

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	101
Committee:	Tech/Scientific Advisory

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

**A. Summary of Proposal**

To modify the PMO section 7 to include micro-droplet formation in the pasteurization processes.

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

Our studies have shown that when raw milk is processed thru a micro-droplet formation process, upstream of a typical HTST pasteurizer, which is described and shown in Grade A Pasteurized Milk Ordinance (2013), the pasteurization process will attain a greater log kill of microorganisms, which will produce milk of a better microbiological quality. We know that the unit does not alter the composition or the characteristics of the raw milk in any way.

The micro-droplet formation process consists of a vessel that is manufactured to 3A Insulated Tank Standards, with all connections utilizing sanitary fittings and all spray devices and nozzles removable for inspection and compliant with 3A standards. The process can be stand-alone prior to Pasteurization, or integrated with a normal pasteurizer, and placed just after the Raw Regenerator of either a pasteurizer or UHT.

The micro-droplet formation process consists of pushing milk through the nozzles of the micro-droplet formation vessel to produce droplets in the order of 100s of microns in size. This weakens the cell and makes it more vulnerable to temperature. Heat can be either integral to the micro-droplet formation vessel or generated in the normal Heating Section of the Pasteurizer.

Micro-droplet formation operates at atmospheric pressure, not vacuum. The micro-droplet formation also has no effect on the Regenerator Pressure, or on the HTST Timing Device. It

will not promote accelerating milk particles or alter hold tube characteristics in any way. The micro-droplet formation achieves a measurable pressure drop by spraying raw milk into the micro-droplet formation vessel chamber through spray nozzles. This process will not have negative effects on any of the PMO acceptable processes, and as such we believe this can and will improve the quality and safety of the Grade A Milk Supply.

**C. Proposed Solution**

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

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO<br><input type="checkbox"/> 2013 MMSR<br><input type="checkbox"/> 2013 Procedures | <input type="checkbox"/> 2011 EML<br><input type="checkbox"/> 2400 Forms<br><input type="checkbox"/> 2013 Constitution and Bylaws |
|--|---|

***Make the following changes to the 2013 PMO:***

Underlined text is to be added.

Page 32

**SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS**

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

No process or manipulation other than pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and/or milk products for the purpose of 32 removing or deactivating microorganisms, provided that filtration, micro-droplet formation, and/or bactofugation processes are performed in the milk plant in which the milk and/or milk product is pasteurized, ultra-pasteurized, aseptically processed and packaged, or retort processed after packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Name:	Philip R. Frechette		
Agency/Organization:	JCS Process and Control Systems Engineering Co.		
Address:	172 Metro Park		
City/State/Zip:	Rochester / New York / 14623		
Telephone No.:	585-943-5272	E-mail Address:	phil@jcs.com

**The Attachments for the Frechette.doc NCIMS Proposal for including micro-droplet formation in Section 7 of the PMO:**

**The Attachment document will be a single document to support the position for the proposal; it will include the following, and will be submitted to NCIMS before March 1<sup>st</sup>, 2015. If this is not an acceptable time frame please contact Philip R Frechette either by phone at cell=(585) 943-5272 or by e-mail at [phil@jcs.com](mailto:phil@jcs.com):**

Attachment Document will be a compilation document of multi documents into a single document that will include:

- Process Drawing of how the micro-droplet formation process will integrate into an HTST
- Process Drawing of how the micro-droplet formation process can be applied to Raw Milk prior to Pasteurization
- Mechanical Drawings of the micro-droplet formation process vessel
- Lab Documentation supporting the milk make up of milk at the inlet and discharge of the micro-droplet formation process
- Lab Results of Micro Challenge Test Runs of the micro-droplet formation process
- Lab Results of Shelf Life Studies of the micro-droplet formation process
- Sensory Report of product from the micro-droplet formation process
- NFL (Process Authority Document of Challenge Test ran by NFL)
- Purdue Food Science Center Documentation on multi Challenge Test Runs of micro-droplet formation process
- Hi Speed Photos of Droplets Formed
- Any other pertinent Documentation



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 102

Committee:

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

**A. Summary of Proposal**

To recognize somatic cell count (SCC) limit for cow (Bovine) milk of >400,000/ml

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

The NCIMS reduced the SCC several years ago to 750,000/ml. The delegates were given ample data and information that the reduction from 1,000,000/ml of SCC to 750,000/ml of SCC was an acceptable and safe level for human consumption. Health problems for both humans and the cow herd were reduced by maintaining this level.

There are import restrictions of various buying countries to accept American milk products produced from herds with a standard of >400,000 SCC. The European Union and other importing entities demand that their purchased milk products be produced from milk of  $\leq 400,000$  SCC. That is their prerogative to request a quality of raw milk to make a final product. The “seller” of that product should meet that quality request. The importing countries allow for various mathematical formulas to be used to allow >400,000 SCC/ml milk to be utilized. The American cooperatives/processors can implement these formulas. They can give incentives for lower SCC produced milk or penalties for >400,000 SCC produced milk from their cooperative members/independent shippers.

The NCIMS delegates, composed of health agencies and agriculture departments, have not accepted prior proposals (NCIMS 2011 & 2013) to make  $\leq 400,000$  SCC/ml a health standard. The delegate consensus may have been that this is a marketing issue, not a health/sanitation issue. Some references from the NCIMS Grade A documents:

The fifth paragraph of the *Grade A Pasteurized Milk Ordinance, 2013 Edition, Preface, page iv*, states, “The *Grade “A” PMO* is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the Public Health Agencies, the milk industry, and many others as the national standard for milk sanitation. The *Grade “A” PMO* adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either Regulatory Agencies or the dairy industry. It represents a “grass-roots” consensus of current knowledge and experiences as such represents a practical and equitable milk sanitation standard for the nation.”

The fourth paragraph of the *Grade A Pasteurized Milk Ordinance, 2013 Edition, Introduction, Section 3, page vii*, states, “This model *Ordinance* discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high quality milk from other milk sheds. (Refer to Section 11.) On repeated requests from the Association of State and Territorial Health Officers and the NCIMS, the USPHS/FDA is actively cooperating in the voluntary program for the Certification of Interstate Milk Shippers. Such a program would be impossible without widespread agreement on uniform standards, such as those of this recommended *Ordinance*.”

The first paragraph of the *Methods of Making Sanitation Ratings of Milk Shippers, 2013 Edition, Preface, page i*, states, “The objective of a rating is to provide an assessment of the Regulatory Agency’s sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the *Grade “A” Pasteurized Milk Ordinance (Grade “A” PMO)* and Related Documents as listed in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)*. Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance and with public health standards as expressed in the *Grade “A” PMO.....*”

The third paragraph of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2013 Edition, Preface, page i*, states, “The procedures accepted by the first Conference in 1950 have been used to advantage by many States in developing sound, and more uniform, milk sanitation programs.....”

All fifty states have adopted the *PMO*, the *Procedures* document and *Methods of Making Sanitation Ratings of Milk Shippers*, or portions thereof, to allow the shipment of milk and milk products between states and territories. In the references stated above, all refer to sanitation regulations of milk and milk products of high quality. The milk and milk products of the United States are recognized as the safest in the world. It has been brought to the attention of the NCIMS that the EU (and other countries) will only accept US milk and milk products that meet their standard of  $\leq 400,000$  SCC/ml for producer milk. Various derogation methods have been put in use by the USDA to allow acceptance of certain higher monthly SCC of individual producers. To date, the system must be meeting the buyers’ demands.

This standard can be enforced by the cooperatives and by private processors with delegated

producer shippers. The US processing industry wants the NCIMS to establish a new SCC standard to ease the movement of processed products to various foreign lands. The 400,000 SCC/ml limit for raw milk has not been established as a human health risk. The health, food sanitation, and milk sanitation departments across the US should not be enforcing a sanitary standard that has not been established without illness/death records, shelf life loss, or equipment deterioration. Also, the health, food sanitation, or milk sanitation departments across the US should not be issuing warnings or suspending permits using the 400,000 SCC/ml standard.

One solution, although not enforceable against permits, would be to notify milk marketing agencies when official monthly sample results from producers exceed the 400,000 SCC/ml buyer standard.

**C. Proposed Solution**

Changes to be made on page(s):		33 and 34	of the (X - one of the following):
<input checked="" type="checkbox"/>	2013 PMO		2011 EML
<input type="checkbox"/>	2013 MMSR		2400 Forms
<input type="checkbox"/>	2013 Procedures		2013 Constitution and Bylaws

Page 33, top half of page: Somatic Cell Count\* & \*\*\*\*\*  
 Page 34, bottom text: \*\*\*\*\* Official sample results of bovine milk with SCC >400,000/ml must be sent to producer's cooperative or processor.

Name: Alf Reeb

Agency/Organization: New Mexico Department of Agriculture

Address: 2604 Aztec, NE

City/State/Zip: Albuquerque, NM 87107

Telephone No.: 505-841-9425      E-mail Address: areeb@nmda.nmsu.edu



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 103

Committee:

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

**A. Summary of Proposal**

Lower the PMO somatic cell count requirement from 750,000 per mL to 400,000 per mL.

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

Export of dairy products has become a significant portion of the US Dairy Market. Exports currently utilize approximately 16% of the US milk supply.

Companies that export product to the European Union (EU), and other locations that have adopted EU Standards, must complete paperwork to certify that all milk utilized in the exported product(s) meets the 400,000 / mL somatic cell count standard. This places an unnecessary burden on companies desiring to do export business.

Lowering the somatic cell count to 400,000 /mL will improve raw milk quality and dairy cow health, while relieving US dairy exporters of the burden to provide additional documentation when exporting product.

**C. Proposed Solution**

Changes to be made on page(s): XVI, Section 7 p33-34, Appendix E p.212, Appendix P p.380 of the (X - one of the following):

- |                                   |  |
|-----------------------------------|--|
| <u>  X  </u> 2013 PMO             | <u>          </u> 2011 EML                     |
| <u>          </u> 2013 MMSR       | <u>          </u> 2400 Forms                   |
| <u>          </u> 2013 Procedures | <u>          </u> 2013 Constitution and Bylaws |

***Make the following change to the 2013 PMO.***

**2013 PMO  
TABLES, PAGE XVI**

- Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examination for Cattle .....  
(Effective January 1, 2016).....  
 Table 12A. Example of Enforcement Procedures for Raw Milk Laboratory Examination for Cattle (Effective January 1, 2017).....  
 Table 13. Sieve Sizes and Designations.....  
 .....

**2013 PMO  
SECTION 7-TABLE 1, PAGES 33-34**

- .....  
 Somatic Cell Count\*... Individual producer milk not to exceed ~~750,000 per mL~~ 600,000 per mL (effective January 1, 2016); and 400,000 per mL (effective January 1, 2017).  
 .....
- .....  
 \* Goat Milk 1,500,000/mL; and Sheep, Water Buffalo and Camel Milk 750,000/mL.  
 .....

**2013 PMO  
APPENDIX E, PAGE 212**

**Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations for Cattle (Effective January 1, 2016)**

Date	Confirmed Somatic Cell Counts per mL	Enforcement Action as Applied to a Standard of <del>750,000</del> <u>600,000</u> per mL
<del>7/10/2013</del> <u>7/10/2016</u>	500,000	No Action Required
<del>8/15/2013</del> <u>8/15/2016</u>	<del>600,000</del> <u>500,000</u>	No Action Required
<del>10/1/2013</del> <u>10/1/2016</u>	<del>800,000</del> <u>700,000</u>	Violative; No Action Required
<u>11/7/2016</u>	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
<del>11/14/2013</del> <u>11/14/2016</u>	1,200,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as <u>a</u> Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this <i>Ordinance</i> . Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i> . (Refer to Section 3.)
<del>11/18/2013</del> <u>11/18/2016</u>	<del>700,000</del> <u>550,000</u>	Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule as cited under <del>11/14/2013-11/14/2016</del> .
<del>11/20/2013</del> <u>11/20/2016</u>	800,000	Violative; No Action Required <b>NOTE:</b> Samples collected prior to <del>11/18/2013</del> <u>11/18/2016</u> are not used for subsequent somatic cell count enforcement purposes.
<del>11/24/2013</del> <u>11/24/2016</u>	<del>700,000</del> <u>550,000</u>	No Action Required
<del>11/29/2013</del> <u>11/29/2016</u>	550,000	No Action Required
<del>12/3/2013</del> <u>12/3/2016</u>	400,000	Permit Fully Reinstated

**Table 12A. Example of Enforcement Procedures for Raw Milk Laboratory Examinations for Cattle (Effective January 1, 2017)**

<u>Date</u>	<u>Confirmed Somatic Cell Counts per mL</u>	<u>Enforcement Action as Applied to a Standard of 400,000 per <del>M</del> mL</u>
<u>7/10/2017</u>	<u>300,000</u>	<u>No Action Required</u>
<u>8/15/2017</u>	<u>400,000</u>	<u>No Action Required</u>
<u>10/1/2017</u>	<u>600,000</u>	<u>Violative; No Action Required</u>
<u>11/7/2017</u>	<u>900,000</u>	<u>Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.</u>
<u>11/14/2017</u>	<u>1,200,000</u>	<u>Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as a Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this Ordinance. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this Ordinance. (Refer to Section 3.)</u>
<u>11/18/2017</u>	<u>350,000</u>	<u>Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule as cited under 11/14/2017.</u>
<u>11/20/2017</u>	<u>800,000</u>	<u>Violative; No Action Required NOTE: Samples collected prior to 11/18/2017 are not used for subsequent somatic cell count enforcement purposes.</u>
<u>11/24/2017</u>	<u>350,000</u>	<u>No Action Required</u>
<u>11/29/2017</u>	<u>350,000</u>	<u>No Action Required</u>
<u>12/3/2017</u>	<u>400,000</u>	<u>Permit Fully Reinstated</u>

*NOTE: Authorize FDA editorial license to delete the Table(s) cited above in future revisions of the PMO when they have reached their expiration date and the next lower SCC level has reached it's effective date.*

**2013 PMO  
APPENDIX P, PAGES 380-381**

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

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

1. No more than one (1) sample with a Standard Plate Count (SPC) >25,000, but less than 100,000;
2. All Somatic Cell Count (SCC) samples  $\leq$  ~~500,000~~ 400,000 (effective January 1, 2016);  
.....

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

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

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

1. May have more than one (1) sample with SPC >25,000;
2. May have one (1) or more SCC sample  $>$  ~~500,000~~ 400,000 (effective January 1, 2016)  
.....

Name:	Cary Frye		
Agency/Organization:	International Dairy Foods Association		
Address:	1250 H St. NW Suite 900		
City/State/Zip:	Washington, DC 20005		
Telephone No.:	(202) 220-3543	E-mail Address:	cfrye@idfa.org



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 104

Committee:

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

**A. Summary of Proposal**

To add consistency to the coliform requirements for Grade A bulk shipped condensed whey and/or whey products as is other bulk shipped Grade A products

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

In Table 1 Chemical, Physical, Bacteriological, and Temperature Standards on pages 33 and 34 of the 2013 PMO allows the coliform standard of bulk shipped products to not exceed 100 per ml. In the case of Grade A Pasteurized Condensed whey and/or whey products this allowance is not present. This will bring consistency to all Grade A products bulk shipped in the PMO.

**C. Proposed Solution**

Changes to be made on page(s): 34 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

Table 1 Chemical, Physical.....

GRADE "A" PASTEURIZED CONDENSED WHEY AND/OR WHEY PRODUCTS	Temperature.....	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit.....	Not to exceed 10 per gram. <i>Provided, that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.</i>

Name:	Mike Wiggs		
Agency/Organization:	Idaho Department of Agriculture		
Address:	2270 Old Penitentiary Rd.		
City/State/Zip:	Boise, Idaho 83712		
Telephone No.:	208-332-8550	E-mail Address:	mike.wiggs@agri.idaho.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 105

Committee:

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

**A. Summary of Proposal**

To remove out dated or not needed language.

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

I do not know of a dairy that does, is going to, or that is checked to see if they scrub the floor of the barn, none the less with a stiff-bristle brush. The word "should" gives some leeway, but language stating the floor of the barn should be kept free of soil would be better.

**C. Proposed Solution**

Changes to be made on page(s): 38 of the (X - one of the following):

- 2013 PMO                       2011 EML  
 2013 MMSR                       2400 Forms  
 2013 Procedures                       2013 Constitution and Bylaws

Modify the 2013 PMO, page 38 Item 3r.

The method of cleaning is immaterial. Dairy operators whose barns are provided with water under pressure should ~~scrub the floors after each milking with a stiff bristled brush.~~ remove

the soil from the floor after each milking. In barns in which water under pressure is not available, the floors may be brushed-dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the sanitarian should require cleaning with water

Name:	Kelly Bench		
Agency/Organization:			
Address:	4438 Oak Rd		
City/State/Zip:	Ontario, Oregon 97914		
Telephone No.:	541-889-9285	E-mail Address:	Kbenchequip@q.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 106

Committee:

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

**A. Summary of Proposal**

Remove the requirement for a two (2) compartment wash vat from the 2013 PMO.

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

A two (2) compartment wash vat is not being used as such in the milk room. The CIP system uses one compartment of a wash vat or utilizes the receiver jar for the wash vat. Small parts are washed in the single compartment of the wash vat in the agitation of the CIP system or the milk tank CIP system.

There is no point enforcing the two (2) compartment wash vat “shall” as the second compartment is only used as a storage container and often a catch-all. The receiver jar would be the one compartment wash vat.

**C. Proposed Solution**

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

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

Modify the 2013 PMO, page 40, Milk House- Construction and Facilities, Item5r.

The milkhouse shall be equipped with a ~~two (2) compartment wash vat~~ and adequate hot water heating facilities. one (1) compartment wash vat, or a CIP in-line reservoir such as a receiver jar.

Name:	Kelly Bench		
Agency/Organization:			
Address:	4438 Oak Rd		
City/State/Zip:	Ontario, Oregon 97914		
Telephone No.:	541-889-9285	E-mail Address:	kbenchequip@q.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 107

Committee:

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

**A. Summary of Proposal**

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

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

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

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

**C. Proposed Solution**

Changes to be made on page(s): 42 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

Modify the 2013 PMO, page 42, Item 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES, ADMINISTRATIVE PROCEDURES

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

Name:	Warren Taylor, Vincent Taylor, Steve Ferreira		
Agency/Organization:	Snowville Creamery LLC, Daisy Brand, Steve Ferreira Consulting		
Address:	32623 OH-143		
City/State/Zip:	Pomeroy, Ohio 45769		
Telephone No.:	740-698-2340	E-mail Address:	info@snowvillecreamery.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 108

Committee:

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

**A. Summary of Proposal**

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

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

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

**C. Proposed Solution**

Changes to be made on page(s): 42 of the (X - one of the following):

X 2013 PMO

2011 EML

2013 MMSR	2400 Forms
2013 Procedures	2013 Constitution and Bylaws

Modify the 2013 PMO, page 42, Item 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES, ADMINISTRATIVE PROCEDURES

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

Name:	Warren Taylor, Vincent Taylor, Steve Ferreira	
Agency/Organization:	Snowville Creamery LLC, Daisy Brand, Steve Ferreira Consulting	
Address:	32623 OH-143	
City/State/Zip:	Pomeroy, Ohio 45769	
Telephone No.:	740-698-2340	E-mail Address: info@snowvillecreamery.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	109
Committee:	Scientific Advisory/Other Species

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

**A. Summary of Proposal**

A proposal to exempt raw goat milk storage/ holding tank from the seventy-two (72) hour cleaning requirement allowing raw goat milk to be stored in a farm milk storage/holding tank for a maximum of seven (7) days. Raw goat milk storage/holding tanks shall be clean and sanitized when emptied. Partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device compliant with the specifications of Appendix H.

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

Current industry practices allow for the storage of raw goat milk in a farm milk storage/holding tank for up to seven (7) days without the tank being cleaned and sanitized every seventy-two (72) hours. Official standard plate counts on raw goat milk support that raw goat milk can be safely stored for this period of time and not violate the standards set in the PMO.

**C. Proposed Solution**

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

- X 2013 PMO
- 2011 EML

2013 MMSR	2400 Forms
2013 Procedures	2013 Constitution and Bylaws

3. There shall not be any partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device complying with the specifications of Appendix H. or other recording device acceptable to the Regulatory Agency, provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every seventy-two (72) hours\*. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency.

\* Raw goat milk may be stored in a farm milk storage/holding tank for up to seven (7) days without the tank being emptied, cleaned and sanitized every seventy-two (72) hours.

Name:	Terrance Philibeck, Food & Dairy Deputy Director		
Agency/Organization:	Michigan Department of Agriculture & Rural Development		
Address:	525 W. Allegan Street		
City/State/Zip:	Lansing, MI 48909		
Telephone No.:	517284-5699	E-mail Address:	Philibeckt1@michigan.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 110

Committee:

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

**A. Summary of Proposal**

To eliminate the requirement to maintain a complete separation between the milking area and cattle housing area due to milking equipment being cleaned and stored in the milking area, on a year around basis rather than on a seasonal basis. On modern dairy facilities proper ventilation in the milking parlor and covered holding areas can be achieved and maintained at all times of the year with the use of various facility ventilation systems.

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

Code# M-1-03-13 of the Index of Memoranda of Information states that “Generally, if milking equipment is being cleaned and stored in the milking area, it is required to maintain a complete separation between the milking area and cattle housing area. However, with this new language, on a seasonal basis only, the milking parlor may be directly connected to the cattle housing area through a completely enclosed holding area if all the requirements listed above are met and being maintained.” Meaning that a division is not necessary during mild weather months when the sides of the holding area are open.

Modern dairy facilities which are power ventilated, cross ventilated or robot barns have the ability through positive pressure ventilation, negative pressure ventilation, or a combination of both positive and negative pressure ventilation systems on a year around basis to maintain frequent air exchange and adequate air quality in the milking parlor. Fans in the covered holding area and cattle housing areas provide the CFMs needed to maintain adequate air quality in those areas as well as the milking parlor even with very minimal air inlet areas.

**C. Proposed Solution**

Changes to be made on page(s):		Pages 51 and 52	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

Modify the 2013 PMO, pages 51 and 52, Section 7, Standards for Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed After Packaging, Item 12r, Utensils and Equipment-Storage.

2. The milking barn or parlor shall be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:
  - a. There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.
  - b. The cattle holding and housing areas are maintained in good repair and reasonably clean.
  - c. With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds,
  - d. A complete separation between the milking area and cattle housing area is not required when the facility is able to maintain frequent air exchange and adequate air quality in the parlor and covered holding area through positive pressure ventilation, negative pressure ventilation or a combination of both positive and negative pressure ventilation.

In addition, construction and cleanliness items identified above shall be evaluated in the appropriate *Ordinance* Sections.

Name:	Shannon Houselog		
Agency/Organization:	Global Dairy, LP		
Address:	46844 SD Hwy 28		
City/State/Zip:	Estelline, South Dakota 57234		
Telephone No.:	605-690-1517	E-mail Address:	global@itctel.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 111  
Committee: Hauling

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

**A. Summary of Proposal**

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

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

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

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

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

**C. Proposed Solution**

Changes to be made on page(s):		58 and 59	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

Modify the 2013 PMO page 58, ITEM 18r. RAW MILK COOLING

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

Modify the 2013 PMO page 59, ITEM 18r. RAW MILK COOLING

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

Name:	Warren Taylor, Vincent Taylor, Steve Ferreira		
Agency/Organization:	Snowville Creamery LLC, Daisy Brand, Steve Ferreira Consulting		
Address:	32623 OH-143		
City/State/Zip:	Pomeroy, Ohio 45769		
Telephone No.:	740-698-2340	E-mail Address:	Info@snowvillecreamery.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 112

Committee:

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

**A. Summary of Proposal**

To specify the applicable requirements of electronic data collection and storage in Appendix H, IV and V for 18r Raw Milk Cooling.

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

18r, Administrative Procedure #3 references Appendix H., IV and V as the requirements to utilize electronic records for farm bulk milk tanks, but does not specify what criteria within those sections are required. Most of the criteria within Appendix H apply to milk plants.

This proposal seeks to clarify the requirements and criteria needed for electronic records on dairy farm bulk milk storage tanks.

**C. Proposed Solution**

Changes to be made on page(s): 59 of the (X - one of the following):

<input checked="" type="checkbox"/> 2013 PMO	<input type="checkbox"/> 2011 EML
<input type="checkbox"/> 2013 MMSR	<input type="checkbox"/> 2400 Forms
<input type="checkbox"/> 2013 Procedures	<input type="checkbox"/> 2013 Constitution and Bylaws

**Modify the 2013 PMO, page 59, 18r. Administrative Procedure #3a.**

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

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

a. The temperature-recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap. Electronic records that comply with ~~the applicable provisions of Appendix H., IV, Temperature-Recording Devices Used in Storage Tanks, and Appendix H., V, Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting, Criteria 4, 9, 11 and 12,~~ with or without hard copy, may be used in place of temperature-recording records.

Name:	Brian Wise		
Agency/Organization:	Ohio Department of Agriculture – Dairy Division		
Address:	8995 E. Main Street		
City/State/Zip:	Reynoldsburg, OH 43068		
Telephone No.:	614-466-5550	E-mail Address:	bwise@agri.ohio.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 113  
Committee: Hauling

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

**A. Summary of Proposal**

To ensure milk tank trucks are washed properly in a timely manner.

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

To establish additional requirements for sanitary transportation practices ensuring safety of food transported in milk tank trucks. The goal is to increase assurances that transportation practices do not create food safety risks due to lack of cleaning facilities to properly clean vehicles between loads. This proposal better ensures that milk trucks will be properly sanitized as specified in the PMO to maintain health and safety standards. The proposed rule builds on current safe food transport practices and is focused on ensuring that persons engaged in the transportation of Grade 'A' milk have the ability to utilize sanitary practices at facilities where unloading is disseminated. In an effort to address prevention of food safety problems in the transportation of milk, it is of utmost importance to have a tank cleaned in a timely manner. Milk moves longer distances and milk tank trucks are not always able to find a tank wash facility within a reasonable distance from the unloading facility. Due to the length of time that tanks could be stationary and unsanitized, it would be proactive, for health and safety purposes, to have the tank given a CIP wash as soon as possible at any Grade A plant, transfer or receiving station that has the ability to wash a tank. This expedited process will ensure against bacteria growth buildup within the tank. The increased timeframe that a milk tank is empty with residue inside, the more difficult it is to clean, as well as an increase in the length of time to clean the tank. This change will help ensure sanitizing of a milk tank when a tank's wash tag is close to expiring. The PMO should be updated and modified to better align with the current mode of transportation of milk.

**C. Proposed Solution**

Changes to be made on page(s):		68	of the (X - one of the following):	
X	2013 PMO		2011 EML	
	2013 MMSR		2400 Forms	
	2013 Procedures		2013 Constitution and Bylaws	

NOTE: Appendix F. contains additional information on dry cleaning of drying equipment, packaging equipment, and dry milk product and dry whey storage containers.

All milk tank trucks that transport Grade "A" milk ~~and milk products~~, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility and is the responsibility of the Grade "A" plant or Grade "A" receiving station to wash and sanitize the milk tank truck in a timely manner. Arrangements may be made at an alternate approved IMS listed cleaning facility by the Grade "A" plant or receiving station to have the milk tank truck washed and remains the responsibility of the Grade "A" plant or receiving station. All milk tank trucks that transport Grade "A" milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. The milk tank truck hauler shall be responsible for the cleaning and sanitizing of the milk tank truck ~~cleaned and sanitized~~ prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank must be re-sanitized, and is the responsibility of the milk hauler.

Name:	Cherie Houser		
Agency/Organization:	International Milk Haulers Association		
Address:	5307 Indigo Way		
City/State/Zip:	Middleton, WI 53562		
Telephone No.:	608-354-7110	E-mail Address:	Cherie@milkhailer.org

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 114

Committee:

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

**A. Summary of Proposal**

This proposal would clarify, in the PMO, that sanitizing drying and dry product equipment is only necessary after the equipment has been wet cleaned.

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

There is some disagreement amongst regulators as to when dryers and dry product equipment is required to be sanitized. On page 217 of the 2013 PMO sanitizing of drying equipment is addressed, but only after wet cleaning. On page 218 and 219 of the PMO dry cleaning is addressed without mention of sanitizing. In these examples the PMO seems to indicate that sanitizing would only be required after wet cleaning. However, on page 75 of the 2013 PMO, in addressing the cleaning of drying equipment the PMO states the following:

“Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved by the Regulatory Agency.” In this example the PMO seems to indicate that sanitizing is required regardless of the type of cleaning method.

However, again on page 75 of the 2013 PMO, addressing dry product storage bins, the PMO states the following:

“Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage

and washed and sanitized at regular intervals.”

In this example the PMO seems to again indicate that sanitizing is only required after wet cleaning.

**C. Proposed Solution**

Changes to be made on page(s):		75	of the (X - one of the following):	
X	2013 PMO			2011 EML
	2013 MMSR			2400 Forms
	2013 Procedures			2013 Constitution and Bylaws

In the 4<sup>th</sup> line of the 2<sup>nd</sup> paragraph add the following:

After the word “After” add the word wet.

The sentence would then read as follows: After wet cleaning, such equipment is sanitized by a method approved by the Regulatory Agency.

Name:	Joe Dittrich		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, Minnesota 55155-2538		
Telephone No.:	651-932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 115

Committee:

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

**A. Summary of Proposal**

This proposal would clarify, in the PMO, that sanitizing drying and dry product equipment is necessary after the equipment has been either wet cleaned or dry cleaned.

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

There is some disagreement amongst regulators as to when dryers and dry product equipment is required to be sanitized. On page 217 of the 2013 PMO sanitizing of drying equipment is addressed, but only after wet cleaning. On page 218 and 219 of the PMO dry cleaning is addressed without mention of sanitizing. In these examples the PMO seems to indicate that sanitizing would only be required after wet cleaning. However, on page 75 of the 2013 PMO, in addressing the cleaning of drying equipment the PMO states the following:

“Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved by the Regulatory Agency.” In this example the PMO seems to indicate that sanitizing is required regardless of the type of cleaning method.

However, again on page 75 of the 2013 PMO, addressing dry product storage bins, the PMO states the following:

“Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.”

In this example the PMO seems to again indicate that sanitizing is only required after wet cleaning.

**C. Proposed Solution**

Changes to be made on page(s):		75	of the (X - one of the following):	
X	2013 PMO			2011 EML
	2013 MMSR			2400 Forms
	2013 Procedures			2013 Constitution and Bylaws

In the 4<sup>th</sup> line of the 2<sup>nd</sup> paragraph add the following:

After the word “After” add the words wet or dry

The sentence would then read as follows: After wet or dry cleaning, such equipment is sanitized by a method approved by the Regulatory Agency.

Name:	Joe Dittrich		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, Minnesota 55155-2538		
Telephone No.:	651-932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal: 116

Committee:

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

**A. Summary of Proposal**

This Proposal provides for the use of cheese cloth or strainer bags that are single use and constructed of non-toxic materials to be used for the purposes of straining whey during the production of yogurt within Item 15p-Protection from Contamination, Administrative Procedures #10 of the PMO.

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

By providing for the flexibility of using cheese cloth or strainer bags that are single use and constructed of non-toxic materials to be used for the purposes of straining whey during the production of yogurt this Proposal allows for a traditional yogurt processing method to be utilized.

**C. Proposed Solution**

Changes to be made on page(s): 83 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

**MAKE THE FOLLOWING CHANGES TO THE 2013 PMO.**

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

**ITEM 15p. PROTECTION FROM CONTAMINATION**

**ADMINISTRATIVE PROCEDURES**

Page 83:

10. Pasteurized milk and/or milk products are not strained or filtered, except through a perforated metal strainer. ~~Provided,~~ provided that:

a. ~~pasteurized~~ Pasteurized milk and/or milk products that are concentrated (condensed) in membrane processing systems may be filtered provided that a single service in-line filter that is sanitized after assembly, may be allowed if it is a part of the membrane processing system.

b. The use of cheese cloth or strainer bags that are single use and constructed of non-toxic materials may be utilized for the purpose of straining whey during the production of yogurt.

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
City/State/Zip:	College Park, MD 20740		
Telephone No.:	(240) 402-2175	E-mail Address:	Robert.Hennes@fda.hhs.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 117
Committee:

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

**A. Summary of Proposal**

Pasteurized Cream should not have to be re-pasteurized when bought from a second party to churn into butter.

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

Although butter is not regulated by the PMO, some states adopt the PMO to regulate other non-Grade A products like butter. There is no reason to re-pasteurize pasteurized cream for use in churning butter when it is delivered in single use aseptic packaging.

**C. Proposed Solution**

Changes to be made on page(s): 93 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2013 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

Amend section 16p (page 93) to add a new number 8.

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

**ADMINISTRATIVE PROCEDURES**

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

8. Pasteurized cream is exempt from re-pasteurization when transported to another plant location for churning into butter.

Name:	Brad Sinko		
Agency/Organization:	Face Rock Creamery		
Address:	680 2nd Street SE		
City/State/Zip:	Bandon, OR 97411		
Telephone No.:	206-399-7767	E-mail Address:	bsinko@facerockcreamery.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	118
Committee:	Scientific Advisory

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

**A. Summary of Proposal**

Modify ITEM 18p. BOTTLING, PACKAGING AND CONTAINER FILLING to permit the transfer of yogurt to a separate plant for retail/consumer packaging without requiring additional pasteurization, if the product can be transported in a sanitary manner and protected from contamination through to its final packaging.

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

Yogurt is inherently safe due to the low pH, lactic acid and live and active cultures. However, 18p does not permit yogurt to be transferred to another plant for packaging without pasteurization at the receiving plant, although cottage cheese and dry cottage cheese curds are permitted. Transferring and packaging of yogurt may be possible to do in ways that adequately control the risk of contamination. This process has been allowed and safely achieved for cottage cheese for many decades. It is notable that cottage cheese has a typical pH of 4.75-5.02, while yogurt is typically lower, around 4.6 or below.

It has been scientifically demonstrated that the innate properties of live and active culture yogurt, as it is generally produced in the U.S., effectively prevent the growth of the primary pathogenic bacteria of concern that could potentially be introduced post-pasteurization and culturing, namely *Listeria monocytogenes*, Shiga-toxigenic *E. coli* (e.g. serotype O157:H7), *Salmonella* spp., and *S. aureus*.<sup>1</sup> As Glass and Bishop show, a final product pH of 4.6 or below is the predominant factor controlling these organisms; however, metabolites produced during the fermentation by

<sup>1</sup> See Appendix 1: Glass, K.A. and J.R. Bishop. (2007) Factors That Contribute to the Microbial Safety of Commercial Yogurt. *Food Prot. Trends*; 27: 380-388.

*Streptococcus thermophilus* (ST) and *Lactobacillus bulgaricus* (LB) also contribute to the overall safety of yogurt. These metabolites include bacteriocins and hydrogen peroxide. In addition, utilization/consumption of available nutrients by the high populations of added starter culture bacteria further ensures that any pathogens introduced after fermentation has been completed are less likely to survive.

The risk of these organisms being introduced either at the original production plant or at the receiving plant can be effectively mitigated through the use of appropriate equipment, good manufacturing practices and environmental, sanitation and process controls as prescribed within the current PMO.

<b>C. Proposed Solution</b>		
Changes to be made on page(s):	119 & 136	of the (X - one of the following):
X	2013 PMO	2011 EML
	2013 MMSR	2400 Forms
	2013 Procedures	2013 Constitution and Bylaws

*First change: page 119, ITEM 18p., first para; insert a new footnote 12 and renumber the subsequent footnotes accordingly –*

“Bottling, packaging and container filling of milk and milk products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment. <sup>11, 12,</sup>”

*Second change: page 136; insert a new footnote 12 and renumber the subsequent footnotes accordingly –*

12. Provided, that yogurt, lowfat yogurt, nonfat yogurt, and yogurt that may have a nutrient content claim via 21 CFR §130.10, may be transported in sealed containers in a protected, sanitary manner from one (1) milk plant to another milk plant for final packaging. The administrative procedures of 18p requirements 2 – 11 continue to apply at both the shipping and receiving plants.

Name:	John Allan
Agency/Organization:	International Dairy Foods Association
Address:	1250 H St, NW, Suite 900
City/State/Zip:	Washington, DC 20005
Telephone No.:	202-737-4332
	E-mail Address: jallan@idfa.org

# Factors That Contribute to the Microbial Safety of Commercial Yogurt

KATHLEEN A. GLASS<sup>1</sup>\* and J. RUSSELL BISHOP<sup>2</sup>

<sup>1</sup>University of Wisconsin-Madison, Food Research Institute, 1925 Willow Drive, Madison, WI 53706, USA; <sup>2</sup>University of Wisconsin-Madison, Wisconsin Center for Dairy Research, 1605 Linden Drive, Madison, WI 53706, USA

## SUMMARY

Yogurt with active cultures, at pH of 4.6 or below, and processed in compliance with Good Manufacturing Practices prescribed by the United States Pasteurized Milk Ordinance, is inherently safe and does not support the growth of pathogenic organisms. More specifically, the safety of commercial yogurt is primarily dependent on the use of pasteurized milk to eliminate vegetative bacterial pathogens and spoilage microorganisms, good manufacturing practices and sanitary operating procedures to reduce the potential for recontamination, and a robust fermentation to produce sufficient acid and other antimicrobial metabolites to prevent growth of pathogens, should recontamination occur. High numbers of live and active starter culture organisms assure safety by generating acid and other antimicrobial metabolites during a short fermentation, preventing growth or causing death of pathogens. Chilling of the acid food to < 7°C within four hours after coagulating the milk (pH ~ 4.6) serves to reduce additional acid production and thus to prevent adverse flavor defects, control spoilage, and enhance quality. Data described in this review support the safety of current US industry practices for the production of commercial yogurt when pH values of the finished product is < 4.6 within 24 hours of filling.

## MANUFACTURING PRACTICES ENSURING THE SAFETY OF YOGURT

Standard commercial yogurt produced in the United States (defined in 21CFR 131.200, 131.203 and 131.206; 62) is inherently safe because of a number of contributing factors. United States regulations require use of pasteurized milk in yogurt production. Current industry practices typically exceed minimum thermal requirements by pasteurizing to 91°C for 40 to 60 seconds (HTST) or to 85°C for 30 minutes (vat). Heating milk and milk mixes to a high temperature denatures the whey proteins, which improves body and ensures destruction of indigenous thermotolerant microflora that may interfere with the rapid growth and acid production of the starter bacteria (31, 61, 64). Pasteurized homogenized milk or milk mix, and any stabilizers or sweeteners, are then cooled to 42 to 45°C in closed vats before concentrated starter culture is added to yield approximately 6 to 7-log CFU/ml or greater of each *Streptococcus thermophilus* (ST) and *Lactobacillus bulgaricus* (LB) culture. Product mixture may then be filled immediately for cup-set yogurt or vat-fermented before filling for blended-style. During the fermentation, regardless of product packaging, the population of yogurt starter culture increases 100- to 10,000 fold to a final concentration of approximately 9

A peer-reviewed article

\*Author for correspondence: 608.263.6935; Fax: 608.263.1114  
 E-mail: kglass@wisc.edu

log CFU/ml and generates lactic acid from the metabolism of lactose. The associated pH reduction causes a destabilization of the micellar casein at a pH of 5.1 – 5.2, with complete coagulation occurring around pH 4.6. At the desired final pH, the coagulated milk is cooled to 4–10°C to slow down the fermentation and retard further acid development. Cultures will continue to metabolize and produce acid after the yogurt is chilled to 7°C or less, although at a slower rate than in yogurt held at elevated temperatures (35).

## EFFECT OF SYNERGISTIC GROWTH OF ACTIVE STARTERS

Lactic acid bacteria starter cultures have long been used to ensure the safety of fermented foods because of their ability to compete with pathogens for nutrients, rapidly produce lactic and other acids to reduce pH, and generate other antimicrobial compounds such as acetaldehyde, diacetyl, hydrogen peroxide, and bacteriocins. If a food substrate is contaminated with high levels of pathogenic bacteria prior to fermentation, such as through cross contamination with raw ingredients, certain pathogens may initially be able to compete with the starter and grow. However, they will be inhibited or die when the level of lactic acid is sufficient to achieve a pH of 4.8 or less (2, 8, 51).

On the other hand, certain factors such as bacteriophages, illegal antibiotic residues, or salt content of 1% or greater inhibit the starter culture activity essential for production of fermented or cultured foods. If starter culture metabolism and the rate of lactic acid production is eliminated or significantly reduced, the resulting environment could permit pathogen growth and toxin production in recontaminated, unfermented substrate stored at ambient temperatures (see reviews 40, 57, 66).

In the case of commercial yogurt, high numbers of live and active ST and LB cultures assure safety through generation of acid and other antimicrobial metabolites during a short (typically 3 to 6 hours) fermentation at 42 to 45°C, thereby preventing growth or causing death of numerous pathogens. Chilling of the acid food to < 7°C after coagulation of the milk (pH ~4.6) serves to diminish

adverse flavor defects by reducing excessive acid production. However, rapid cooling (within 4 hours) does not appear to provide any safety advantage over the slow cooling (within 96 hours) currently practiced by US manufacturers because the higher levels of lactic acid production associated with extended fermentation provide an additional barrier to microbial growth.

Numerous studies have demonstrated that symbiotic growth of ST and LB results in greater acid production than when either strain is used individually (29, 35). Both thermophilic bacteria generate lactic acid by fermenting lactose. LB specifically demonstrates mild proteolytic activity in milk and is primarily responsible for production of flavor and aroma components (acetaldehyde, acetone, acetoin, and diacetyl) (6). During the early stages of fermentation, the amino acids released by the proteolysis of casein stimulate growth of ST. The coccus begins to grow faster than the rod and is responsible for the primary acid production. ST utilizes excess oxygen and produces carbon dioxide and formic acid, which in turn stimulates growth of LB. As the acid concentration increases and the pH decreases from 4.4 to 4.2, ST growth is inhibited, but the lactobacilli continue to grow and produce acid until the substrate reaches pH 3.5 to 3.8.

The synergistic growth of ST and LB is important not only to the physical, chemical, and sensory characteristics of yogurt, but also to its safety. Dineen et al. reported that *E. coli* O157:H7 was more sensitive to the inhibitory properties exerted by *L. bulgaricus* than to those of *S. thermophilus* but that co-culture of ST-LB reduced populations of *E. coli* O157:H7 more than either culture used alone (15).

## EFFECT OF ACIDITY

Although the use of Good Manufacturing Practices (GMPs) and proper processing are integral to food safety, the acidity of yogurt is a significant factor in inhibiting and inactivating bacterial pathogens should the product be inadvertently recontaminated and stored at non-refrigerator temperatures. Pathogens can survive in yogurt for extended periods if post-fermentation contamination occurs, regardless of storage temperature (see results from Challenge Studies sec-

tion, following). However, as total acidity increases, survival time decreases (38).

Low pH, by itself, decreases the activity of bacterial enzymes and transport systems. Other factors, such as type of acid and total acidity as well as buffering capacity of the substrate, are also pertinent to bacterial survival and growth capabilities (10, 29). In addition, the lag phase for a microorganism increases if the pH of the substrate is outside the range of optimal growth pH (29). For example, the minimum pH for growth in laboratory media under otherwise ideal conditions for *S. aureus* is 4.0 to 4.3 when inorganic acids are used; range is much higher (pH 4.9 to 5.1) with use of organic acids such as lactic or acetic acid (27, 37, 39, 57). In acidified pasteurized milk stored at 37°C for 24 hours, populations of *S. aureus* decreased > 2 logs in milk acidified to pH 4.5 with lactic acid, but grew > 2.5 log in milk acidified with HCl to the same pH value (58). The pH requirements are more stringent for toxin production than for growth, with the minimum pH for staphylococcal enterotoxin production reported to be 5.1 (53). Enterotoxin production, like growth, is inhibited more effectively when the pH is reduced by lactic acid rather than by hydrochloric acid (42).

Spores of pathogens such as *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens* survive pasteurization. However, they are unlikely to grow at pH < 4.8 when stored at or below typical room temperatures. The USDA-ARS Pathogen Modeling Program 7.0 predicts probability < 0.01 for growth of *C. botulinum* at 20°C through 29 days in laboratory media acidified to pH 4.8 (60). Minimum pH for growth of common *B. cereus* strains is 4.8 in media acidified with HCl or 5.6 in media acidified with lactic acid; the organism is reported to die suddenly in yogurt when the pH reaches 4.5 (27, 42). *C. perfringens* growth is limited at pH 5.5, and the organism is reported to be inactivated after several days at pH 5.0 (27, 42).

## EFFECT OF OTHER METABOLITES

In addition to generating lactic acid, the two primary starter cultures required by the Standard of Identity for yogurt (21 CFR 131.200, 131.203 and 131.206, *S. thermophilus* and *L. bulgaricus*) are known to generate other

antimicrobial metabolites (62). Gilliland and Speck demonstrated that lactic streptococci reduced growth of *Salmonella* and *S. aureus* in milk, even when the pH was maintained at pH 6.6 during starter growth (20). These researchers, as well as many others, have reported that metabolites such as hydrogen peroxide, bacteriocins, acetaldehyde, and diacetyl, are antagonistic to bacterial pathogens and spoilage microorganisms (1, 4, 13, 14, 20, 28, 30).

Hydrogen peroxide is a toxic reduction product of molecular oxygen, which inhibits *S. aureus* and other pathogens (2, 13, 14; see review 19). Diacetyl inhibited growth of *E. coli* O157:H7 and *Salmonella* Typhimurium when added to laboratory media at a concentration of 50 ppm (30). Acetaldehyde (at 500–1000 ppm) has been shown to be inhibitory to other lactic acid starter or probiotic bacteria (66). Levels of these compounds produced by LB cultured alone are lower than those typically considered sufficient for antimicrobial activity individually (32). However, studies have shown that when LB is co-cultured with ST in yogurt, 1400–1700 ppm acetaldehyde and 165–200 ppm diacetyl can be produced (7).

Based on a study that neutralized hydrogen peroxide and acid produced by ST-LB cultures in yogurt, Attaie et al. suggested that bacteriocin or other antimicrobial production by ST and LB may also contribute to the inhibition of *S. aureus* (2). Numerous bacteriocins that are effective against pathogenic and spoilage bacteria are produced by ST and LB, as well as by adjunct starters (4). Most are active at the low pH values associated with yogurt (10). Several strains of ST produce the bacteriocin thermophilin, which has activity against Gram-positive bacteria such as *L. monocytogenes* and *Clostridium tyrobutyricum* (36, 65). Adjunct lactic acid bacteria, such as *L. acidophilus*, have been shown to produce the bacteriocin acidophilin, which inhibits *S. aureus*, *E. coli*, *Pseudomonas fluorescens*, and *P. fragi* (2, 54, 55). Other research demonstrates greater kill of *S. aureus* and *L. monocytogenes* during yogurt fermentation and storage at 4 or 22°C when a bacteriocin-producing ST was used, rather than a starter that did not produce bacteriocins (5; N. Benkerroum, personal communication, April 4, 2005).

## INTERNATIONAL OUTBREAKS ASSOCIATED WITH CONTAMINATED YOGURT

To date, no recognized foodborne disease outbreaks have been associated with yogurt in the United States. The enviable record of safety is due primarily to the consistent use of multiple safeguards, including proper GMPs (production in a sanitary environment, use of safe and suitable ingredients such as pasteurized milk) and use of active starter cultures for essential acid development. In contrast, each of the outbreaks associated with contaminated yogurt that have been reported in other countries in the past two decades were associated with improper processing, contamination with raw milk, and/or inadequate acid production (9, 12, 41, 42, 44, 63).

In the United Kingdom, 27 cases of botulism, including 1 death, were associated with the consumption of yogurt that contained insufficient thermally-processed hazelnut puree. Although yogurt itself had been manufactured properly, the preformed botulinum toxin in the contaminated hazelnut puree was stable at the low pH of the product during refrigerated storage (12, 44). Investigations into several outbreaks of *Salmonella* and *E. coli* O157:H7 in the UK, Scotland, and British Columbia similarly revealed violations of good manufacturing practices. Improper practices included using a single pump for transferring raw milk and distributing pasteurized milk for fermentation without intermediate disinfection, failure to record time/temperature for pasteurization, and overall poor hygienic practices (9, 17, 41, 63). Two outbreaks of staphylococcal enterotoxin poisoning, resulting in a total of 47 cases, were reported to New Zealand authorities and linked to yogurt made in institutional kitchens (42). Both outbreaks were attributed to contamination of food by handlers and to slow growth of yogurt starter culture due to fermentation at room temperature (approximately 25°C) rather than at the prescribed 42 to 45°C necessary for rapid acid development (R. Whyte, Institute of Environmental Science & Research Limited, New Zealand, personal communication, April 4, 2005).

## VERIFICATION OF YOGURT SAFETY BY CHALLENGE STUDIES

Numerous studies have evaluated the survival of pathogens during production and storage of yogurt; however, all conditions have not been tested for each pathogen. Table 1 summarizes inactivation or survival rates for pathogens in yogurt at various temperatures from representative studies. In all reported studies, pathogens died in yogurt with pH ≤ 4.6, in contrast to the growth predicted at pH 4.6 with use of the USDA-ARS Pathogen Modeling Program 7.0 (60). As described above, the enhanced inhibitory properties of yogurt compared with laboratory media are due to several factors: lactic acid as the predominant acid, generation of antimicrobial metabolites, and active competition of the starter cultures with pathogens for nutrients.

Few pathogenic bacteria are able to survive extended periods in the harsh, acidic environment of yogurt. Although the pH of commercial yogurt is generally less than 4.4, some unusual varieties may have pH values that exceed 4.6. Data from multiple challenge studies suggest that if the pH is < 4.6 within 24 hours of the beginning of fermentation, the probability of pathogen growth in yogurt at the non-standard pH values is very low.

The enteric pathogen *E. coli* O157:H7 is noted to be particularly acid resistant (16) and therefore would pose the greatest risk of extended survival in yogurt. Factors that would control growth or survival of *E. coli* O157:H7 should be sufficient to ensure the overall safety of these products with regard to other pathogens. Any potential risks associated with *E. coli* O157:H7 can be mitigated by standard pasteurization of raw ingredients to eliminate the pathogens and good manufacturing practices to prevent any recontamination of the milk (9, 41). However, numerous research studies have demonstrated that, should the product be inadvertently contaminated, fermentation by the ST-LB culture and prolonged exposure to the high-acid environment (pH ≤ 4.6) provide an additional hurdle to inactivate pathogens, especially when the product is stored at non-refrigeration temperatures. Research conducted using other acidic foods, such as apple cider and

**TABLE 1. Pathogen inactivation in yogurt, minimum pH values for pathogen growth, and predicted growth potential in laboratory media adjusted with HCl to pH 4.6 and with no competitive microflora**

	Modeled time to 1-log increase to pH 4.6 laboratory media at 20°C <sup>a</sup>	Yogurt storage temperature	Initial pH	Log reduction (time) in pH < 4.6 <sup>b</sup> yogurt	Ref.
<i>L. monocytogenes</i>	2.85 days	4°C	4.54	4 (12 wk)	52
		4°C	4.44	4 (3 wk)	52
		4°C	4.19	3 (2 wk)	52
		4°C	4.02	2 (1 wk)	52
		8°C	4.35 to 4.52	2 to 3.5 (28 d)	59
		4°C	3.8 to 4.1	4 (13 to 27 d)	11
<i>S. aureus</i>	3.18 days	7°C	4.3	2 (10 d)	5
		7°C	3.7 to 4.1	2 to 3 (1 d)	38
		23°C	3.7 to 4.1	2 to 3 (1 d)	38
<i>Salmonella</i>	not modeled	42°C	4.54	3 (6 h)	49
		37°C	3.85	6 (1 h)	49
<i>E. coli</i> O157:H7	0.88 days	4°C	4.65	0.8 (7 d)	25
		4°C	4.65	>3 (35 d)	25
		12°C	4.65	1.0 (7 d)	25
		12°C	4.65	>3 (35 d)	25
		4°C	4.47	4 (16 d)	26
		10°C	4.47	4 (13 d)	26
		4°C	4.4 to 4.5	1 to 2 (7 d)	34
		4°C	4.39	6 (17 d)	26
		10°C	4.39	6 (15 d)	26
		4°C	4.2	1 (5 d)	43
		25°C	4.2	5 (48 h)	43
		4°C	4.17	6 (8 d)	26
		10°C	4.17	6 (5 d)	26
		4°C	4.1	0.8 (72 h)	3
8°C	4.1	2.7 (72 h)	3		
17°C	4.1	3 (72 h)	3		
22°C	4.1	4 (74 h)	3		

<sup>a</sup>Based on Pathogen Modeling Program 7.0 (60)

<sup>b</sup>Based on yogurt fermented at 42°C with standard ST-LB starter cultures

mayonnaise, further supports the contention that *E. coli* O157:H7 demonstrates lower tolerance of acid conditions when held at ambient temperatures than when refrigerated (7, 67). Multiple challenge studies in yogurt confirm that acid content and temperature both have effects on pathogen survival.

Hudson et al. suggested that survival of *E. coli* O157:H7 in commercial yogurt with live cultures was dependent on both pH and storage temperature (26). Shorter survival times were reported in yogurt with initial pH of 4.17 than yogurt at pH 4.39 or 4.47. Similarly, at any given pH,

pathogen viability was lower in yogurt stored at 10°C than at 4°C. Populations of *E. coli* O157:H7 decreased 6 log units, to undetectable levels, within 5 and 8 days at 10 and 4°C respectively for yogurt with pH 4.17, within 7 and 15 days at 10 and 4°C respectively for yogurt with pH 4.39, and within 17 days at both 10 and 4°C for yogurt with pH 4.47. Similar trends were observed for strawberry-flavored full-fat and nonfat yogurt (21). Populations of *E. coli* O157:H7 decreased by > 2.5 and 1 log CFU/g after two weeks in nonfat and full-fat yogurt, respectively, when cooled slowly from 27 to 7°C over 96

hours and then held at 7°C. The pathogen was more stable in products stored at a constant 7°C, with approximately 0.7 log decrease for both yogurt types at the end of the two-week testing interval. The pH values of the products decreased from an initial 4.4 to 4.2 when stored at a constant 7°C, whereas the products that were cooled slowly had final pH values of approximately 4.1 due to extended acid production.

Govaris et al. (22) inoculated milk with ST-LB starter culture and 4.8 log *E. coli* O157:H7 prior to preparation of set yogurt (22). Products were fermented

at 42°C for 3 hours to coagulate the milk and then stored at 4 or 12°C. Populations of *E. coli* O157:H7 decreased approximately 1 log unit during the fermentation to pH 4.4 and to undetectable levels in yogurt after 5 and 7 days storage at 12 and 4°C, respectively.

Bachrouri et al. (3) similarly observed accelerated inactivation at higher storage temperatures. The researchers inoculated finished, retail, plain yogurt (with live ST-LB cultures; initial pH 4.1) with > 4 log CFU *E. coli* O157:H7 per g yogurt and stored the product at 4, 8, 17, and 22°C (3). Populations of *E. coli* O157:H7 decreased 0.8 and 2.7 log in yogurt stored 72 hours at 4 and 8°C, respectively. Storage at ambient temperatures increased the death rate, yielding a 3 and 4 log decrease in yogurt stored at 17 and 22°C, respectively.

Ogwara et al. (43) compared the behavior of *E. coli* O157:H7 in African yogurt and in recontaminated milk fermented at 43, 37, 30, and 25°C, and then stored at 4 or 25°C (43). Data revealed that in spite of the recontamination, *E. coli* O157:H7 did not grow in milk rapidly fermented at 43°C (final pH 4.0 at 24 h), but did increase in recontaminated milk during slow fermentation at the lower temperatures (final pH at 24 h was 5.1, 4.6, and 4.4, for 25, 30, and 37°C, respectively). In yogurt stored at 4°C, populations of pathogen decreased approximately 8 and 2 log CFU/g for product fermented at 43 and 25°C, respectively. In all fermented milk samples stored at 25°C, no viable *E. coli* O157:H7 were recovered after 5 days regardless of fermentation temperature.

Guyara and collaborators reported a > 3 log reduction of *E. coli* O157:H7 in inoculated retail yogurt (pH 4.2 or lower) stored at either 4 or 12°C for 7 days (25). For pH 4.65 yogurt, populations of the pathogen declined 0.8 and 0.1 log when stored at 4 and 12°C, respectively, for 7 days. At day 35, a >3 log reduction was observed regardless of storage temperature.

The effect of the adjunct culture, *Bifidobacterium bifidum*, used in addition to the standard ST-LB cultures was evaluated by co-inoculating high and low levels of *E. coli* O157:H7 with yogurt starters in pasteurized milk (34). Product was fermented at 42°C for 5 hours until the pH was 5.1–5.2, and then stored at

4°C for 7 days. As seen with traditional yogurt, the pH continued to decrease during refrigerated storage to achieve a final pH 4.5–4.6; a concomitant decrease in viable *E. coli* O157:H7 was observed. No significant difference was observed between the traditional yogurt and the bifido yogurt, but continued acid production and pH decrease were deemed important in reducing pathogen populations.

Dineen et al. (15) demonstrated that populations of *E. coli* O157:H7 decreased from 2 log CFU/g to less than detectable levels in three brands of retail low-fat yogurt during storage for 6 to 14 days at 4°C. The acidity remained constant during the 2-week refrigerated storage with pH values of 4.0, 4.0, and 4.2 for the varieties made with ST-LB only, ST-LB with *L. acidophilus*, and ST-LB with *L. acidophilus* and *L. bifidus*, respectively. These data suggest that survival of this pathogen is diminished in an acidic environment, even at refrigeration temperatures.

Survival of *E. coli* O157:H7 in yogurt has been shown to be influenced by the presence of colanic acid (CA), which is polysaccharide slime on the surface of the bacterial cell that increases the pathogen's resistance to acid (33). Wild-type cells with CA demonstrate the longer survival in yogurt (initial pH 4.7) stored at 15°C than at 4°C, whereas there was little difference in survival in mutant strains without CA. However, *E. coli* O157:H7 declined in all treatments during the 3-week storage period.

*Salmonella* Typhimurium grows in laboratory media acidified to pH 4.4 with lactic acid, but is inactivated in cultured skim milk with the same pH value (45). In spite of the potential to tolerate extreme pH values, challenge studies reveal that *Salmonella* will not grow during early stages of yogurt production and will be inactivated during extended fermentation (49). Populations of *Salmonella* Typhimurium remained constant during the first 4 hours of fermentation in the presence of ST-LB culture as the pH decreased from 6.25 to 4.54 in plain yogurt (0.34% lactic acid). *Salmonella* died rapidly thereafter, decreasing > 3 log CFU/g to undetectable levels during the next 3 hours at 42°C as the pH continued to decline to 4.15. Other research noted bactericidal activity when lactic acid reduced the pH of the environment to 4.5, causing the internal pH of

the cell to be reduced to 5.3 and causing cell death (48).

A study evaluating the survival of several serotypes of *Salmonella* in Egyptian yogurt demonstrated that *Salmonella* Typhimurium was the serotype most resistant to adverse pH conditions (18). As reported for many of the *E. coli* O157:H7 studies, *Salmonella* survival was lower when yogurt was stored at elevated temperatures (30–32°C) than at refrigeration temperatures (4°C). The pathogen was inactivated to less than detectable levels at 16 and 23 days (final pH 4.5) or 11 and 19 days (final pH 4.0) when stored at 4°C and room temperature, respectively.

The behavior of Gram-positive bacteria, including spore-formers, which can survive pasteurization, is similar to that of the enteric pathogens in the presence of extreme acid conditions. While pathogens may be able to survive or grow in laboratory media with pH adjusted to < 4.8 under otherwise optimal conditions, few can grow or produce toxin in acidic foods such as yogurt.

No data for challenge studies evaluating the behavior of sporeforming pathogens have been published. However, the safety of yogurt related to these hazards can be predicted based on “worse-case scenarios” reported for growth in laboratory media. The addition of competitive microflora (starter cultures) will further inhibit growth or toxin production by these pathogens. *B. cereus* generally does not grow at pH 4.8 in media adjusted with HCl, or at pH 5.6 when lactic acid is used as the acidulant (27). The pathogen has been reported to be inactivated by 0.1 M acetic, formic and lactic acids in nutrient broth and will die suddenly in yogurt when the pH reaches 4.5 (42). The minimum pH for growth for Group I (proteolytic) *Clostridium botulinum* is considered to be 4.6; however, growth would be slow (27). Outgrowth of Group II (nonproteolytic) spores, which are also able to grow at refrigeration temperatures, are prevented at pH 5.0 or lower. *C. perfringens* growth is slight at pH 5.5, and vegetative cells will die at pH 5.0.

More extensive research has been completed that studies the fate of *S. aureus* and *L. monocytogenes* in yogurt and acidified dairy products. The lag phase of *S. aureus* at 27°C is over 25 hours and generation time is 2 hours in laboratory

media adjusted to pH 4.5 with HCl (60). If the pH of the substrate is less than 4.4, *S. aureus* will die at both refrigeration (7°C) and ambient temperatures (23°C) (39). Neither growth nor toxin formation was detected in milk acidified to pH 4.5 with lactic acid (58), but additional reports suggest that growth is slight in milk acidified to pH 5.1 to 5.2 (37). The minimal pH for enterotoxin production is more stringent than that required for multiplication and is generally limited to values greater than 5.1 (37, 53, 57, 58).

*S. aureus* is noted for being a poor competitor. However, staphylococcal food intoxications are possible if a food is recontaminated, if acid development by starters is inadequate, and if inhibitory pH is not reached quickly (40). Although acid production is important in preventing staphylococcal growth, Reiter et al. (47) reported that even when lactic acid in milk was neutralized, lactic acid bacteria starter culture still retained inhibitory activity against *S. aureus*. If starter activity was poor because of bacteriophage infection, the pathogen was able to multiply. For this reason, hygienic manufacturing practices are essential to prevent recontamination, and starter activity should be monitored to verify proper fermentation.

Several published studies provide evidence demonstrating the control of *S. aureus* in properly fermented yogurt (2, 5, 38). For example, when *S. aureus* was added as a post-fermentation contaminant in retail yogurt (pH 3.7 to 4.1), populations of *S. aureus* decreased by > 3 log within 1 day, regardless of whether it was stored at 7 or 23°C (38). In another study, yogurt was produced in the laboratory by co-inoculating milk with *S. aureus*, *S. thermophilus*, *L. bulgaricus*, and *L. acidophilus* (2). *S. aureus* grew approximately 1.5 log during the first 4 hours of fermentation until the pH reached 4.8. After the yogurt had reached pH 4.8, populations of *S. aureus* decreased > 3 log during an additional 4 hours at 42°C. To further demonstrate the effect of cultures, beyond acid production, acidified yogurt was produced by adding lactic acid to milk, mimicking the pH changes during fermentation of standard yogurt. Although the populations of *S. aureus* also decreased when the pH 4.8 was reached, the decline was much less dramatic. The greater bactericidal activity associated with standard yogurt

and acidophilus yogurt was attributed to high levels of hydrogen peroxide (0.88 µg/ml) produced by the starters. Results for initial growth and subsequent kill of the pathogen during refrigerated storage were confirmed by Pazakova et al. (46). Trends were comparable regardless of the concentration of *S. aureus* introduced at the onset of fermentation.

Similar results were observed when yogurt was produced with bacteriocin-producing ST and a non-producing strain of LB (5). *S. aureus* grew 1.5 log during the early stages of fermentation at 40°C, but decreased > 3.5 log when the mixture reached pH 4.4 at the end of an 8-hour fermentation. Differences in storage temperature appeared to have little effect on viability after fermentation. Populations of *S. aureus* continued to decrease during storage at 7 and 22°C and were undetectable (additional 2 log decrease) at 10 days at both temperatures (N. Benkerroum, personal communication, e-mail April 4, 2005).

On the basis of the potential for *L. monocytogenes* as an environmental contaminant, comprehensive studies have also evaluated the behavior of *L. monocytogenes* in fermented milk products and yogurt (5, 11, 23, 24, 50, 52, 56, 59). Two studies by Schaack and Marth demonstrated that the behavior of *L. monocytogenes* during the fermentation and storage of yogurt was similar to that of the other pathogens described in this review (50, 52). Slow growth of *L. monocytogenes* (1 log increase) was observed during the initial 5-hour fermentation of yogurt with use of either ST alone or ST-LB cultures. After the pH reached 4.8, populations declined as the pH continued to decrease to 4.5 and to 4.0 during additional time at fermentation temperature and during storage at 4°C, respectively. Greater acid production and greater kill of *L. monocytogenes* were reported for yogurt fermented with ST-LB cultures than with ST alone. The pH decreased more rapidly when product was fermented at 42°C than at 37°C, which translated to decreased survival time of *L. monocytogenes* during refrigerated storage. *L. monocytogenes* survived 12 hours in refrigerated product previously fermented with 1.0% ST-LB culture at 42°C (final pH 3.8–3.9) but survived 1–2 weeks in similar product fermented at 37°C (final pH 4.0).

In addition, two research groups compared the differences in listerial survival in retail plain yogurt versus vanilla yogurt with sugar (11, 59). In one study, the type of yogurt (plain vs. with vanilla with sugar) had no obvious effect on pathogen survival when yogurt was stored at 4°C (11). *L. monocytogenes* decreased 2–3 logs during the first 8–12 days, while the pH values of 3.8–4.2 remained similar to 0-time samples. A second study evaluated the survival of *L. monocytogenes* that was inoculated into low-fat and nonfat plain or flavored yogurt (pH ranging from 4.35 to 4.52) and stored at 8°C (59). In the latter study with higher-pH yogurt, listerial populations decreased more gradually, demonstrating a < 1 log decrease in 14 days at 8°C. The most significant decrease was observed at 28 days; populations of *L. monocytogenes* decreased 2.5 log in low-fat plain and vanilla yogurt and in fat-free plain yogurt, whereas a 3.5 log decrease was observed for the fat-free vanilla. Slight additional inhibitory effect by vanillin was observed.

Benkerroum et al. (5) reported that storage at either 7 or 22°C had no effect on survival of *L. monocytogenes* in pH 4.4 yogurt, but survival of *L. monocytogenes* was significantly decreased when yogurt was fermented with a bacteriocin-producing strain of ST (Bac<sup>+</sup> ST). Populations of *L. monocytogenes* decreased > 8 log after 8 to 24 hours fermentation with Bac<sup>+</sup> ST, but only 1 log in the Bac<sup>-</sup> ST yogurt.

## CONCLUSIONS

Multiple factors contribute to the microbiological safety of commercial yogurt. Assuming that the milk used in yogurt production is pasteurized and adjunct ingredients are free of vegetative pathogens, good manufacturing practices and sanitation will minimize the risk of post-processing contamination. Rapid acid production to pH values ≤ 4.8 will prevent the outgrowth of any surviving spores of mesophilic and psychrotrophic strains of *Clostridium botulinum* and *Bacillus cereus* during refrigerated or ambient temperature storage. Similarly, *S. aureus* will not produce enterotoxin at these low pH values. While certain vegetative pathogens such as *E. coli* O157:H7 and *L. monocytogenes* are more acid tolerant than the sporeformers, research has demonstrated that as the pH

decreases to pH 4.6, the substrate will inhibit growth and can be bactericidal. Studies comparing the effect of fermentation and storage temperatures in yogurt further suggest that storage temperatures greater than 4°C will enhance the demise of vegetative pathogens by increasing acid production.

Acidity is one of the principal factors in controlling growth, but other metabolites produced during the ST-LB fermentation contribute to the overall safety of yogurt. Although strains may vary in their ability to produce bacteriocins or the level of hydrogen peroxide accumulated in the substrate during fermentation, utilization of nutrients by the high populations of added starter bacteria will compete with low levels of contaminants.

Scientific studies confirm that the current US practice of cooling yogurt to 7°C over 96 hours does not cause any additional safety risks, provided the pH is at or below 4.6 within 24 hours of filling. However, products should be cooled as rapidly as possible to decrease over-production of acid that may reduce quality of the product and to control spoilage. Environmental controls are essential to prevent recontamination with acid-tolerant microorganisms that may have long survival times.

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35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 119  
Committee: Other Species

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

**A. Summary of Proposal**

The USDA APHIS Programs on Tuberculosis and Brucellosis eradication were designed for cattle and bison. While there is little known risk from TB or brucellosis in areas where the diseases have been eradicated in cattle and bison there is a concern that there is not sufficient data to prove there is no risk. This proposal follows the same options as the conference has allowed on other species for brucellosis and extends the testing requirements for TB. This includes an option that puts the specifics of each state plan into the hands of the State Veterinarian as they are the most knowledgeable of the risks in their state.

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

At the 2011 Conference Proposal 120 asked a committee to look at the issue of TB and brucellosis in small ruminants. The Other Species Committee was tasked with this and the following is the proposal that we have developed. There is no public health significance from the adoption of this proposal where there is little risk of tuberculosis developing in dairy animals in areas where the cattle and bison are accredited as free; this added precaution is further insurance that TB will not spread and go undetected in sheep, goats, water buffalo, camels or other dairy animals.

**C. Proposed Solution**

Changes to be made on page(s): 124 and 125 of the (X - one of the following):

- |                                 |  |
|---------------------------------|--|
| <u>X</u> 2013 PMO               | <u>        </u> 2011 EML                     |
| <u>        </u> 2013 MMSR       | <u>        </u> 2400 Forms                   |
| <u>        </u> 2013 Procedures | <u>        </u> 2013 Constitution and Bylaws |

**SECTION 8. ANIMAL HEALTH ...**

1. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be from herds 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 Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and shall comply with one (1) of the options cited under 3 below.

2. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions: ...

**NOTE:** Under the Federal USDA Bovine Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, cattle are the only dairy animal currently covered by both the Federal USDA brucellosis and tuberculosis programs. All other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within ~~the program~~ these programs and shall comply with one (1) of the options cited under 3 below.

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

- a. Has passed an annual whole herd or flock brucellosis and/or tuberculosis test testing as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC) using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or

- b. Has passed an initial whole herd brucellosis and/or tuberculosis test testing, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or
- c. Has passed an annual random ~~blood~~-individual animal brucellosis and/or tuberculosis testing program, using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis), sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or
- d. Has passed a USDA APHIS approved bulk milk test for the specific disease and species, at USDA APHIS recommended frequency, with an implementation date based on the availability of the bulk milk test once USDA APHIS has approved such a test for the specific disease and species (The brucellosis ring test is USDA APHIS approved for the bovine species and is not suitable for most non-bovine species.); or
- e. Is determined to be free of brucellosis and/or tuberculosis as provided by the development and implementation of a State administered brucellosis-free and/or 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 brucellosis-free and/or tuberculosis-free status. The surveillance program shall be documented and the official annual written State brucellosis-free and/or tuberculosis-free certification shall be retained on file with the State Regulatory Agency. This official annual written State brucellosis-free and/or 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 brucellosis-free and/or tuberculosis-free certification.

(Refer to the **NOTE:** on page 31.) ....

Name:	Daniel L. Scruton, NCIMS Other Species Milk Committee,		
Agency/Organization:	Vermont Agency of Agriculture Food and Markets		
Address:	116 State Street		
City/State/Zip:	Montpelier, VT 05620-2901		
Telephone No.:	802-828-2433	E-mail Address:	<a href="mailto:lshinckley@yahoo.com">lshinckley@yahoo.com</a> <a href="mailto:dan.scruton@state.vt.us">dan.scruton@state.vt.us</a>



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	120
Committee:	Other Species/Scientific Advisory/ICP

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

**A. Summary of Proposal**

This proposal removes the current language under Section 8 of the Pasteurized Milk Ordinance (PMO) and replaces it with updated language which addresses animal health programs more generally and refers these issues to the Federal and State animal health officials. By making this change, the PMO will still emphasize animal health for the purposes of food safety, but defer the specifics of these programs to the experts in this area.

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

The status of animal health in the dairy industry has progressively improved through the years due to the presence of strong animal health monitoring programs implemented by the United States Department of Agriculture's Animal Plant Health Inspection Service (APHIS) and individual State animal health authorities. Diseases which were once commonplace have now been eliminated or very nearly so. As disease prevalence changes, animal health authorities (APHIS and State agencies) adapt their surveillance programs to reflect the current disease status in various animal populations.

When these changes are made, the PMO does not always reflect these changes and this sometimes results in testing for diseases that are really not a health issue for a certain species or using a test that isn't reliable or validated in a certain species. For example, under the PMO, a goat farm can be required to test their whole herd for *Brucella abortus* because the Federal eradication program does not cover Brucellosis for goats. Since *Brucella abortus* is basically the cattle species of Brucella, it doesn't make sense to require testing in goats as they

are only very occasionally infected and almost always then when they have been in contact with infected cattle. And for this same reason, there are not reliable tests for this. But because of the way this requirement is written in the PMO, herd owners have been forced to pay for testing of their entire herd to sell their milk as Grade A.

With respect to diseases that can be transmitted to humans through raw milk, such as Brucellosis or Tuberculosis, knowing and understanding the health status of an animal population is important. However, requiring certain animal health testing protocols or monitoring programs in the PMO, some of which are substantially more than APHIS or State agencies require, does not make much sense given the strength of the current animal health monitoring programs implemented by APHIS and State animal health authorities.

The PMO is a model food safety standard which is adopted by Food Safety programs and agencies. Animal health can be a food safety issue; however, in this case it is one that is adequately controlled by other factors. Food safety officials can and should feel confident in using monitoring programs implemented by animal health experts for these diseases. In addition, because the PMO requires all milk to be pasteurized, we can have further confidence that these disease-causing bacteria, which could potentially be transmitted to humans through raw milk, are addressed during the production process. Because of this, a more general statement that adopts Federal and State specific monitoring programs would be a more appropriate way to address these issues in the PMO.

**C. Proposed Solution**

Changes to be made on page(s): 124-127 of the (X - one of the following):

- |                 |                 |                 |                              |
|-----------------|-----------------|-----------------|------------------------------|
| <u>  x  </u>    | 2013 PMO        | <u>        </u> | 2011 EML                     |
| <u>        </u> | 2013 MMSR       | <u>        </u> | 2400 Forms                   |
| <u>        </u> | 2013 Procedures | <u>        </u> | 2013 Constitution and Bylaws |

SECTION 8. ANIMAL HEALTH

1. ~~All milk for pasteurization, ultra pasteurization, aseptic processing and packaging or retort processed after packaging shall be from herds 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.~~
2. ~~All milk for pasteurization, ultra pasteurization, aseptic processing and packaging or retort processed after packaging 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 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, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and shall comply with one of the options cited under 3 below.

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

- a. Has passed an annual whole herd or flock brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or
- b. Has passed an initial whole herd brucellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals; or
- c. Has passed an annual random blood testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or
- d. Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on the availability of the test; or
- e. Is determined to be free of brucellosis as provided by the development and implementation of a State administered brucellosis free herd certification program involving a documented surveillance program, which includes records supporting the tests required in this Section, and an official annual written certification from the State Veterinarian documenting their brucellosis free status. The surveillance program shall be documented and the official annual written State brucellosis free certification shall be retained on file with the State Regulatory Agency. This official annual written State brucellosis free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, etc.) that are covered within the documented surveillance program and contained within the official annual written State brucellosis free certification.

(Refer to the NOTE: on page 31.)

The following table<sup>14</sup> will provide the random sampling size needed to achieve 99% confidence with a P value of 0.05:

Herd/Flock Size	Sampling Size	Herd/Flock Size	Sampling Size
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86
250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	71	100000	90

4. For diseases other than brucellosis and tuberculosis, the Regulatory Agency shall require such physical, chemical or bacteriological tests, as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Regulatory Agency directs.

5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.

1. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be from herds in areas which comply with the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS) program requirements for Tuberculosis and Brucellosis. Herds in known infected areas, including States with program statuses of less than Accredited Free, shall be monitored within an established monitoring program that has been deemed acceptable by APHIS and the State Animal Health authorities.

a. Monitoring programs for other species that are not covered under a formal USDA APHIS Eradication Plan for Brucellosis and Tuberculosis, such as (but not limited to) goats, sheep, or water buffalo, shall comply with State specific monitoring programs.

2. For diseases other than Brucellosis and Tuberculosis, the Regulatory Agency shall work in conjunction with USDA APHIS and/or State Animal Health authorities to develop appropriate monitoring programs as it deems necessary.

NOTE: For the ICP, references to USDA APHIS and/or State in Items 1 through 5 and 2 above shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "accredited veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

## PUBLIC HEALTH REASON

The health of the animal is a very important consideration, because a number of diseases of cattle, including tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcal infection and streptococci infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk. ~~The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of dairy animals and removal of the reactors from the herds, and the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists; however, constant vigilance against this disease must be continued by industry and Regulatory Agencies. Strong monitoring programs for these diseases in animals are maintained by Federal and State animal health experts and have historically demonstrated the ability to control and in some cases, eliminate these diseases. Ultimately, pasteurization effectively controls the transmission of these bacteria to humans. The combination of these control measures ensures milk and milk products are free of these bacteria.~~

## ADMINISTRATIVE PROCEDURES

~~BOVINE TUBERCULOSIS: All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the current edition of 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, as published by USDA. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over, including any commingled beef animals. Dairy cattle less than two (2) years of age and already milking shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Regulatory Agency.  
(Refer to Appendix A.)~~

Upon request, the Regulatory Agency must provide evidence to show that the State participates in applicable Federal and/or State animal health monitoring programs. This information may be in any form that adequately demonstrates the current program status of the State or details program procedures. In the event that no Federal program exists for a certain disease or animal species, the State may use documentation provided solely from State animal health officials to document the types of programs that exist within that State.

NOTE: For the ICP, an official letter or other official correspondence attesting to the Brucellosis and Tuberculosis accreditation status of the locality in which the herd is located, including the date of accreditation or recertification ~~or certificate identifying the animals tested, the date of injection, the date of the reading of the test and the results of the test signed by the Country's Veterinary Services~~ shall be provided as directed by the TPC.

~~BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of Brucellosis Eradication, Recommended Uniform Methods and Rules, as published by USDA. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption. A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the Regulatory Agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty (30) days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen (13) months following the last annual blood tests, the Regulatory Agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty (30) days of written notice shall result in immediate suspension of the permit. (Refer to Appendix A.)~~

~~NOTE: For the ICP, a certificate identifying each animal signed by the Country's Veterinary Services and director of the laboratory conducting the testing, shall be provided as directed by the TPC.~~

Name:	Nicole Neeser, DVM, MPH		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St. Paul, MN 55155		
Telephone No.:	651-201-6225	E-mail Address:	nicole.neeser@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 121

Committee:

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

**A. Summary of Proposal**

Remove that statement quoting the NMC on page 164, Milking Methods, paragraph 1, indicating a thirty (30) second prepare time. On page 165, paragraph 4 removed the statement of machine stripping the cow. Page 164, paragraph 6 remove the statements on number of units.

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

Paragraph 1. In the modern parlors when the cows come into the parlor they are prepared and the milking cluster is attached. Dry milking is done with a pre dip which does not take very long. Cows are often seen in the holding pen dripping milk; milk let down has already happened. A large amount of Oxytocin shots are given for milk let down. This possibly is due to milk let down happening in the holding pen and then cow holds up her milk in the parlor, or they are waiting too long in the parlor. There is no need to take 30 seconds more in the parlor for milk let down, or to state a required time frame. The operator is getting the milker on the cow as soon as she comes into the parlor, of course after the pre dip.

Paragraph 3. It is important that the milker does not ride up on the udder. The size of the inflation opening precludes the inflation from riding up on to the udder. The inflation should be high enough on the teat so the body of the inflation can contract and relax on the teat.

Paragraph 4. The modern milking machine is automatic take-off. The operator does not stay near the machine though the operator is near enough to pick-up a milker when it falls off, or the automatic take-off will retract the milker. The automatic take-off does not have a stripping step.

Paragraph 6. In modern parlors with automatic take-offs one operator can handle 25 machines or more. Remove the first paragraph of paragraph 6. Even in parlors with bucket type milkers an operator can handle 3 machines.

The individuals that are inspecting the dairies most likely have never milked a cow by hand or with any type of a machine. I have not seen any individuals doing the inspection timing when the milker is put on. The same goes with observing stripping or the number of milkers per operator. This is language that is not used and is out dated. If an operator needs the instruction from the PMO on how to milk a cow the operator has no business being a dairyman or an operator, and will/do shortly go out of business as there most likely are other things the operator does not know how to do. Successful dairymen and inspectors ignore this section.

<b>C. Proposed Solution</b>
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Changes to be made on page(s): 164 and 165 of the (X - one of the following):

- |                               |  |
|-------------------------------|--|
| <u>  x  </u> 2013 PMO         | <u>      </u> 2011 EML                     |
| <u>      </u> 2013 MMSR       | <u>      </u> 2400 Forms                   |
| <u>      </u> 2013 Procedures | <u>      </u> 2013 Constitution and Bylaws |

Modify the 2013 PMO, page 164 and 165, Milking Methods, The NMC considers—line 1.3 and 6

The NMC considers proper milking procedure to include the following:

- ~~1. Before the milking unit is applied to the udder, the operator takes thirty (30) seconds to prepare the lactating animal in the recommended manner to obtain milk letdown, and the milking machine should be applied immediately thereafter;~~
2. The teat cups are attached in a manner to limit the volume of air drawn into the system;
3. ~~The teat cups are positioned as low on the teats as practicable~~
4. ~~The operator stays near the machine and, at the end point of milk removal, the claw is briefly pulled down to open the teat cavity and remove the strippings. Stripping by machine should not extend over a period of more than fifteen to twenty (15-20) seconds. Prolonging stripping can be injurious to the udder;~~
5. Before removing the machine, the vacuum to the teat cups is broken and the cups removed in a gentle manner; and
6. ~~To avoid over milking, the operator should limit the number of machines in use. Two (2) bucket type units, two (2) movable pipeline units or three (3) fixed units, in a walk through barn, usually represent maximum workloads with conventional milking systems.~~  
Hooded, or small-mouthed pails may be used for carrying only that milk which has been drawn into them by hand-milking. Their extended use as carrying pails is considered hazardous in view of their inability to be covered or otherwise protected from flies, dust, splash, etc.

Name:	Kelly Bench		
Agency/Organization:			
Address:	4438 Oak Rd		
City/State/Zip:	Ontario, Oregon 97914		
Telephone No.:	541-889-9285	E-mail Address:	kbenchequip@q.com



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 122

Committee: Tech

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

**A. Summary of Proposal**

This proposal would clarify that the PMO does not allow any flow promoting device(s) on a continuous flow pasteurization system which utilizes a magnetic flow meter based timing system (MFMBTS), to be installed between the timing pump and the magnetic flow meter.

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

There is disagreement amongst regulators as to whether flow promoting devices are allowed between the timing pump and the magnetic flow meter of a MFMBTS. On page 234 of the 2013 PMO (item 1. near the bottom of the page) is the following:

“The timing system’s flow promoting device(s) shall be located upstream from the magnetic flow meter.”

The PMO seems to indicate that any flow promoting device(s) would be allowed provided it is upstream of the magnetic flow meter.

On page 235 of the 2013 PMO (top of the page item 4) is the following:

“All flow-promoting devices, which are upstream of the FDD and which are capable of generating flow through the FDD, shall be properly inter-wired 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 in “Product” run mode, or “CIP” mode after the (10) minute time delay has timed out.”

The PMO again seems to indicate that any flow promoting device would be allowed provided it is upstream of the FDD (and magnetic flow meter) and properly inter-wired with the FDD.

However, in recent FDA training courses, it has been indicated to state rating officers that pasteurization systems (with flow promoting devices located between the timing pump and the magnetic flow meter) are not allowed and would be debited on FDA check ratings.

**C. Proposed Solution**

Changes to be made on page(s):		235	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

After the last sentence in item 4 “so that they are incapable of producing flow.” Add the following sentence:

Flow promoting devices are not allowed between the timing pump and magnetic flow meter.

Name:	Joe Dittrich		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, Minnesota 55155-2538		
Telephone No.:	(507) 932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 123  
Committee: Tech

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

**A. Summary of Proposal**

This proposal would clarify that the PMO does allow any flow promoting device on a continuous flow pasteurization system which utilizes a magnetic flow meter based timing system (MFMBTS), to be installed between the timing pump and the magnetic flow meter, if properly inter-wired with the flow diversion device (FDD).

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

There is disagreement amongst regulators as to whether flow promoting devices are allowed between the timing pump and the magnetic flow meter of a MFMBTS. On page 234 of the 2013 PMO (item 1. near the bottom of the page) is the following:

“The timing system’s flow promoting device(s) shall be located upstream from the magnetic flow meter.”

The PMO seems to indicate that any flow promoting device(s) would be allowed provided it is upstream of the magnetic flow meter.

On page 235 of the 2013 PMO (top of the page item 4) is the following:

“All flow-promoting devices, which are upstream of the FDD and which are capable of generating flow through the FDD, shall be properly inter-wired 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 in “Product” run mode, or “CIP” mode after the (10) minute

time delay has timed out.”

The PMO again seems to indicate that any flow promoting device would be allowed provided it is upstream of the FDD (and magnetic flow meter) and properly inter-wired with the FDD.

However, in recent FDA training courses, it has been indicated to state rating officers that pasteurization systems (with flow promoting devices located between the timing pump and the magnetic flow meter) are not allowed and would be debited on FDA check ratings.

**C. Proposed Solution**

Changes to be made on page(s):		235	of the (X - one of the following):	
X	2013 PMO			2011 EML
	2013 MMSR			2400 Forms
	2013 Procedures			2013 Constitution and Bylaws

After the last sentence in item 4 “so that they are incapable of producing flow.” Add the following sentence:

Any flow promoting device(s) which meet all of the above requirements may be installed between the timing pump and magnetic flow meter.

Name:	Joe Dittrich		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, Minnesota 55155-2538		
Telephone No.:	(507) 932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 124  
Committee: Tech

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

**A. Summary of Proposal**

This proposal clarifies language in the 2013 PMO with regard to Appendix H – Section II – Air Under Pressure – Milk Product-Contact Surfaces, final filter efficiency.

This proposal also updates the 2013 PMO’s “commercially sterile air” filter efficiency criteria, so that it is consistent with the current 3-A Accepted Practice (604-05) criteria.

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

1. The PMO (and the 3-A Accepted Practice for Air Under Pressure, # 604-05) both give the impression that the “Filter Performance” criteria for final filters, found on page 244 of the 2013 PMO, refers to the final particulate filter (shown as # 7 in Figure 44, # 10 in Figure 45 and # 7 in Figure 48). This is not the case.

Final particulate filters are designed to remove line scale and rust particles encountered after the compressed air leaves the coalescing filter. The “Final filter efficiency” listed under “Filter Performance” on page 244 of the 2013 PMO refers to the final coalescing filter (# 6 in Figure 44, # 5 in Figure 45 and # 4 in Figure 48) and not the final particulate filter. It is the coalescing filter which is designed to remove the aerosolized moisture and oil that is entrained in compressed air. So, it is the coalescing filter which must meet the Dioctylphthalate Fog Method (DOP) efficiency criteria, not the final particulate filter (referred to in the diagrams as “Final Filter”).

2. In addition, the current standard for commercially sterile air (99.999%) is listed in the latest 3-A Accepted Practices for Supplying Air Under Pressure . . . (604-05). The 2013 PMO

criteria for commercially sterile air (99.99%) reflects an earlier 3-A Accepted Practice and should be updated.

**C. Proposed Solution**

Changes to be made on page(s):		244 - 250	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

**Make the following changes to:**

The 2013 Pasteurized Milk Ordinance – Appendix H, Section II. Air for Drying Equipment and Air Under Pressure – Direct Contact With Milk and Milk Products and Milk Product-Contact Surfaces – Air Under Pressure – Milk Product Contact Surfaces

**Page 244 of the 2013 PMO (citation starts at line 15)**

**Filter Performance:** Intake air filter efficiency shall be at least 98% SAE J726<sup>2</sup>, June 1987<sup>3</sup> using Air Cleaner (AC) coarse test dust. Final coalescing filter efficiency shall be at least 99% as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns).<sup>4</sup> When commercially sterile air is required, the final coalescing filter efficiency shall be at least ~~99.99%~~ 99.999%<sup>5</sup> as measured by the DOP test.

**Page 245 of the 2013 PMO (line 19)**

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

**Add footnote 5 at the bottom of page 244 of the 2013 PMO**

<sup>5</sup> 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-05 - Section D6.6.1.

Name:	Brian Moyer, Sanitation Rating Officer		
Agency/Organization:	WI Dept. of Agriculture – Division of Food Safety		
Address:	P. O. Box 8911		
City/State/Zip:	Madison, WI 53708 - 8911		
Telephone No.:	(608) 963-9646	E-mail Address:	brian.moyer@wisconsin.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 125  
Committee: Tech

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

**A. Summary of Proposal**

This proposal would add test procedures for Steam-Block Type Flow Diversion Devices (SB-FDD) to Appendix I of the Pasteurized Milk Ordinance (PMO).

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

There are Grade A pasteurization plants in some states that utilize SB-FDD on their pasteurizers, and adding the proposed testing procedures to the PMO will provide guidance to the regulatory personnel (in those states) responsible for quarterly testing of this equipment.

There is no Public Health significance regarding this proposal.

**C. Proposed Solution**

Changes to be made on page(s): 278 and 298 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

On page 278 after item 7) add the following:

Note: See Steam-Block Type Flow Diversion Valve Systems Testing Procedures in Appendix I (Test 1-A and 5-A)

On page 287 after the last sentence in item 8 “in compliance with Item 16p. (D).” add the following:

Test 1-A.

**Steam Block Type Flow Diversion Device**

**Steam Block Temperature Elements (SBTE) – Temperature Accuracy**

**Reference: Item 16p (B) and (D)**

**Application: To all SBTE used to measure temperature for alarmed steam-block zones during pasteurization**

**Frequency: Upon installation; at least once each three (3) months thereafter; whenever the temperature element has been replaced; or whenever the regulatory seal has been broken**

**Criteria: Within +/- 0.25 degrees C (+/- 0.5 degrees F) @ 250 degrees F.**

**Apparatus:**

- 1) Indicating thermometer that has been found accurate following the specifications of Test 1) of this Appendix or an acceptable test thermometer**
- 2) Oil or other suitable media bath and agitator; and**
- 3) Suitable means of heating the media bath**

**Method: Expose all SBTE and the indicating thermometer (or acceptable test thermometer) to the media bath of uniform temperature**

**Procedure:**

- 1) Heat the media bath to at least 250 degrees F**
- 2) Stabilize the media bath temperature and agitate continuously**
- 3) Then insert all SBTE and the indicating thermometer (or an acceptable test thermometer) to indicated immersion point**
- 4) Compare each SBTE reading with the indicating thermometer (or an acceptable test thermometer) temperature reading**
- 5) Repeat the comparison of readings**
- 6) Record the temperature reading for each element (identify the appropriate steam-block zone) and the indicating thermometer (or acceptable test**

thermometer)

Corrective Action: When the SBTE temperature differs from the indicating thermometer (or acceptable test thermometer) by more than 0.25 degrees C (.5 degrees F), the element is to be repaired or replaced. Retest after repair or replacement.

On the top of page 298 after the words “in compliance with Item 16p. (D).” add the following:

Test 5-A.

### Steam Block Type Flow Diversion Device – Proper Assembly and function

Reference: Item 16p (B) and (D)

Application: To All pasteurizers utilizing a SB- FDD

Frequency: Upon installation; at least once each three (3) months thereafter; or whenever the regulatory seal has been broken

Criteria: The SB-FDD shall function properly during normal operating conditions and, shall de-energize the timing pump (and all flow-promoting devices) and activate all appropriate alarms in the event of malfunction or incorrect assembly

### Test 5A.1) SB-FDD Leakage Past Valve Seats

Apparatus:

- 1) Two (2) oil or other suitable media baths and agitators; and
- 2) Suitable means of heating the media bath

Method: Observe that when the minimum alarmed set points for the primary and secondary steam block zones are not maintained, control logic alarms will be activated and the steam block valves will open to full port drain

Procedure:

- 1) With both of the SBTE in the hot baths at a temperature above the alarm set point and the pasteurization system operating on water and the FDD in diverted flow

2) Lower the temperature to the primary zone temperature element (TE). When the temperature goes below the alarm set point (i.e. 215 degrees F), the following must occur within one (1) second:

- 1) Control logic alarm is activated
- 2) Primary steam block valves open to create full port to drain
- 3) Flow promoting devices continue to run

3) Record the temperature of the SBTE for the primary steam block zone when the unit went into alarm status:

4) Place the TE for the primary steam block zone back into the hot oil bath. After both SBTE are above the alarm set point temperatures, lower the temperature to the TE for the secondary steam block zone. When the temperature goes below the alarm set point, the following must occur within one (1) second:

- 1) Control logic alarm is activated
- 2) Secondary steam block valves open to create full port to drain
- 3) Flow promoting devices continue to run

5) Record the temperature of the TE for the secondary steam block zone when the unit went into alarm status:

6) With the TE for the secondary steam block zone still below the alarm set point temperature, test the unit for catastrophic failure. Lower the temperature to the TE for the primary steam block zone. When the temperature goes below the alarm set point, the following must occur within one (1) second:

- 1) Control logic alarm is activated
- 2) The primary and secondary steam block valves are open to create full port to drain
- 3) All flow promoting devices must stop

7) Record the temperature of the TE for the primary steam block zone when the unit went into alarm status for catastrophic failure:

Corrective Action: If any of the responses take more than one (1) second, adjustments or repairs are needed immediate

## Test 5A.2) SB-FDD Operation of Valve Stems

Apparatus:

- 1) Oil or other suitable media bath and agitator; and
- 2) Suitable means of heating the media bath; and
- 3) Ice

Method: Observe the SB-FDD for ease of movement

Procedure:

- 1) With the TE from each steam block zone (both) in the hot bath above the alarm set point, and the pasteurizer operating in forward flow
- 2) Remove both of the TE from the hot bath and place them in ice, causing the

unit to move to divert flow, emergency shut-down

3) Note the freedom of movement of all valve stems

4) Repeat this procedure several times (to observe all steam block valves)

5) Record the results:

Corrective Action: If any of the primary or secondary steam block zone valves are slow-moving or sluggish, adjustments shall be made immediately

## Test 5A.4) SB-FDD Device Assembly

Apparatus:

1) Oil or other suitable media bath and agitator; and

2) Suitable means of heating the media bath; and

3) Ice

Method: Observe the function of the timing pump (and all flow promoting devices) when any of the SB-FDD valves are improperly assembled

Procedure:

1) Prior to running this test, place the pasteurization unit switch to “product” and start the timing pump (to make sure it will run), then turn off the timing pump (the unit is not running during this test)

Note: This test must be run in diverted flow, controlled shut-down mode. When testing the valves in the primary steam block, the TE for the secondary steam block is to be placed in cold water (below alarm set point), while the TE for the primary steam block is in hot oil bath (above alarm set point). When testing the valves for the secondary steam block, the TE for the primary steam block is to be in cold water (below alarm set point), while the TE for the secondary steam block is in hot oil bath (above alarm set point).

2) With the system off and in divert (switch on product) and with the SBTE in one of the above stated positions, disassemble each valve (one at a time) per valve manufacturer test procedures. With one valve disassembled (all others properly assembled) the timing pump shall not start and the steam block zone control logic alarm shall be activated. Re-assemble this valve and repeat this procedure with all of the other steam block valves (reset control logic if needed between each test to clear fault condition – to place timing pump in active status)

3) Record the results

4) Re-seal valves as necessary (if solenoid valves are on valve actuator)

Corrective Action: If the timing pump starts, or the control logic alarm is not

activated (for any of the valves) - adjustments or repairs are needed immediately

## Test 5A.6) SB-FDD Response Time

### Apparatus:

- 1) Oil or other suitable media bath and agitator; and
- 2) Suitable means of heating the media bath; and
- 3) Ice; and
- 4) Stopwatch; and
- 5) (Optional) Sanitary pressure gauge and pneumatic testing device for checking and adjusting the differential pressure controller switch settings (to cause system divert for testing purposes)

Method: Determine that the SB-FDD reaches the fully diverted flow, emergency shut-down position (from forward flow) in less time than it takes for product to travel from the last alarm-monitored position in the system to the Flow Diversion Device (FDD) (including a 20% safety margin).

Example: If the travel time of the product from the outlet of the pasteurized regenerator to the FDD is calculated to be 20 seconds, the FDD must change from the forward flow position to the fully diverted, emergency shut-down position in 16 seconds or less

### Procedure:

- 1) With the pasteurizer running in forward flow and both of the SBTE in hot bath above the alarm set point
- 2) Cause the unit to divert (low temp at hold tube, improper pressure in regenerator, etc.)
- 3) Immediately place both SBTE in cold bath (below alarm set point)
- 4) Record the time it takes for the FDD to change from forward flow to the fully diverted, emergency shut-down position:

Corrective Action: If the response time (including a 20% safety margin) is longer than the product travel time – adjustments or repairs are needed

immediately.

Use the following formula to compute the travel time of the product:

Volume (in gallons) of product that will travel, divided by the flow rate of the unit (gallons per second) equals the travel time of product (in seconds)

For example: What is the travel time of product in a pasteurizer where the internal pipe diameter is 2.38 inches and the length of pipe between the outlet of the regenerator (last alarm-monitored position) and the FDD is 361 inches. The flow rate of the unit has been determined to be 1.38 gallons per second

$$\underline{\text{Volume} = 3.1416 (\pi) \times r^2 \times L}$$

r = radius of internal pipe diameter

L= length of pipe between the outlet of the regenerator and the FDD

Therefore: Volume = 3.1416 x 1.42 x 361

Volume= 1605 inches<sup>3</sup> (cubic inches) of product

1 gallon =231 cubic inches

Therefore: 1605 cubic inches = 6.95 gallons (1605 divided by 231)

Then: T=V/F

Where: T=travel time of product

V=volume

F=unit flow rate

Therefore: 6.95 (gallons) divided by 1.38 (GPS)

T = 5.03 seconds for product to travel from the outlet of the regenerator to the FDD

Then: 5.03 x .20 (20% safety margin) = 1.00 second (safety margin)

5.03 - 1.00 = 4.03 seconds

Therefore, in this example, the SB-FDD must change from the forward flow position to the fully diverted flow, emergency shut-down position in 4.03 seconds or less

## 5A.7) SB-FDD Time Delay Interlock with Timing Pump

Application: To all SB-FDD with a manual forward flow switch

Apparatus: None

Method: Determine that the FDD does not assume a manually induced forward flow position while the timing pump (or any flow promoting device capable of causing flow through the FDD) is operating

Procedure:

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

- 1) The FDD immediately moves to the diverted flow position
- 2) The timing pump and all flow promoting devices are de-energized, or effectively valved-out of the system
- 3) The FDD remains in the diverted flow position until all flow promoting devices have completely stopped or have been valved-out of the system
- 4) The FDD may then assume the forward flow position
- 5) Record the results
- 6) Time delay controls are to be sealed

Corrective Action: If the above sequence of events does not occur – adjustments or repairs are needed immediately.

## 5A.8) SB-FDD CIP Time Delay Relay

Application: To all continuous flow pasteurizer systems utilizing a SB-FDD in which it is desired to run the timing pump and/or other flow promoting devices during the CIP cycle without the controls required during product processing

Criteria: When the control switch is moved from “process” to “CIP”, the FDD shall immediately move to the diverted position. The FDD shall remain in the

diverted position for at least ten (10) minutes, with all Public Health controls required in “process” mode functioning, before starting the normal cycling in the “CIP” mode.

**Apparatus: Stopwatch**

**Method: Determine that the set point on the time delay relay is equal to or greater than ten (10) minutes.**

**Procedure:**

- 1) Operate the pasteurizer in forward flow, with the control switch on “process”**
- 2) Move the control switch to the “CIP” position. The FDD should immediately move to the divert flow position. Start the stopwatch.**
- 3) Check all controls that are required to be in operation during normal “process” mode and in diverted flow (booster pump stops, etc.).**
- 4) Stop the stopwatch when the “CIP” timer times out**
- 5) Record the results**
- 6) Time delay relay must be sealed**

**Corrective action: If the FDD does not remain in the diverted flow position, or if any of the Public Health controls are not functioning during these ten(10) minutes, immediate adjustments or repairs are needed**

Name:	Joe Dittrich and Dana Mock		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, MN 55155-2538		
Telephone No.:	651-285-8455	E-mail Address:	Joe.dittrich@state.mn.us



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 126

Committee: Tech

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

**A. Summary of Proposal**

This proposal would add additional instruction options to perform HTST test 9.2.2 on page 304. The option would allow for usage of the raw regenerator section differential pressure controller sensing element.

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

The purpose of the test 9.2.2 is to determine if the booster pump in a milk to milk regenerator HTST system will stop if the differential pressure is not maintained. When testing, if the raw pressure transmitter is used and the other end capped on the pressure tee, it will give the same result as when the pasteurized transmitter is used. Raising the air pressure on the raw sensor until the differential is not maintained is simulating the same test as reducing the pasteurized air pressure to obtain the test result.

When testing large systems there is a lot of water under pressure on the pasteurized side of the regenerator when removing the sensor and there is not on the raw side. When replacing the sensor after the test is completed, this simplifies the connections by the operator and contributes to safer testing method.

**C. Proposed Solution**

Changes to be made on page(s): 304 of the (X - one of the following):

X	2013 PMO	2011 EML
	2013 MMSR	2400 Forms
	2013 Procedures	2013 Constitution and Bylaws

On page 304, in item 1, after the word “pasteurized” add the following:

or raw regeneration section differential pressure controller sensing element to a testing tee with the other end of the testing tee capped.

On page 304, change item 5 to read as follows:

If using the pasteurized side differential controller, decrease the air supply to the testing tee until the pasteurized milk and/or milk product differential pressure controller sensing element pressure is less than 14 kPa (2 psi) greater than the pressure on the raw milk and/or milk product side differential pressure controller sensing element. If using the raw side differential controller, increase the air supply to the testing tee until the pasteurized milk and/or milk product differential pressure controller sensing element pressure is less than 14 kPa (2 psi) greater than the pressure on the raw milk and/or milk product side differential pressure controller sensing element. The booster pump shall stop running. Ensure that the FDD remains in the forward-flow position and the timing pump continues to operate.

On page 304, in the middle of the page, in the Note: after the word “pasteurized” add the following:

or raw regenerator section differential pressure controller sensing element ports are capped before the timing pump is turned on.

Name:	Dana Mock		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert St. N		
City/State/Zip:	St. Paul, MN 55155		
Telephone No.:	507-634-6436	E-mail Address:	Dana.mock@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 127

Committee: Tech

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

**A. Summary of Proposal**

This proposal will add to the PMO an additional procedure for testing pasteurization holding times (tests 11.1 and 11.2).

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

A salt timing system is being tested by the Minnesota Department of Agriculture that utilizes a manually operated switch contact that is energized when the salt is injected at the beginning of the legal holding tube as an alternative to sensing a change in conductivity. Changing the PMO procedure wording in Test 11 will allow for usage of this device as an alternative to the existing timing meters that rely on conductivity change to start the test.

In side by side (holding time) comparison testing, using the manually operated switch contact to initiate the timer proved to be equal to current standard equipment using conductivity sensors. The development of the device is in response to a common problem with conductivity change detection at the start of the legal holding tube.

**C. Proposed Solution**

Changes to be made on page(s): 312, 315, 316 of the (X - one of the following):

- |  |                                     |
|--|-------------------------------------|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML   |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms |

On page 312, in item 5., after the word “conductivity” add the following:

or comparable start signal upon injection at the beginning of the legal holding tube”

On page 315, at the bottom of the page in item 6., after the word “conductivity” add the following:

or comparable start signal upon injection at the beginning of the legal holding tube”

On page 316, in item 4., after the word “conductivity” add the following:

or comparable start signal upon injection at the beginning of the legal holding tube”

Name: Dana Mock

Agency/Organization: Minnesota Department of Agriculture

Address: 625 Robert St. N

City/State/Zip: St. Paul, MN 55155

Telephone No.: 507-634-6436

E-mail Address: Dana.mock@state.mn.us



_____	_____
_____ 2013 MMSR	_____ 2400 Forms
_____ 2013 Procedures	_____ 2013 Constitution and Bylaws

Appendix I  
Page 312

Test 11.1

2. Install one (1) electrode at the beginning of the legal holding tube and the other electrode at the end of the legal holding tube. A valve switch may be used to start the timing sequence at the beginning of the legal holding tube.

5. The accurate time measuring device shall start when it detects a change in conductivity at the beginning of the legal holding tube- or the operation of a valve switch starts the holding time by injecting the conductive solution.

Page 315

11.2A

Test Option 1

3. Install one (1) electrode at the beginning of the legal holding tube or utilize a valve switch to begin the timing sequence

6. The accurate time measuring device shall start when it detects a change in conductivity at the beginning of the legal holding tube or utilize a valve switch to begin the timing sequence.

Page 316

Test Option 2

1. Install one (1) electrode at the beginning of the legal holding tube or utilize a valve switch to begin the timing sequence

4. The accurate time measuring device shall start when it detects a change in conductivity at the beginning of the legal holding tube or the operation of a valve switch to inject conductive solution.

Name: Glenn A. Goldschmidt

Agency/Organization: Quest Industrial, LLC

Address: 303 North 29<sup>th</sup> Avenue

City/State/Zip: Monroe, WI 53566

Telephone No.: 715-250-0943

E-mail Address: glenn.goldschmidt@questindustrial.com



# 35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 129

Committee: Tech

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

## A. Summary of Proposal

This proposal would clarify (in the PMO) that timing pumps controlled by variable frequency drives (VFD) would not be required to have milk-to-water (adjusted pasteurization holding time) tests done on the quarterly pasteurization tests.

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

There is disagreement amongst regulators regarding gear driven timing pumps (with variable frequency drives) over the need to do the milk-to-water holding time conversion tests. On page 312 of the 2013, in reference to timing pumps, the PMO states that the milk-to-water conversion tests must be run on all gear driven timing pumps. The question is, if there is a variable frequency drive controlling the pump speed, is this considered gear driven or electronically driven?

## C. Proposed Solution

Changes to be made on page(s): 312 of the (X - one of the following):

- |                          |                                       |
|--------------------------|---------------------------------------|
| <u> X </u> 2013 PMO      | <u> </u> 2011 EML                     |
| <u> </u> 2013 MMSR       | <u> </u> 2400 Forms                   |
| <u> </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

At the bottom of the page (last line) in section a., after the word “pumps”, add the following:

(except those controlled by variable speed frequency drive)

The last line would then read as follows: a. For all gear driven timing pumps (except those controlled by variable speed frequency drive) complete Procedures 12 through 16 below.

Name:	Joe Dittrich and Dana Mock		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, MN 55155-2538		
Telephone No.:	(507) 932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 130

Committee: Tech

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

**A. Summary of Proposal**

This proposal would clarify (in the PMO) that timing pumps controlled by variable frequency drives (VFD) would be required to have milk-to-water (adjusted pasteurization holding time) tests done on the quarterly pasteurization tests.

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

There is disagreement amongst regulators regarding gear driven timing pumps (with variable frequency drives) over the need to do the milk-to-water holding time conversion tests. On page 312 of the 2013, in reference to timing pumps, the PMO states that the milk-to-water conversion tests must be run on all gear driven timing pumps. The question is, if there is a variable frequency drive controlling the pump speed, is this considered gear driven or electronically driven?

**C. Proposed Solution**

Changes to be made on page(s): 312 of the (X - one of the following):

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML                     |
| <input type="checkbox"/> 2013 MMSR           | <input type="checkbox"/> 2400 Forms                   |
| <input type="checkbox"/> 2013 Procedures     | <input type="checkbox"/> 2013 Constitution and Bylaws |

At the bottom of the page (last line) in section a., after the word “pumps”, add the following:

(including those controlled by variable speed frequency drive)

The last line would then read as follows: a. For all gear driven timing pumps (including those controlled by variable speed frequency drive) complete Procedures 12 through 16 below.

Name:	Joe Dittrich and Dana Mock		
Agency/Organization:	Minnesota Department of Agriculture		
Address:	625 Robert Street North		
City/State/Zip:	St Paul, MN 55155-2538		
Telephone No.:	(507) 932-0663	E-mail Address:	Joe.dittrich@state.mn.us

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 131  
Committee: Tech

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

**A. Summary of Proposal**

To add additional clarification within Appendix I – Test 15, further defining which control devices require testing for Electromagnetic Interference.

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

Only those devices that have the potential to directly cause a status change of another public health related device are required to be tested.

As shown below M-I-07-3 15 dated January 29, 2007 directly addresses the requirement for testing of the Digital Reference Thermometer. A modification to Part 15 will eliminate questions from the field with respect to testing requirements for this device.

M-I-07-3 15 January 29, 2007

**31. PMO, Section 7, Items 16p(E); and Appendix I**

The following questions relate to APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS II. TEST PROCEDURES – Test 15 of the PMO.

a. Are digital reference thermometers required to be tested?

*No. Test 15 only applies “To all electronic **controls** (emphasis added) used to assure compliance with public health safeguards on continuous flow pasteurization and aseptic processing equipment that are installed in milk plants where hand-held communication devices are used.”*

**C. Proposed Solution**

Changes to be made on page(s): 335 of the (X - one of the following):

<input checked="" type="checkbox"/>	2013 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2013 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2013 Procedures	<input type="checkbox"/>	2013 Constitution and Bylaws

**TEST 15.  
ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD  
COMMUNICATION DEVICES**

**Application:** To all electronic control devices used to assure compliance with public health safeguards on HTST and HHST continuous-flow pasteurization equipment that are installed in milk plants. Electronic control devices are defined as having the potential to cause direct state change influence on another public health related device within the same system.

Name: Gary Ratajczak – Product Manager Regulatory Controls

Agency/Organization: Anderson Instrument Co., Inc.

Address: 156 Auriesville Rd.

City/State/Zip: Fultonville, NY 12072

Telephone No.: 518-922-9222

E-mail Address: gratajczak@andinst.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 132  
Committee: SSSC/Scientific  
Advisory

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

**A. Summary of Proposal**

The Society of the Plastics Industry’s (SPI) Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) proposes that the NCIMS clarify the status of regrind and its use under the Grade “A” Pasteurized Milk Ordinance” (PMO), specifically Appendix J, “Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products” to permit the use of production scrap as regrind, provided that manufacturers comply with the proposed Good Manufacturing Practices for the proper handling of the source material. These GMP, which are attached to this submission, could be considered to constitute a protocol for recycling that has been reviewed and accepted by FDA (as submitted to FDA on January 16, 2015, letter attached).

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

SPI’s member companies have a critical interest in the availability of safe, effective, and cost-efficient materials for containers and closures for milk and milk products.<sup>1</sup> Although the PMO currently permits the use of regrind in the manufacture of containers and closures for milk and milk products, we understand that inspectors have been broadly objecting to its use. Because the use of regrind has a number of benefits, such as preventing waste and reducing resource consumption, and does not present a safety concern, we respectfully request that the NCIMS clarify the status of regrind and its use under the PMO.

As you know, with regard to packaging for Grade “A” milk products, the PMO requires that all single-service containers and closures for milk and milk products “shall be non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.”<sup>2</sup> Compliance with this requirement is established when (1) all single-service containers,

closures, gaskets, and other articles that milk or milk products come in contact with are non-toxic, and (2) when the manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with the requirements of Appendix J, “Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products.”<sup>3</sup> The term “non-toxic materials” is defined in Appendix J as “materials that are free of substances, which may render the product injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and meet the requirements of the [Federal Food, Drug, and Cosmetic Act] as amended.” Ultimately, therefore, the standard for packaging materials is that they must have a suitable regulatory status as determined pursuant to FDA’s indirect food additive regulations and must be suitably pure for the intended use. This “suitable purity” requirement means that the packaging must be safe and must not alter the organoleptic properties of the food (e.g., taste, odor, etc.).

In the fabrication of plastic containers and closures, the PMO appears to permit the use of “Plastic Molding, Forming, Extrusion, and Laminating Resins,”<sup>4</sup> which means:

- (a) Resins or an intimate admixture of resins with other ingredients, which meet the requirements of the FFD&CA as amended;
- (b) Plastic composed solely of clean cuttings or regrind, provided they have been handled and maintained in a clean, sanitary manner; and
- (c) Recycled plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

Thus, regrind is explicitly permitted for use in the manufacture of containers and closures, provided it has been properly handled. “Regrind” is defined in Appendix J as:

Clean plastic material that is trimmed from the container or closure, and imperfectly formed containers or closures, which result from the manufacture of single-service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container or closure which comes from an unapproved source or whose source, chemical content or treatment is unknown, or which may have poisonous or deleterious material retained in the plastic, which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one (1) approved plant to another, shall be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

However, the PMO expressly prohibits the use of “containers, resin, and flashing on the floor, floor sweepings of production materials and production scrap” unless they comply with a recycling protocol approved by FDA.<sup>5</sup> Production scrap is defined as “material which remains from the manufacture of single-service containers or closures, that has been handled or treated in such a manner that it does not comply with the definition for “broke and trim” or “regrind”, but may be collected for recycling. It may contain material such as containers or trim that have fallen on the floor.”<sup>6</sup> However, facility inspectors have been interpreting the PMO very narrowly, and generally prohibiting the use of materials as regrind. This prohibition is an

unnecessary waste of materials and resources given the protections that already are in place in the PMO and when additional safeguards can easily be established to address any other concerns that may arise.

Plastic material that is intended for reintroduction as raw material stream undergoes processing during regrinding as well as when the ground plastic is reintroduced and goes through the manufacturing process. The high heat that the resin undergoes during processing would be more than sufficient to kill any microbiological contamination. Because the PMO already contains stringent standards for the cleanliness of manufacturing plants, the presence of any foreign contamination, such as dust and debris, is likely to be minimal. Nevertheless, acknowledging that concerns may remain regarding the sanitary nature of the raw material, SPI has developed good manufacturing practices for the use of regrind that should address any such concerns. These GMP are attached for your review. We respectfully submit that these GMP could be considered to constitute a protocol for recycling that has been reviewed and accepted by FDA.

The GMP would specifically establish practices for the processing of regrind source material that is collected from the floor, including the use of dust separators, magnets, or filtration, as necessary. The GMP would also establish best practices for the use of regrind, generally. If a company follows GMP, there is no safety concern from the use of this material in the manufacture of containers and closures. Also, the use of regrind helps to reduce environmental waste and the cost of the finished product, because the manufacturer is able to reuse more scrap resin, and. For these reasons, provided that a facility agrees to adopt these GMP guidelines, we respectfully submit that raw material collected from the floor should be permitted for use as regrind and request that FDA clarify this in the PMO.

<sup>1</sup> Founded in 1937, The Society of the Plastics Industry, Inc., is the trade association representing one of the largest manufacturing industries in the United States. SPI's members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw materials suppliers. The U.S. plastics industry employs 900,000 workers and provides more than \$373 billion in annual shipments, both foreign and domestic. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with particular interest and expertise in packaging for food, drugs, cosmetics, and related products. The Committee has worked cooperatively with government agencies on regulatory issues relating to packaging since its formation in 1957.

<sup>2</sup> Item 11p. Construction and Repair of Containers and Equipment

<sup>3</sup> See items 10 and 11 of the "Administrative procedures" to Item 11p.

<sup>4</sup> Although this is provided as a defined term, the term itself never is used in the substantive standards provided in Appendix J.

<sup>5</sup> Item 16.c. of Standard D, Appendix J.

<sup>6</sup> Item 13 of Standard B, Appendix J.

**C. Proposed Solution**

Changes to be made on page(s): 323 of the (X - one of the following):

<input checked="" type="checkbox"/>	2013 <del>1</del> PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2013 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2013 Procedures	<input type="checkbox"/>	2013 Constitution and Bylaws

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

D. FABRICATION PLANT STANDARDS

16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES

c. Containers, resin and flashing on the floor, floor sweepings of production materials and production scrap ~~are prohibited from being reused~~ may be used as regrind, in accordance with the “Good Manufacturing Practices for the Use of Regrind in the Fabrication of Containers and Closures for Grade “A” Milk and Milk Products” (GMP) incorporated in and attached to this Appendix. This shall not preclude the use of these materials when they comply with a recycling protocol that has been reviewed and accepted by FDA.

Name: Devon Wm. Hill, Counsel for the Society of the Plastics Industry Food, Drug, and Packaging Materials Committee

Agency/Organization: Keller and Heckman LLP

Address: 1001 G Street NW, Suite 500W

City/State/Zip: Washington, DC 20001

Telephone No.: (202) 434-4279

E-mail Address: hill@khlaw.com

# GOOD MANUFACTURING PRACTICES FOR THE USE OF REGRIND IN THE FABRICATION OF CONTAINERS AND CLOSURES FOR GRADE “A” MILK AND MILK PRODUCTS

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## I. Introduction

The purpose of this guideline is to describe general principles of good manufacturing practices (GMP) for the use of regrind in the production of milk bottles. These GMP guidelines aim to ensure rework material cleanliness, to avoid introducing contamination, and to remove any inadvertently introduced contamination.

## II. Background

### A. The Grade “A” Pasteurized Milk Ordinance

The “Grade “A” Pasteurized Milk Ordinance,” (PMO) contains standards for the production of Grade A pasteurized milk and milk products. The PMO was developed by the U.S. Department of Health and Human Services Public Health Service (PHS) and the Food and Drug Administration (FDA) as a model regulation intended to be voluntarily adopted by state and local milk control agencies. More specifically, the PMO includes standards for milk production, acceptable equipment and production techniques, as well as milk labeling rules. Almost all of the states have adopted the PMO or slightly altered versions of it.

With regard to packaging for Grade A milk products, the PMO requires that

“All single-service containers, closures, gaskets, and other articles that milk and milk products come in contact with shall be non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.”<sup>1</sup>

Compliance with this requirement is established when (1) all single-service containers, closures, gaskets, and other articles that milk or milk products come in contact with are non-toxic and (2) when the manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with the requirements of Appendix J, “Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products.”<sup>2</sup>

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<sup>1</sup> Item 11p. Construction and Repair of Containers and Equipment

<sup>2</sup> See items 10 and 11 of the “Administrative procedures” to Item 11p.

Appendix J details the requirements for the manufacture of containers for milk and milk products that would ensure the production of safe and sanitary packaging. Its standards apply broadly throughout the plastics supply chain, with only resin manufacturers exempted.

## **B. Regrind**

The use of regrind is a common practice in the manufacture of plastic materials and articles. Regrind is scrap material produced during the manufacturing process that is ground up and reintroduced as a source of raw material. Waste material may result from a variety of scenarios during plastic manufacturing, including samples for testing, equipment malfunctions, and production changeover. The use of regrind helps to reduce environmental waste and the cost of the finished product, because the manufacturer is able to reuse more scrap resin.

“Regrind” is defined in Appendix J as:

Clean plastic material that is trimmed from the container or closure, and imperfectly formed containers or closures, which result from the manufacture of single-service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container or closure which comes from an unapproved source or whose source, chemical content or treatment is unknown, or which may have poisonous or deleterious material retained in the plastic, which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one (1) approved plant to another, shall be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

## **III. GMP for Use of Regrind**

The PMO requires that all Grade “A” milk or milk products be produced to chemical, physical, bacteriological, and temperature standards and sanitation requirements.<sup>3</sup> From a packaging perspective, containers and closures must be manufactured from non-toxic materials, which Appendix J defines as “materials that are free of substances, which may render the product injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and meet the requirements of the [FD&C Act] as amended.” To comply with the FD&C Act, a plastic used in contact with food must have a suitable regulatory status as determined pursuant to FDA regulations in 21 C.F.R. Parts 174-186 and must be suitably pure for its intended use, as required under 21 C.F.R § 174.5(a)(2).

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<sup>3</sup> See Section 7, “Standards for Grade “A” Milk and Milk Products.

**A. Regrind should be sourced only from trimmings of containers or closures or from imperfectly formed containers or closures that have a suitable regulatory status under the Federal Food, Drug, and Cosmetic Act (FD&C Act)**

Limiting the source of regrind material to product trimmings or imperfectly formed containers or closures helps to ensure that when the regrind is reintroduced into the raw material stream there would be no impact on the regulatory status of the finished material under FDA law and regulations because only FD&C Act-compliant materials should be used as raw materials.

**B. Regrind should be Clean and Sanitary**

There are many aspects to ensuring that regrind is clean and sanitary for use. Appendix J includes many requirements that would assist with achieving this goal, as described below, and additional guidance also is provided. No specific guidance is provided for compliance with bacteriological requirements, because when regrind is reintroduced into the raw material stream it will undergo sufficient high heat treatment that no bacteria would be expected to survive. Any residual contamination that should survive will be addressed by the bacterial standards provided in Section C, “Bacterial Standards and Examination of Single-Service Containers and Closures,” of Appendix J.

1. Source material for regrind that is collected in clean and sanitary containers immediately from the process stream (*i.e.*, material does not touch the floor or any other surface of the fabrication room) and appropriately stored may be reintroduced into the raw material stream without additional sanitation procedures, provided it has not been commingled with other regrind source material. Source material for regrind that has been collected from the floor must be appropriately processed so as to remove any insects, dust, condensation and other contamination, including using dust separators, magnets to remove metal fragments, or filtration to remove other hard objects.
2. Regrind shall be suitably segregated from other waste materials, production scrap, and non-food-grade regrind. Containers used for storage of regrind shall be covered, clean, impervious, and properly identified, in accord with Section D.14.d. of Appendix J.
3. Whenever pressurized air is directed at regrind, it shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor and shall otherwise comply with the applicable requirements of Appendix H of the PMO, as required by Section D.13.b. of Appendix J.
4. All regrinding operations should be conducted in rooms separate from the fabricating room, except that they may be conducted within the fabricating room, provided such operations are kept clean and free of dust, as required by Section D.5.b. of Appendix J.
5. All grinders, shredders and similar equipment used for regrinding shall be installed above the floor or installed in such a manner that they are protected, so

that floor sweepings and other contaminants cannot enter the grinder or shredder, in accord with Section D.15.d. of Appendix J, unless the plant's Hazard Analysis and Critical Control Points (HACCP) plan addresses the processing for floor sweepings to ensure product is clean and sanitary for use as regrind.

6. Processed regrind awaiting reintroduction into the production stream should be covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination, in accord with Section D.13.a. of Appendix J.

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 133

Committee: SSCC/Lab

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

**A. Summary of Proposal**

The purpose of this proposal is to bring the PMO App J and the 2400 series forms into agreement on sample size.

FDA-NCIMS form 2400i, Pasteurized Milk Containers, rev 10-13, item 26a states one sample is 5 – 50 square centimeter (cm<sup>2</sup>) areas or 250 cm<sup>2</sup> of product contact surface. A sample set is 4 times one sample or 4 – 250 cm<sup>2</sup> areas. However the PMO, Appendix J, repeatedly bases regulatory action on 3 out of 4 samples where a sample size is given to be 4 - 50 cm<sup>2</sup> areas.

Since the 2400 forms are based on science it would make sense to change the definition of a sample set for the swab test to agree with the 2400 forms.

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

Sampling and testing of containers is confusing enough without two FDA/NCIMS official documents making differing statements.

There is no public health significance. The testing will not change, the sample set size will agree with the 2400 forms.

**C. Proposed Solution**

Changes to be made on page(s): 339, 340 of the (X - one of the following):

X	2013 PMO	2011 EML
	2013 MMSR	2400 Forms
	2013 Procedures	2013 Constitution and Bylaws

From 2013 PMO, page 339

1. "Sample Set" shall mean:
  - a. For the rinse test, a minimum of four (4) containers shall be tested.
  - b. For the swab test, a minimum of four (4), ~~50~~ 250 square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product- contact surface area smaller than ~~50~~ 250 square centimeters, more than four (4) containers or closures to equal at least ~~50~~ 250 square centimeters times four (4) shall be required to be swabbed.

From 2013 PMO, page 340

5. A sample set from each manufacturing line, as defined in these Standards, shall consist of a minimum of four (4) containers or closures, when the rinse test is used, or a minimum of four (4) ~~50~~ 250 square centimeters (cm<sup>2</sup>) areas of surface, when the swab test is used.

Name:	Debra Hall		
Agency/Organization:	Indiana State Board of Animal Health, Dairy Division		
Address:	1202 East 38 <sup>th</sup> Street, Discovery Hall, Suite 100		
City/State/Zip:	Indianapolis, IN 46205		
Telephone No.:	317-544-2385	E-mail Address:	dhall@boah.in.gov

Name:	John Spanczak		
Agency/Organization:	Illinois Dept of Public Health Laboratory		
Address:	2121 West Taylor Street		
City/State/Zip:	Chicago, IL 60612		
Telephone No.:	312-793-1047	E-mail Address:	John.Spanczak@Illinois.Gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal: 134  
Committee: Tech

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

**A. Summary of Proposal**

This Proposal addresses concerns cited in Appendix Q-Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization, Ultra-pasteurization or Aseptic Processing and Packaging, Item 1r-Abnormal Milk, Item 13r-Milk – Flanks, Udders and Teats of the PMO, and provides guidance for written procedures for milk with abnormalities, computer system(s) verification, and general computer requirements for Automatic Milking Installations (AMI).

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

With the increased use of AMIs that utilize computerized systems and new technologies on Grade “A” dairy farms, this Proposal provides general guidance for AMI computer systems and clarification as to how AMI computer systems for the detection of abnormal milk and teat preparation are to be monitored and maintained.

**C. Proposed Solution**

Changes to be made on page(s): Pages 383-384 of the (X - one of the following):

X 2013 PMO                      \_\_\_\_\_ 2013 EML  
2013 MMSR                      \_\_\_\_\_ 2400 Forms

***MAKE THE FOLLOWING CHANGES TO THE 2013 PMO.***

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

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

*Page 383:*

**GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS**

AMIs have computer systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves; have data collection, storage and reporting systems; and have communication network capabilities for multiple uses and locations.

The dairy farm shall have an identified representative(s) that has been trained and certified by the manufacturer of the AMI to make program changes to the AMI system.

A manufacturer’s written or electronic user’s guide addressing the computer system’s monitoring and controlling functions and of the computer system’s data collection, storage and reporting information shall be provided and shall explain the computer system’s architecture, the software used, the devices controlled, the sensors or instruments monitored, and testing procedures for all of their computer system components. This guide/overview may be presented in text or in a graphical representation. This document shall bear the name of the identified representative of the dairy farm assigned to administer this computer system and shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA. This documentation shall explain:

1. The computer system’s architecture, the software used, the devices controlled or monitored and their locations, and the sensors or instruments monitored and their locations;
2. The reporting interface of the computer system’s data collection, storage and reporting information;
3. The testing procedures for all of the computer system’s components;
4. The backup procedure for ensuring the safe collection and storage of the data of all reports;
5. The procedure for any changes or maintenance to the computers, devices, instrumentation, sensors hardware, etc. This procedure shall explain how the identified dairy farm representative shall ensure that when a physical change occurs the information affected has been checked for accuracy and which personnel are authorized to make such changes; and
6. The listing and explanation of the reports available on the computer system, instructions on how to access the reports and examples of each report with a description of their content.

The data supporting the electronic reports shall be stored in a database or data archival system

in a Write Once, Read Many (WORM) or equivalent.

The computer system shall provide an anomalies report indicating any computer system or communication failure that could have affected the validity of the required reports. This anomalies report shall be automatically attached to any report that may have been affected by the computer system anomaly.

**NOTE:** A separate error log or computer system log will not suffice for meeting this requirement, since any anomaly requires an evaluation and investigation to correlate the anomaly.

A written or electronic record shall be maintained at the dairy farm identifying any changes or updates to the devices, computer system's data collection, storage and reporting information, software, drivers, networking or servers in order to assure the collection, storage or reporting of any data required for compliance with this Ordinance has not been compromised. This record shall contain the name of the identified dairy farm representative assigned to administer the computer system and the record shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

A verification of all computer system's controlled functions shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency. Whenever any changes, updates or observed anomalies that could have affected the reliability or accuracy of the computer system's reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed and verified by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and FDA Regional Milk Specialists (RMSs) during ratings and check ratings, respectively. Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

#### **ITEM 1r. ABNORMAL MILK**

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silo basis and shall not be any different for a herd using AMI technology.

The dairy farm shall have an identified representative(s) that has been trained and certified by the manufacturer of the AMI to make program changes to the AMI system. In addition, the dairy farm shall have a documented written procedure in place to ensure that milk with abnormalities is properly detected and diverted; and that equipment used for the milking of healthy animals has not become contaminated. The procedure shall also document when a physical change to the AMI system has occurred; that the recorded information affected has been checked for accuracy; and which personnel are authorized to make those changes.

A verification of all computer system's controlled functions responsible for properly detecting and diverting abnormalities in milk, to include conductivity and color sensors, shall be

conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the manufacturer's technician; or other means accepted by the Regulatory Agency. Whenever any changes, updates or observed anomalies that could have affected the reliability or accuracy of the computer system's reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and RMS during ratings and check ratings, respectively. Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) are identified through an appropriate identification system so that their milk will be automatically excluded from the milk offered for sale, provided that the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized.

*Page 384:*

#### **ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS**

AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES #4** of this *Ordinance*: "Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking." Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer's teat prep protocol verification procedures on file at the dairy farm.

A verification of all computer system's controlled functions responsible for proper teat preparation shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the manufacturer's technician; or other means accepted by the Regulatory Agency. Whenever any changes to the teat prep protocol, updates or observed anomalies that could have affected the reliability or accuracy of the computer system's reporting system occur following the commissioning of the computer system, these changes, updates or observed anomalies shall be immediately evaluated and investigated; and if corrections are warranted, they shall be addressed. The records addressing any of these actions shall bear the signature of the authorized vendor representative and/or the identified dairy farm representative; and shall be reviewed by the Regulatory Agency during routine dairy farm inspections and by the SRO and RMS during ratings and check ratings, respectively. Written or electronic records for all of these required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, SRO and/or FDA.

Name: CFSAN

Agency/Organization: Food and Drug Administration

Address: 5100 Paint Branch Parkway

City/State/Zip: College Park, MD 20740

Telephone No.: (240) 402-2175

E-mail Address: Robert.Hennes@fda.hhs.gov



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 135

Committee:

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

**A. Summary of Proposal**

In 2014 M-I-14-8 was issued with guidance on how AMI abnormal milk installations should be evaluated. The M-I demonstrated a major shift from the intent of the language in Appendix Q. This proposal is an attempt to clarify the requirements for an Automatic Milk Installation (AMI) with regard to abnormal milk sensing. The MI is incorrect in its inclusion of milk conductivity under its verification requirements as conductivity is not required in conventional systems or AMI. Abnormal milk is defined in the PMO as “A-1. **Abnormal Milk:** Milk that is visibly changed in color, odor and/or texture.” It is also going beyond what is required of conventional milkers in suggesting that producers need to have written records on any changes they make to abnormal milk sensors as we do not require conventional milking systems to track all the training they give to each milker and any time they give further instruction to the milkers. Ultimately it is the milk in the bulk tank that is the judge. The only time a conventional system would be marked for abnormal milk is if an inspector observed abnormal milk going into the milk for sale or if the bulk milk tank is off in color or texture. The only real requirement should be that the system has a sensor and that the sensor is turned on. Even that is more stringent than we hold conventional systems to but is reasonable given that the producer does not have someone there to observe milking.

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

There is no public health significance to change noted in this proposal as the current intent of Appendix Q will be met in a manner more consistent with what is done when conventional milking systems are evaluated. Abnormal milk sensing is performed in conventional milking system based on a judgment-call from the person milking the animals. There is no test given to people that want to milk to standardize what abnormal milk is. There is no reason to add a

great deal of testing to AMI systems. Annex C in American Society of Agricultural and Biological Engineers (ASABE) standard AD20966:2007 gives manufacturers guidance on the evaluating abnormalities in milk. AMI abnormal milk settings are based on the judgment of persons more knowledgeable than the typical milker and are inherently more consistent and therefore will remain safer than conventional systems.

**C. Proposed Solution**

Changes to be made on page(s):		_____ of the (X - one of the following):	
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

**ITEM 1r. ABNORMAL MILK**

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silo basis and shall not be any different for a herd using AMI technology.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) are identified through an appropriate identification system so that their milk will be automatically excluded from the milk offered for sale, provided that the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized. The requirement that there be an active abnormal milk sensor system is to be deemed by the state regulatory authority as in compliance as long as the system is active and no off color or texture milk is noted by the regulatory authority. Active is determined by having the producer show reports of diverted milk. If no animals have produced abnormal milk sufficient to cause a divert in the prior 6 months the producer will demonstrate that the system is active by means acceptable to the state regulatory authority.

Name:	Daniel L. Scruton		
Agency/Organization:	Vermont Agency of Agriculture Food and Markets		
Address:	116 State Street		
City/State/Zip:	Montpelier, VT 05620-2901		
Telephone No.:	802-828-2433	E-mail Address:	<a href="mailto:dan.scruton@state.vt.us">dan.scruton@state.vt.us</a>

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 136

Committee:

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

**A. Summary of Proposal**

To keep the requirements of Appendix Q, Item 18r. Raw Milk Cooling, the same as Section 7, Item 18r. Raw Milk Cooling.

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

Appendix Q addresses requirements for Automatic Milking Installations (AMIs). The requirements outlined in Appendix Q, Item 18r. Raw Milk Cooling, are more stringent than those requirements found in Section 7, Item 18r. Raw Milk Cooling. If the requirements outlined in Section 7, 18r. Raw Milk Cooling are adequate for non-AMI farms, they should also be adequate for AMIs.

This proposal seeks to keep the requirements found in Appendix Q, Item 18r. Raw Milk Cooling, the same as Section 7, Item 18r. Raw Milk Cooling.

**C. Proposed Solution**

Changes to be made on page(s): 385 of the (X - one of the following):

- |          |           |                 |            |
|----------|-----------|-----------------|------------|
| <u>X</u> | 2013 PMO  | <u>        </u> | 2011 EML   |
|          | 2013 MMSR | <u>        </u> | 2400 Forms |

**Modify the 2013 PMO, page 385, Appendix Q, Item 18r. Raw Milk Cooling**

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

**ITEM 18r. RAW MILK COOLING**

For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less ~~after starting the milking operation and the milk shall be cooled within two (2) more hours, of the commencement of the first milking, and~~ to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). ~~The milk in the farm bulk milk tank/silo shall not exceed 7°C (45°F) after that time.~~ Farm bulk milk tank/silo recording thermometers are recommended if not already required by this *Ordinance*.

Name: Brian Wise

Agency/Organization: Ohio Department of Agriculture – Dairy Division

Address: 8995 E. Main Street

City/State/Zip: Reynoldsburg, OH 43068

Telephone No.: 614-466-5550

E-mail Address: bwise@agri.ohio.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 137  
Committee: Scientific Advisory

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

**A. Summary of Proposal**

To update guidance (M-I-06-05) regarding Item 15r of the PMO to better reflect organic dairy production practices under the Organic Foods Production Act by developing guidance acceptable to FDA that licensed veterinarians may prescribe certain safe and effective GRAS and plant-based substances (draft list attached) in accordance with state veterinarian practice requirements, for use in maintaining animal and herd health. Guidance is sought that will recognize these substances may be regulated differently than unapproved animal drugs under the PMO.

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

The last update to the M-I-06-05 guidance on Item 15r of the PMO appears to have occurred in 2006. Since that time the organic dairy industry has grown significantly and organic herd and animal health maintenance practices are much better documented and understood. Organic dairy farmers have fewer treatment options than their conventional counterparts due to statutory restrictions. Certain GRAS substances and plant-based substances could be allowed for animal and herd treatment purposes under the direction of a licensed veterinarian because the substances can be demonstrated to pose a *de minimis* risk of dangerous or unhealthy residues or other adverse public health impact that can be corroborated in each application by the professional judgment of the prescribing veterinarian. When subject to prescriptive veterinary oversight regarding labeling and use, such substances fall below the threshold of regulatory significance for public or animal health risks associated with unapproved animal drugs.

### C. Proposed Solution

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

_____ 2013 PMO	_____ 2011 EML
_____ 2013 MMSR	_____ 2400 Forms
_____ 2013 Procedures	_____ 2013 Constitution and Bylaws

Organic Valley requests the Chair assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board. We request development of appropriate language for adoption at the earliest possible opportunity.

Name: Melissa Hughes—General Counsel

Agency/Organization: CROPP Cooperative/Organic Valley Family of Farms

Address: 1 Organic Way

City/State/Zip: La Farge, Wisconsin 54639

Telephone No.: 888-444-6455

E-mail Address: [melissa.hughes@organicvalley.com](mailto:melissa.hughes@organicvalley.com);

Name: William J. Friedman

Agency/Organization: \_\_\_\_\_

Address: \_\_\_\_\_

City/State/Zip \_\_\_\_\_

Telephone No.: \_\_\_\_\_

E-mail Address: <mailto:pedlarfarm@gmail.com>

**Friedman attachment # 137**

### **Discussion Materials for Organic Livestock Use**

Plant based products derived from - dried plant material, infusions or decoctions (teas), or extracts of the following;

**Garlic** – *Allium sativum*

**Thyme** – *Thymus vulgaris*

**Oregano** – *Origanum vulgare*

**Cayenne pepper** – *Capsicum annuum*

**Aloe vera** – *Aloe barbadensis*

**Neem** – *Azadirachta indica*

**American (Purple) Coneflower** - *Echinacea augustifolia, Echinacea purpurea*

**St. John's wort** – *Hypericum perforatum*

**Leopard's bane** – *Arnica montana*

**White willow** – *Salix alba*

**Blue Cohosh** – *Caulophyllum thalictroides*

**Tea tree** – *Melaleuca alternifolia*

