

~~2~~**3**. Immediately record and identify on the recording thermometer chart, the observed indicating **and/or airspace** thermometer temperature reading and the time at which this comparison was made. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or other methods acceptable to the Regulatory Agency.

NOTE: This Test shall be performed while the pasteurization operating temperatures are within the accurate range for the specific thermometers and charts used.

Corrective Action: If the mercury-actuated recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by the operator. If the digital recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the recording temperature should be adjusted to agree with the indicating thermometer. Retest the thermometer after adjustment.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	117
Committee:	Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 107 – 111 of the (X - one of the following):

XXX	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

SUBSTITUTE SOLUTION FOR PROPOSAL 117

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

June ??, 2011

IMS-a-45
Supplement 2

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

From: Dairy and Egg Branch (HFS-316)

Subject: Additional Action from the 2005 National Conference on Interstate Milk Shipments (NCIMS) Related to Proposal 126 as Passed in Proposal 117

from the 2011 NCIMS Conference

The 30th National Conference on Interstate Milk Shipments (NCIMS) was held in Columbus, Ohio, May 12-17, 2005. FDA responded in writing to the NCIMS Conference Chair on September 2, 2005 and met with the NCIMS Executive Board on September 27, 2005 concerning all of the Proposals passed during the 2005 Conference. FDA did not concur with Proposals 126, 127 and 128 relating to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO. FDA and the Executive Board mutually concurred with all of the other Proposals and changes cited in IMS-a-45, which was issued October 1, 2005.

IMS-a-45, page 39, states:

"FDA NON-CONCURRED WITH THIS PROPOSAL

Proposal: 126
Document: 2003 PMO (Section 7-Item 17p)
Page: 102

NOTE: THE NON-CONCURRENCE WITH PROPOSALS 126 AND 127 IS BASED ON THE LACK OF CONCLUSIVE EVIDENCE TO SUPPORT THESE PROPOSALS AT THIS TIME, AFTER A REVIEW OF THE SPECIFIC DATA SUBMITTED TO FDA. INDUSTRY DATA DEVELOPMENT AND FDA REVIEW IS CONTINUING ON THESE PROPOSALS AND IN THE FUTURE ADDITIONAL INFORMATION MAY BE PRESENTED TO THE NCIMS EXECUTIVE BOARD FOR RECONSIDERATION OF THESE PROPOSALS.

Make the following changes to ***SECTION 7. STANDARDS FOR GRADE "A' MILK AND MILK PRODUCTS*** *on Page 102:*

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All pasteurized milk and milk products, except those to be cultured and cottage cheese with a pH of 5.3 or less, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing. All condensed whey and whey products shall be cooled during the crystallization process to 7°C (45°F) or less within 48 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 48 hour time period begins when cooling is started.
All pasteurized milk and milk products, except for cottage cheese with a pH of 5.3 or less, shall be stored at a temperature of 7ºC (45ºF) or less and maintained thereat until further processed.

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, or the product is inherently safe

and does not support the growth of pathogenic organisms.

ADMINISTRATIVE PROCEDURES

3. All pasteurized milk and milk products, except those to be cultured and cottage cheese with a pH of 5.3 or below*, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing.
4. All pasteurized milk and milk products shall be stored at a temperature of 7ºC (45ºF) or less and be maintained thereat until further processed. Provided that cottage cheese (except hot packed cottage cheese) with a pH of 5.3 or below shall be packaged at 13ºC (55ºF) or less and cooled to a temperature of 7ºC (45ºF) or less 72 hours of packaging*. If surge tanks or balance tanks are used between the evaporator and the drier, such tanks shall hold the product at a temperature of 66°C (150°F) or more, or shall be completely emptied and cleaned after each 4 hours of operation or less.

*The following ***Note** is not intended for placement in any NCIMS document.*

***Note: The dairy industry will be responsible for providing FDA with scientific information for evaluation on cottage cheese product.**

Since the September 27, 2005 NCIMS Executive Board meeting, the Dairy Industry has submitted scientific data to FDA addressing Proposal 126 (Cold Filled Cottage Cheese with a pH of 5.3 or below, packaged at a temperature of 13ºC (55 ºF) or less and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of packaging).

FDA's Center for Food Safety and Applied Nutrition's (CFSAN) staff has reviewed the Dairy Industry's submitted scientific data and has reached the following conclusions based on the specific scientific data submitted. Those conclusions are identified by the specific criteria and parameters cited below. They address the appropriate changes to be incorporated into Item 17p-Cooling of Milk and Milk Products within the 2011 Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), which are warranted to address FDA's consensus conclusions from their review of the specific scientific data submitted. Additions are identified as being underlined and deletions are identified as being ~~struck through~~.

CHANGES TO ITEM 17p.-COOLING OF MILK AND MILK PRODUCTS OF THE 2009 GRADE "A" PASTEURIZED MILK ORDINANCE (PMO) PAGES 107-112

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7ºC (45ºF) 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.
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 7ºC (45ºF) 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. NOTE: IMS-a-45 (Supplement 1) approved language as of March 10, 2011 (effective date of April 1, 2011) is identified in red throughout this document.
   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~~;~~, ~~and~~ or
   d. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (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 13ºC (55°F) or less*; and

~~6~~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, ~~and~~ 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 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 7ºC (45ºF) 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**; and
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 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or
   d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

   *Critical factors including, but not limited to, pH, filling temperature, ~~and~~ 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 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.

   ** 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 (50ºF) 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 7ºC

(45ºF).
Aseptically processed milk and 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, 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 7ºC (45ºF) 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 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each four (4) hours of use or less. ***
3. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7ºC (45ºF) 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~~;~~, ~~and~~ or

(4) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (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 13ºC (55°F) or less*; and

~~f~~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, ~~and~~ 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 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.

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

a. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

b. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

c. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;

d. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and

e. 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 7°C (45°F) 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 7°C (45°F) 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 13ºC (55°F) or less*, cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or

(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 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, filling temperature, ~~and~~ 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 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.

** 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.

5. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above () and below () shall be completely emptied and cleaned after each six (6) hours of operation or less. ***
6. Each refrigerated room in which milk and milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.
7. 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.
8. On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).
9. 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 entering the milk or milk product.

d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.

10. Recirculated cooling water, which is used in coolers and 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 by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use.

11. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.

12. Water from an open**,** evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times.

If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop it must be protected by an Isolation System to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The Isolation System shall include:

a. Tower water heat exchangers shall be constructed, installed and operated so that the intermediate cooling media water in the heat exchanger will automatically be under greater pressure than the open tower water in the heat exchanger at all times**.**

b. The tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down.

c. The Isolation System shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller will be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the Isolation System to a fail-safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure.

d. The intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water in the tower water heat

exchanger Isolation System, and shall be open to the atmosphere at this elevation. During a shut down the intermediate cooling water shall not drain from the tower water heat exchanger.

e. The Isolation System shall meet one (1) of the following:

(1) In a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger. (Refer to Figures 8, 9, and 10 in Appendix D., VII.)

In this application, the Isolation System shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

i) Closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve;

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open);

iii) The drain valve and any pipes or pumps located between the drain valve and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;

iv) De-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger; and

v) If a tower water return pump is used, a bypass line may be used to flood the dry pump at start up.

(2) In a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger. (Refer to Figures 11 and 12 in Appendix D., VII.)

In this application, the Isolation System shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

i) De-energizing the “local tower water supply pump”, if present. (Refer to Figure 11 in Appendix D., VII.);

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger;

iii) Open a full port drain valve prior to a check-valve in the tower water return line. This drain valve must be normally open (spring-to-open); and

iv) The drain valve and any pipes or pumps located between it and the heat exchanger must be lower than the lowest liquid level in the heat exchanger.

(3) Variations from the above Isolation Systems may be individually evaluated and found to also be acceptable by the Regulatory Agency, if the level of protection required by this ADMINISTRATIVE PROCEDURE is not compromised.

TESTING: A means to test the response of this Isolation System must be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the Regulatory Agency on installation; every six (6) months thereafter; and following repair or replacement.

*** **NOTE:** Nothing shall be construed as barring other time and temperature relationships, which have been recognized by FDA to be equally efficient and which are approved by the Regulatory Agency.

SECTION IX. APPLICATION OF CONFERENCE AGREEMENTS, A. **IMPLEMENTATION OF CHANGES**, Items 3. and 4. of the 2009 *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* states:

> "3. Those issues with which PHS/FDA does not concur will be referred to the NCIMS Executive Board for further discussion (within thirty (30) days if possible). If mutual concurrence is obtained, the changes shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States by IMS-a, following the Conference at which the changes were approved, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.
>
> 4. If mutual concurrence cannot be reached, the matter will be referred to the next Conference for further discussion. In the interim period between the PHS/FDA-NCIMS Executive Board Meeting (referred to in 3. above) and the next NCIMS Conference, PHS/FDA will consider additional information that becomes available concerning Proposals for which there was not mutual concurrence. If review of this additional information causes PHS/FDA to reconsider its position, PHS/FDA may bring Proposals back to the NCIMS Executive Board for reconsideration and the establishment of an alternative effective date."

Based on FDA's review of the additional submitted scientific data from the Dairy Industry related to Proposal 126, since the September 27, 2005 NCIMS Executive Board/FDA meeting to discuss Actions taken at the 2005 Conference, FDA has elected to reconsider its original position of non-concurrence with Proposal 126. Proposal 117 as passed at the 2011 NCIMS Conference identified FDA's documented changes to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO related to Proposal 126 from the 2005 NCIMS Conference. Proposal 117 from the 2011 NCIMS Conference also established an effective/implementation date of June 15, 2011.

The specific wording cited within Item 17p, contained within this IMS-a, will be incorporated into the 2011 Grade "A" PMO when it is updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory and Rating Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers in your region. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at http://www.fda.gov at a later date.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-a-97

June ??, 2011

Implementation Date: June 15, 2011

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Specified Microbial Inhibitors and/or Preservatives Accepted By FDA For Use In The Production Of Cottage Cheese That Will Be Filled At 13ºC (55°F) Or Less, Cooled To 10ºC (50°F) Or Less Within Twenty-Four (24) Hours Of Filling, And Cooled To 7°C (45°F) Or Less Within Seventy-Two (72) Hours Of Filling

This is the accompanying document as referenced in IMS-a-45 (Supplement 2)-Additional Action from the 2005 National Conference on Interstate Milk Shipments (NCIMS) Related to Proposal 126, dated June ??, 2011, with an effective/implementation date of June 15, 2011 as passed in Proposal 117 from the 2011 NCIMS Conference.

The 30th National Conference on Interstate Milk Shipments was held in Columbus, Ohio, May 12-17, 2005. FDA responded in writing to the NCIMS Conference Chair on September 2, 2005 and met with the NCIMS Executive Board on September 27, 2005 concerning all of the Proposals passed during the 2005 Conference. FDA did not concur with Proposals 126, 127 and 128 relating to Item 17p-Cooling of Milk and Milk Products of the Grade “A” PMO. FDA and the Executive Board mutually concurred with all of the other Proposals and changes cited in IMS-a-45, which was issued October 1, 2005.

Since the September 27, 2005 NCIMS Executive Board meeting, the Dairy Industry has submitted scientific data to FDA addressing Proposal 126 (Cold Filled Cottage Cheese with a pH of 5.3 or below, packaged at a temperature of 13ºC (55 ºF) or less and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of packaging).

FDA's Center for Food Safety and Applied Nutrition's (CFSAN) staff has reviewed the Dairy Industry's submitted scientific data and has reached the following conclusions based on the specific scientific data submitted. Those conclusions are identified by the specific criteria and parameters cited below. They address the appropriate changes to be incorporated into Item 17p-Cooling of Milk and Milk Products within the 2011 Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), which are warranted to address FDA's consensus conclusions from their review of the specific scientific data submitted.

Following are CFSAN's conclusions based on the specific scientific data submitted for review and the specific criteria and parameters for the cold filled packaging of cottage cheese at a temperature of 13ºC (55 ºF) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to a temperature of 7ºC (45ºF) or less within seventy-two (72) hours of filling as cited in the Grade "A" PMO:

"**ITEM 17p. COOLING OF MILK AND MILK PRODUCTS**

ADMINISTRATIVE PROCEDURES

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

5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and: …

   c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**; or
   d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97; filled at 13ºC (55°F) or less*; cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

   *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 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.

** 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."

The following Table includes the FDA accepted specified microbial inhibitors and/or preservatives, at the specified concentration, for use in the production of cottage cheese that will be cold filled packaged at 13ºC (55°F) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling at the time of the issuance of this M-a:

PRODUCT BRAND NAME	FOOD INGREDIENTS	SPECIFIED CONCENTRATION TO BE USED	MANUFACTURER
Sea-i®	Glucose (common name is corn sugar, also call *D*-glucose), Glucose Oxidase, Whey (Lactperoxidase, Lactose, and Casein)	0.03% Bioactive Protein I Or 0.04% Bioactive Protein I	Bienca Products
MicroGARD 430	Cultured Skim Milk Blend, NFDM and Maltodextrin	0.15% Fermentate D	Danisco
DURAFresh™ 5015 And DURAFresh™ 5015 + Fargo 763	Cultured Skim Milk and Skim Milk Powder Cultured Skim Milk and Skim Milk Powder and Lactic Acid Starter Culture or Starter Culture	0.1% Fermentate E 0.1% Fermentate E + 0.1% Culture	Kerry Ingre□ients Flavours
Pura Q™ Safe-	Cultured Whey	0.15%	Purac

RS20P	and Calcium Lactate	To 0.5% Fermentate	

NOTE: Proposal 117 as passed at the 2011 NCIMS Conference provided for the issuance of IMS-a-45 (Supplement 2) and accompanying M-a-97 with an effective/ implementation date of June 15, 2011. It also provided that future updates to M-a-97 that add, delete or revise the listing of FDA acceptable specified microbial inhibitors and/or preservatives for use in the production of cottage cheese that will be filled at 13ºC (55°F) or less; cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling; and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling will not require a public comment period or follow the protocol established in the *Procedures* document for the issuance of M-a's.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

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

Robert F. Hennes, RS, MPH
CAPT, U.S. Public health Service
Dairy and Egg Branch

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	118
Committee:	

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

C. Proposed Solution

Changes to be made on page(s): 103 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Amend the 2009 PMO, page 103, Section 7, Standards for Grade "A" Milk and Milk Products, item 16p (E) (1) (c).

c. **Continuous-Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow Meter Based Timing Systems:** Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in Subitem a. above, except (3), (4), (5), ~~and~~ (6), and (7), and in addition, shall include the following:
(1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
(2) A continuous record of the flow rate.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	119
Committee:	

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

C. Proposed Solution

Changes to be made on page(s): p. 107 - 110 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

AMENDMENT TO PROPOSAL 119
4/22/2011

- **Double underlined text is new proposed wording in the original proposed solution.**
- **~~Double struck through~~ text is wording in the original proposed solution that is proposed to be deleted.**

2009 PMO
SECTION 7, ITEM 17p, PAGES 107-110

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of ~~7oC (45oF)~~ 7ºC (45ºF) 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.
~~If~~ 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., the tanks and/or vessels used to blend and hold ~~such~~ the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless ~~it shall be~~ the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or ~~more~~ greater and ~~be~~ maintained thereat ~~until the time of injection~~.
All pasteurized milk and milk products,…….

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall……
2. All whey and whey products…..
3. ~~If~~ 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., the tanks and/or vessels used to blend and hold ~~such~~ the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless ~~it shall be~~ the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or ~~more~~ greater and ~~be~~ maintained thereat ~~until the time of~~ ~~injection~~.
~~3~~4. All pasteurized milk and milk products,…..
~~4~~5. All pasteurized milk and milk products,…..
~~5~~6. All pasteurized milk and milk products……
~~6~~7. Each refrigerated room……
~~7~~8. Each storage tank shall……
~~8~~9. On delivery vehicles,…..
~~9~~10. All surface coolers…….
~~10~~11. Recirculated cooling water,…..
~~11~~12. Recirculated cooling water…….
~~12~~13. Water from an open,…….

2009 PMO
APPENDIX H, PAGE 219

….
6. ~~If~~ 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 ~~such~~ the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless ~~it shall be~~ the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or ~~more~~ greater and ~~be~~ maintained thereat until the time of injection.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	120
Committee:	Other Species

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 117, 118 and 129 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

SUBSTITUTE SOLUTION TO PROPOSAL 120 OTHER SPECIES COMMITTEE

- **Double underlined text is new proposed wording in the original proposed solution.**
- **~~Double struck through~~ text is wording in the original proposed solution that is proposed to be deleted.**
- **All changes are enlarged to 16 point for clarity**

2009 PMO SECTION 8, PAGES 117-118

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

one (1) of the following conditions:

a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or

b. An Area which fails to maintain such status:

(1) Any herd shall have been accredited by USDA or

(2) Shall have passed an annual tuberculosis test; or

(3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

~~**NOTE:** Under the Federal USDA Bovine TB Eradication Program, only cattle and other hooved mammals (goat, sheep, water buffalo, etc., bison, and captive cervids are covered within the USDA State TB status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and shall comply with the option cited below.~~

~~Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing, defined under this *Ordinance*, shall be from a herd or flock that is determined to be free of tuberculosis as provided by the development and implementation of a State administered tuberculosis-free herd certification program involving a documented surveillance program, which includes records supporting the tests required in this Section, and an official annual written certification from the State Veterinarian documenting their tuberculosis-free status. The surveillance program shall be documented and the official annual written State tuberculosis-free certification shall be retained on file with the State Regulatory Agency. This official annual written State tuberculosis-free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, etc.) that are covered within the documented surveillance program and contained within the official annual written State tuberculosis-free certification.~~

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

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

b. Meet USDA requirements for ~~an individually certified herd~~ a Certified Brucellosis-Free Herd; or

c. Participating in a milk ring testing program at least two (2) times per year at

approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or

d. Have an individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months.

NOTE: Under the Federal USDA Brucellosis Eradication Program…

2009 PMO
APPENDIX A. ANIMAL DISEASE CONTROL, PAGE 129

Copies of the ~~*Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*~~ *Bovine Tuberculosis Eradication: Uniform Methods and Rules (available at http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/tb-umr.pdf)*, and ~~recommended~~ *Brucellosis Eradication~~,~~: ~~Recommended~~ Uniform Methods and Rules, (available at http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/umr_bovine_bruc.pdf)*, current at the time of the adoption of this *Ordinance* are available electronically using the hyperlinks above or may be obtained from your State Veterinarian or:

Veterinary Services
Animal and Plant Health Inspection Service
U. S. Department of Agriculture
~~Federal Center Building~~
~~Hyattsville, MD 20782~~
4700 River Road, Unit 43
Riverdale, MD 20737
http://www.aphis.usda.gov/animal_health/

Or

Federal Area Veterinarian in Charge
VS, APHIS, USDA
Your State Capitol

It is recommended that Regulatory Agencies initiate and/or promote a mastitis control program. A well-planned and extended educational phase will encourage the support of producers and reduce the problems of enforcement. …….

STUDY COMMITTEE

The Other Species committee recommends that the Conference Chair

assign an ad-hoc committee to develop acceptable program options for the control of tuberculosis and brucellosis for hooved mammals not covered by the USDA Bovine Tuberculosis and Brucellosis Eradication Programs.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	123
Committee:	Tech

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

C. Proposed Solution

Changes to be made on page(s): 218 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Pasteurized Milk Ordinance.

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

Appendix H. Pasteurization Equipment and Procedures and Other Equipment

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

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

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When the FDD is in **the** ~~inspect~~ **"Inspect"** mode;
   b. When the timing pump is not in operation; and
   c. When the temperature is below the required **minimum legal** pasteurization temperature and the FDD is not in the fully diverted position.

~~Note: In the case of a meter-based system, the slurry pump may remain energized provided the injection point has Double-Block and Bleed valves and will allow product under pressure to release to a drain. The valves shall be tested to assure they fully isolate the system in~~

~~conjunction with all events in which the FDD moves to diverted flow.~~

NOTE: The slurry pump may remain energized provided:

A spring-to-close and air-to-open blocking valve is located between the slurry injection pump and the slurry injection valve (s) described in 2 below.

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. . . .

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	124
Committee:	Tech

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

C. Proposed Solution

Changes to be made on page(s): 221 and 222 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

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

*Make the following changes to the **2009 PMO**.*

Pages 221-222:

MAGNETIC FLOW METER BASED TIMING SYSTEMS ~~FOR~~ WITHIN ~~HTST~~ CONTINUOUS FLOW ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS

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

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

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

1. A ~~sanitary~~ magnetic flow meter which has been reviewed by FDA or one (1) which ~~is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within 0.5 seconds of each other~~ meets the following criteria for accuracy and reliability:

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

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

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

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

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

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

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

Calibration: The calibration shall be based on multiple points for the entire range of the magnetic flow meter for MBTS application. The magnetic flow meter shall be tested against a traceable NIST standard. The procedure(s) used for the magnetic flow meter calibration is documented and available to the Regulatory Agency.

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

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

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

4. A flow alarm, with an adjustable set point, shall be installed within the system which will automatically cause the FDD to be moved to the divert position whenever excessive flow rate causes the milk or milk product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the Regulatory Agency in accordance with the procedures of Appendix I, Test 11, 2.A and B at the frequency specified. The flow alarm adjustment shall be sealed. **NOTE:** Test 11, 2.A is not applicable to HHST systems.

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

6. For HTST systems, ~~When~~ when the legal flow rate has been reestablished, following an excessive flow rate, a time delay ~~must~~ shall be instituted, which will prevent the FDD from assuming the forward-flow position ~~until~~ for at least a minimum of fifteen (15) ~~seconds, for milk or milk product,~~ or twenty-five (25) seconds ~~for eggnog and similar products, of continuous legal flow has been re-established~~ depending upon the product being pasteurized and the temperature being utilized. The time delay ~~must~~ shall be tested and sealed by the Regulatory Agency ~~and if it is of the adjustable type shall be sealed~~.

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

7. For HTST systems, ~~A~~ a sanitary check valve or normally closed automatically controlled sanitary valve shall be installed with the magnetic flow meter to prevent a positive pressure in the raw milk or milk product side of the regenerator whenever a power failure, shutdown or flow-diversion occurs. **NOTE:** This provision is not applicable to HHST systems.

8. For HTST systems, ~~When~~ when a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the FDD is in the diverted-flow position. Care ~~should~~ shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk or milk product.

Caution ~~should~~ shall also be observed with such bypass systems and any valves used in them so that raw milk or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs. **NOTE:** This provision is not applicable to HHST systems.

9. ~~Most systems will utilize a dual stem FDD and will be using the timing pump during the CIP cleaning cycle. All public health controls, required of such systems, must be applicable.~~ When switching to the "CIP" position, the FDD ~~must~~ shall move to the divert position and ~~must~~ shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST systems the booster pump cannot run during this ten (10) minute time delay.

10. All MBTS pasteurization systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(E) can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.

11. 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 ~~the~~ a magnetic flow ~~meter based timing systems~~ MBTS shall comply with the following placement conditions:

1. The timing ~~pump~~ system's flow promoting device(s) shall be located ~~downstream~~ upstream from the ~~raw milk or milk product regenerator section, if a regenerator is used~~ magnetic flow meter.

2. The magnetic flow meter shall be placed ~~before the holding tube and~~ after ~~any bypassed regenerator(s)~~ the last raw product regenerator outlet and upstream of the holding tube ~~any bypassed regenerator(s)~~. There shall be no intervening flow-promoting components between the magnetic flow meter and the holding tube.

3. For HTST systems, ~~The~~ when a ~~control valve~~ sanitary check valve or normally closed automatically controlled sanitary valve, as described in #7 above, is used with ~~the~~ a variable or constant speed flow promoting device, ~~may~~ it shall be located downstream ~~of the magnetic flow meter~~ of the last regenerator outlet and upstream of the holding tube. **NOTE:** This provision is not applicable to HHST systems.

~~4. The magnetic flow meter, the sanitary check valve or normally closed control valve, shall all be located upstream from the start of the holding tube.~~

~~5~~ 4. All flow-promoting devices, which are upstream of the FDD~~, such as booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps~~ and which are capable of generating flow through the FDD, shall be properly interwired with the FDD so that they may run and produce flow through the system at sub-legal temperatures, only when the FDD is in the fully diverted position and ~~when~~ in "Product" run mode, or "CIP" mode after the ten (10) minute time delay has timed out. Such flow promoting devices shall be de-energized in "Inspect" mode. Separators or clarifiers that continue to run, after they are de-energized ~~must~~ shall be automatically valved-out of the system, with fail-safe valves, so that they are incapable of producing flow.

~~6~~ 5. There shall be no product entering or leaving the system, i.e., cream or skim milk from a separator or other product components, between the magnetic flow meter and the ~~FDD~~ holding tube.

~~7~~ 6. The magnetic flow meter shall be so installed that the milk or milk product has contact with both electrodes at all times when there is flow through the system. This is most easily

accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with the product and the horizontal line shall remain full of liquid during operation. ~~They should~~ Magnetic flow meters shall not be mounted on a ~~high~~ horizontal line that may be only partially full and thereby trap air.

~~8~~ 7. The magnetic flow meter shall be piped in such a manner that at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the magnetic flow meter, before any elbow or change of direction takes place. Except that other piping configurations upstream and downstream of the magnetic flow meter may also be used if they have been reviewed and found acceptable to FDA and the Regulatory Agency.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	126
Committee:	

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

C. Proposed Solution

Changes to be made on page(s): 252 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

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

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING

CRITERIA

Page 252

8. The electronic computerized data collection, storage, and reporting system shall provide for any signatures or initials required by this *Ordinance*. Acceptable operator signatures or initials, captured electronically, may be any combination of alpha and/or numeric characters that identify the individual performing the test or operation. Input of this signature or initials may be done by any means, including, but not limited to, a biometric reader, a card or radio frequency device, or by simple direct entry that provides a unique identifier directly associated with a specific person. Input of this signature or initials must occur each time it is required by this *Ordinance*. ~~A~~ ~~In~~ **Except that in** the case of pasteurization and aseptic processing records, ~~a~~ ~~login~~ **the operator's signature or initials** must occur whenever an

operator changes and at a minimum frequency of once every twenty-four (24) hours.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	127
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 256 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

SUBSTITUTE SOLUTION TO PROPOSAL 127 4/30/2011

2009 PMO
APPENDIX H, VI, PAGE 256

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 shall be controlled by direct hard-wiring from the output terminal bus of the computer to the device. This includes solenoids, motor speed controls, such as frequency drives, and motors located within the HTST or HHST system. The wiring connections must 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-~~regulatory~~ **public health** computer systems provided that regulatory limits cannot be altered or disabled.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	128
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X Substitute Solution
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s): 258 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

SUBSTITUTE SOLUTION TO PROPOSAL 128 4/30/2011

2009 PMO
APPENDIX H, VI, PAGE 258

17. Computers require high quality; clean, well-regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in public health computer RAM. To assure the public health computer will execute its functions error free the following items parameters must be considered:

a. A "clean" power source that is relatively free of spikes, interference and other irregularities shall be supplied to the public health computer.

b. The correct program should be confirmed at the time of sealing. (Refer to the criteria cited within #9 of this Section).

c. The output bus "last state" switch should be in the "off" or "fail-safe" position which will stop all functions of the HTST or HHST pasteurizer in case of a spurious program error.

d. All public health computer outputs shall not have any operator override switches and must be wired in a manner that only allows the public health PLC complete control.

~~Some mechanical and electrical components also deteriorate with age. One (1) solution is to have two (2) permanent programs in the public health computer; one (1) in RAM and one (1)~~

~~in ROM. Through a self-diagnostic test, these two (2) programs could be compared routinely. If there were differences in the programs, the public health computer would go into default mode. Another solution would be to download the program from some form of ROM to RAM at every start up. A third solution could be to have the public health computer read the program directly from unchangeable ROM. However, this approach is practical only in large volume (home appliances, etc.) applications. For most small volume applications, the ROM's are field alterable, such as EPROMS, EEPROMS and EAPROMS. These types of computer programs cannot be relied upon to maintain a permanent record.~~ It is necessary that the installer or designer for the public health PLC ensure that the proper program is in the public health computer memory before the Regulatory Agency seals the computer. It is also necessary that any program changes be written to the ~~regulatory~~ **public health** computer's back-up chip if one exists.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	129
Committee:	HACCP

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

C. Proposed Solution

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

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Modify the 2009 PMO, page 267
Milk and Milk Product Continuous-Flow (HTST and HHST) Pasteurization --- CCP Model HACCP Plan Summary.

Modify the footnote at the bottom of the model table on page 267 of the 2009 PMO to read as below:

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