33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	201
Committee:	

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

A. Summary of Proposal

Amend Pasteurized Milk Ordinance (PMO) definition X. Milk Products: Section 6 to provide clarification on how different forms and types of milk and milk derived ingredients will be determined on a minimum weight basis for non-standard milk products.

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

During the 2009 NCIMS Conference the Milk Industry Foundation (MIF) worked with FDA and the Conference Delegates on amendments passed for PMO definition X. It was MIF's understanding that minimum of sixty-five percent (65%) by weight of individual milk or milk products described in definition X item 6 would be determined on an actual weight of the milk or milk ingredient used regardless of the form being liquid, concentrated or dried.

During 2010 FDA made case-by-case interpretations that if a concentrated or dried milk ingredient was used to produce a non-standard milk product, the minimum 65% weight of the milk should be determined by adding any water present in the formula to reconstitute the dried and concentrated milk back to a single strength basis of milk (8.25% milk solids-non-fat).

The dairy industry and regulatory officials need written clarification in the PMO to define how various milk and milk products or combinations of milk products will be determined on a minimum weight basis. There are many different types of milk products that can be used to formulate non-standard milk and milk products such as milk, concentrated milk, evaporated milk, dried milk, liquid whey, whey protein concentrate, whey protein isolate, milk protein concentrates, caseinate, and milk permeate. The federal standard of identity for milk (21 CFR131.110) can be used as a reference to determine the single strength basis of reconstituted

forms of dried, evaporated and concentrated (by heat or filtration) milk. However, many other milk derived ingredients such as whey, whey proteins, milk proteins, milk and whey protein isolates, lactose, casein do not have federal standards or means to determine a single strength basis. There is no public health significance or rationale for requiring the weight of a milk derived ingredient to be determined on a single strength basis. Also many of these milk derived ingredients are highly processed and concentrated forms of dairy. Therefore, any milk derived ingredient, other than milk, concentrated milk, evaporated or dried milk should be determined on the actual weight of the ingredient used.

C. Proposed Solution

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

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

PMO Page 6:

X. **MILK PRODUCTS:** Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)[2].
3. Whey and whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, and Section 1, Definition QQ of this *Ordinance*.
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR 130.10-requirements for foods named by use of a nutrient content claim and a standardized term.
5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols".
6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products. (<u>The weight of milk, concentrated milk, condensed milk, evaporated milk, dried milk shall be determined by reconstituting the amount of the ingredient used with water in the formula to determine the single strength basis of milk (CFR 131.110) to a minimum milk solid non-fat of 8.25%. Milk derived ingredients e.g.; liquid whey, concentrated whey, dried whey, whey protein concentrate, whey protein isolate, milk protein concentrate, milk protein isolate, caseinate, and milk permeate shall be determined on the actual percentage weight of the ingredient used to make up the finished product.</u>)

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	202
Committee:	

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

A. Summary of Proposal

This proposal would allow regulatory milk plant product samples to be collected by industry personnel under the approval and direction of the regulatory agency.

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

There is continued loss of resources such as staff and funding issues impact all participants of the Interstate Milk Shipment Conference. By providing more flexibility to the regulatory agency, state programs will be better able to meet and maintain the requirements of the IMS program.

The collection of raw milk producer samples under the direction of the regulatory agency is allowed for in Section 6 of the 2009 PMO as well as vitamin samples for assay analysis.

Under Appendix J.- Standards For The Fabrication Of Single-Service Containers And Closures For Milk And Milk Products, Single Service Container plants that are located within or outside of the United States are required to collect and have analyzed single service containers as outlined in Section C. of Appendix J. These container collections are not required to be conducted by a regulatory agency and yet the collection and analysis of such single service containers by the industry have been done successfully over the years.

Allowing for similar raw milk producer sampling protocols for plant samples of raw milk, heat-treated and finished milk products with regulatory agency oversight will provide for flexibility in the management of regulatory resources without impacting public health protection.

C. Proposed Solution

Changes to be made on page(s): 3, 23, 130 of the (X - one of the following):

X 2009 PMO _____ 2009 EML

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

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

SECTION 1. DEFINITIONS

Section 1 on page 3 would read in part…

M. Dairy Plant Sampler: A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee <u>or designee</u> of the Regulatory Agency and is evaluated at least once every two (2) year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official. Sampling Surveillance Officers or properly delegated Sampling Surveillance Regulatory Officials are not required to be evaluated for sampling collection procedures.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Section 6 on page 23 would read in part……

……

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained ~~by~~ <u>under the direction of</u> the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from milk plants offering such products for sale, shall be collected ~~by~~ <u>under the direction of</u> the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat (skim) milk, each fat level of reduced fat or lowfat milk and milk product defined in this *Ordinance*, (including aseptically processed milk and milk products for drug residue tests) shall be collected ~~by~~ <u>under the direction of</u> the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. …

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Appendix B. on page 130 would read in part……

I. MILK SAMPLING AND HAULING PROCEDURES

The dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance.* These persons are delegated by the Regulatory Agency or employees of the Regulatory Agency and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official. These individuals are evaluated using Form FDA 2399 - MILK SAMPLE COLLECTOR EVALUATION FORM, which is 1derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	203
Committee:	Hauling/MMSR

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

A. Summary of Proposal

Proposal would allow the use of now available technology for the collection, storage, and transmission of information related to the milk picked up at farms in an electronic format.

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

In an effort to enhance information access, availability, and reduce paperwork a number of pilot projects are underway across the country to create systems that allow the milk hauler to collect, store and transmit all of the information previously entered manually on paper as milk was picked up, transported and delivered. Units, carried by the milk hauler, provide for visual access to stored information as the milk is collected. Transmission of the stored information following completion of the milk pickup process or at the point of delivery then provides several options to create a printed version of the information.

The use of electronic recording devices is already encouraged for pasteurization equipment and it is logical to expand electronic collection of data to electronic manifests. For reference, the 2009 statement on electronic recording devices for pasterurization equipment is below (from page 250):

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

Electronically collecting data, storing data and reporting information with computers can be a beneficial replacement for circular chart recorders and/or hand-written records. This method of presenting PMO required information should essentially replace and duplicate the purpose and functionality of their manual or chart recorder counterparts. These would include CIP records,

pasteurization records, raw and heat-treated product storage tank's temperature and cleaning requirements and temperature monitors for membrane filtration. This criteria for the evaluation addresses the difference between manual records or chart recorders and electronic or computer record keeping. These differences are identified in the criteria below that address the verification of system reliability, security and dependability and what information is available and accurate for assuring public health safety and inspection."

C. Proposed Solution

Changes to be made on page(s): PMO 15, 16, 132, 133, 137, 138; MMSR 85 of the (X - one of the following):

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

Make the following change to the 2009 PMO.
~~Strike out~~ text to be deleted and underlined text to be added.

Pages 15 & 16

SECTION 4. LABELING

All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement or electronic record shall be prepared containing at least the following information:

1. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;
2. Permit identification of the hauler, if not an employee of the shipper;
3. Point of origin of shipment;
4. Milk tank truck identification number;
5. Name of product;
6. Weight of product;
7. Temperature of product when loaded;
8. Date of shipment;
9. Name of supervising Regulatory Agency at the point of origin of shipment;
10. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;
11. Seal number on inlet, outlet, wash connections and vents; and
12. Grade of product.

All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

Each milk tank truck containing milk shall be accompanied by documentation or electronic record, weigh ticket, or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant.

Pages 132 and 133

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

3. **Milk Quality Checks:**

a. Examine the milk by sight and smell for any off odor or any other abnormalities that would class the milk as not being acceptable. Reject if necessary.

b. Wash hands thoroughly and dry with a clean single-service towel or acceptable air dryer immediately prior to measuring and/or sampling the milk.

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

4. **Milk Measurements:**

a. The measurement of the milk shall be taken before agitation. If the agitator is running upon arrival at the milkhouse, the measurement can be taken only after the surface of the milk has been quiescent.

b. Carefully insert the measuring rod, after it has been wiped dry with a single-service towel, into the tank. Repeat this procedure until two (2) identical measurements are taken. Record measurements on the farm weight ticket or electronic record.

c. Do not contaminate the milk during measurement.

6. **Pump Out Procedures:**

a. Once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk is below the level that will cause over-agitation.

b. When the milk has been removed from the tank, disconnect the hose from the outlet valve and cap the hose.

c. Observe the inside surfaces of the bulk tank for foreign matter or extraneous material and record any objectionable observations on the farm weight ticket or electronic record.

d. With the outlet valve open, thoroughly rinse the entire inside surface of the tank with warm water.

Pages 137 and 138

7. **Labeling:** The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading, electronic record or weight tickets is the responsibility of the bulk milk hauler/sampler. A milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station is required to be marked with the name and address of the milk plant or hauler and the milk tank truck shall be under a proper seal. All shipping documents or electronic record must contain the following information as outlined in Section 4- Labeling, of this *Ordinance*:

a. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS BTU identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;
b. Permit identification of the hauler, if not an employee of the shipper;
c. Point of origin of shipment;
d. Milk tank truck identification number;
e. Name of product;
f. Weight of product;
g. Temperature of product when loaded;
h. Date of shipment;
i. Name of supervising Regulatory Agency at the point of origin of shipment;
j. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;
k. Seal number on inlet, outlet, wash connections and vents; and
l. Grade of product.

All information contained on the above described documents <u>or electronic record</u> shall be verified by the Regulatory Agency and recorded on the appropriate inspection sheet for any bulk milk tank trucks under inspection.

Make the following change to the 2009 MMSR.
~~Strike out~~ text to be deleted and <u>underlined</u> text to be added.
Page 85
3. All milk and milk products properly labeled (*Grade "A" PMO*, Section 4 - LABELING).

a. Prorate by Product: Number of different products correctly labeled vs. total number of products, including raw.
b. Include in Label Review:

1.) A representative label(s) for all products produced, including raw. Products are labeled according to the *Grade "A" PMO* definition(s) and requirements and applicable CFRs.
2.) Vehicles hauling milk must be properly identified with the name and address of the milk plant or hauler. (Include under raw milk.)
3.) Milk cans from producers properly identified. (Include under raw milk.)
4.) Bills-of-lading and farm weight tickets <u>or electronic record</u> contain all the required information, including BTU #. (Include under raw milk where applicable.)

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	204
Committee:	MMSR

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

A. Summary of Proposal

To amend the current requirement found in Section 5 *Inspection of Dairy Farms and Milk Plants* and the Methods of Making Sanitation Ratings of Milk Shippers (MMSR) Appendix A *Guidelines for Computing Enforcement Ratings Part I-Dairy Farms* and *Part II Milk Plants* that requires permit suspension for consecutive violations of the same requirement of the 2009 Pasteurized Milk Ordinance (PMO).

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

The current language found in the 2009 PMO Section 5 and MMSR Appendix A identifies that the permit of any dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor shall be subject to permit suspension/court action if two successive inspections disclose a violation of the same requirement. As it is currently written, this language does not recognize that the same section of the PMO may be consecutively violative but occur under different sets of operative facts or circumstances. When consecutive alleged violative conditions are observed to occur in the same section or requirement of the PMO, but clearly are a result of a different operative facts or circumstances, subjecting the permit holder to suspension or court action potentially deprives them of their right to due process under 42 U.S.C. 1983. This statute exposes the individual inspector to personal liability for the due process violation. This statute states that

"*Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress.*"

For example, an inspection of a milk plant finds the walls in the receiving bay are unclean and debited under item 9p. A follow-up inspection finds that the previous observations of unclean receiving bay walls have been corrected, but the walls inside the cooler are unclean and item 9p is debited again. According to the 2009 PMO Section 5 and 2009 MMSR Appendix A, the permit is now subject to suspension/court action. This exposes the permit holder to a clear 'harm' simply because another violative condition was identified under the same PMO section, even though the milk plant corrected the initial violative condition. As currently written, the guidelines do not provide the permit holder with reasonable notice and an opportunity to correct or rebut the violations giving rise to the suspension. Under these circumstances, the individual inspector could potentially be sued in his personal capacity for a constitutional deprivation of rights under 42 U.S.C 1983.

This proposal respectfully requests that the Conference amend the current language found in Section 5 of the 2009 PMO and Appendix A in the 2009 MMSR to more specifically identify and limit permit suspension/court action to occurrences where two successive inspections disclose a violation of the same requirement when the same set of operative circumstances or facts continue to exist.

C. Proposed Solution

Changes to be made on page(s): p.19 of 2009 PMO, and p.76/p.83 of 2009 MMSR of the (X - one of the following):

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

Amend the 2009 PMO, p. 19, Section 5 Enforcement Procedures.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement where the same set of operative facts or circumstances are found to exist.

Amend the 2009 MMSR, p.76 Appendix A Part I-Dairy Farms.

SANITATION REQUIREMENTS

a. Inspected prior to the issuance of a permit. (PI*)
b. Permit issuance based on compliance. (PI*)
c. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. (PS*)
d. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for consecutive violation(s) of the same requirements of Section 7 where the same

set of operative facts or circumstances are found to exist. (PS*)

Amend the 2009 MMSR, p. 83 Appendix A Part II-Milk Plants.

SANITATION REQUIREMENTS

a. Inspected prior to the issuance of a permit. (PI)*
b. Permit issuance based on compliance. (PI)*
c. Notice issued for intent to suspend permit if inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. (PS)*
d. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for sanitation and/or uncorrected critical processing elements; or
3.) Section 5 for consecutive violation of the same requirement of Section 7 where the same set of operative facts or circumstances are found to exist. (PS)*

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	205
Committee:	MMSR

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

A. Summary of Proposal

To eliminate the sampling and testing requirement for bulk shipped heat treated milk products.

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

The testing of the heat-treated milk and milk products is only for bulk shipment of the product. It has been turned into an issue that if they ship it once then they always ship the product. To keep track and to defend on ratings and other issues has been difficult. The testing requires an antibiotic test as per Section 6. Currently there is not an approved test for heat-treated cream. Back at the 2009 NCIMS conference a proposal was submitted to bring raw bulk shipped cream into the same testing requirements as per heat-treated products and was defeated and the word from the conference delegates was that it was not needed since it would be pasteurized at the point of use. The heat-treated products must also be pasteurized at the point of use. The difference between 124 degrees and 125 degrees is so minimal that it would not affect the safety of the product if we did not test the product. It does not need to be tested if used in house.

C. Proposed Solution

Changes to be made on page(s): 23,29 PMO, 82 MMSR of the (X - one of the following):

X	2009 PMO		2009 EML
X	2009 MMSR		2400 Forms

Page 23 PMO

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank or from a properly installed and operated in-line-sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.
It shall be the responsibility of the industry plant sampler to collect a representative sample of milk from each milk tank truck or from a properly installed and operated aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck.

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

~~3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from milk plants offering such products for sale, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.~~

~~4.~~3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized (including Aseptically Processed and Ultra-Pasteurized) milk and milk products required sampling and testing is to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products with no validated and accepted methods are not required to be tested.

Page 29 PMO Table 1

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS ~~AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS~~	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat. **NOTE:** Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.4°C (40°F), where sample temperature is >4.4°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**.....	Not to exceed 20,000 per mL, or gm.*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform****.....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase*****.....	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.

Page 82 MMSR

1. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the plant, shall be collected, prior to pasteurization, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

b. During any consecutive six (6) months, at least four (4) samples of each milk product processed, as defined in Sections 1 and 6 of the *Grade "A" PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

However, if the production of any Grade "A" condensed or dry milk product, as defined in the *Grade "A" PMO,* is not on a yearly basis, at least five (5) samples shall be taken within a continuous production period.

~~c. During any consecutive six (6) months, at least four (4) samples of heat-treated products shall be collected in~~
~~at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates~~
~~separated by at least twenty (20) days.~~

~~d~~ c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase,
and cooling temperature) in an official or officially designated laboratory.

d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products made at least annually in an
IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed
and records are available. Each fortified product is evaluated separately.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	206
Committee:	Other Species

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

A. Summary of Proposal

This Proposal updates the Somatic Cell Count regulatory threshold to reflect advances in on-farm practices and commercial standards for milk marketed by U.S. dairy producers.

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

Changes in on-farm practices and the application of commercial standards at the farm level have resulted in a large and continuing decline in average Somatic Cell Count (SCC) levels in the United States. The average U.S. dairy producer bulk tank SCC has decreased from 596,000 per mL in 1984[1], to 298,000 per mL in 2001[2], to 227,000 per mL in 2009[3]. The bulk tank SCC of eighty-nine percent of milk marketed in 2009[4] was below 400,000 per mL.

On October 26, 2010, delegates to the National Milk Producers Federation (NMPF) Annual Meeting passed a resolution to support lowering the SCC regulatory threshold at the 2011 National Conference on Interstate Milk Shipments.

The NMPF resolution called for reducing SCC levels in a stepwise fashion to allow producers sufficient time to meet the lowered SCC requirements (600,000 per mL effective Jan. 1, 2012; 500,000 per mL by Jan. 1, 2013; and 400,000 per mL by Jan. 1, 2014). This is similar to the

[1] Jones, G. M. 1986. Journal of Dairy Science. 69: 1699-1707.
[2] USDA. June 2007. Determining U.S. Milk Quality Using Bulk Tank Somatic Cell Counts, 2006
[3] USDA. July 2010. Determining U.S. Milk Quality Using Bulk Tank Somatic Cell Counts, 2009
[4] *Ibid.*

stepwise process employed over twenty years ago when the SCC regulatory threshold was last reduced from 1,500,000 to 750,000 per mL.

The regulatory SCC threshold is not derived for food safety reasons, the NMPF resolution also included a provision for regulatory discretion — while assuring public health — to temporarily allow for seasonality-dependent increases or increases directly resulting from events outside of human control, as well as continuation of current regulatory enforcement of a warning notice when two of the last four Somatic Cell Count tests exceed the limit, and suspension when three of the last five Somatic Cell Count tests exceed the limit. Regulatory discretion allows the competent regulatory authority to make informed decisions on a case-by-case basis.

C. Proposed Solution

Changes to be made on page(s): 24, 29, 30, 201 of the (X - one of the following):

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

Make the following change to the 2009 PMO.

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

Page 24
NOTE: When multiple samples of the same milk or milk products, except for aseptically processed milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count<u>*</u> and temperature determinations only.

Whenever two (2) of the last four (4) consecutive bacterial counts (except those for aseptically processed milk and milk products), somatic cell count<u>*</u>, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts (except those for aseptically processed milk and milk products), somatic cell counts<u>*</u>, coliform determinations or cooling temperatures.

<u>*The competent regulatory authority may authorize on a case-by-case basis, temporary deviation from the SCC standard due to short-term seasonal variation, natural disaster(s), or events or other acts of god. The competent regulatory authority will ensure that any temporary</u>

deviation does not compromise food safety. Any authorized temporary deviation from the SCC standard would not be a violation requiring notification or suspension so long as the producer does not violate the 2 of 4 and 3 of 5 provisions therein. [as footnote]

Page 29
Somatic Cell Count*... Individual producer milk not to exceed ~~750,000 per mL.~~ 600,000 per mL (effective January 1, 2012); 500,000 per mL (effective January 1, 2013); and 400,000 per mL (effective January 1, 2014).

Page 30
* Goat Milk 1,500,000/mL; The competent regulatory authority may authorize on a case-by-case basis, temporary deviation from the SCC standard due to short-term seasonal variation, natural disaster(s), or events or other acts of god. The competent regulatory authority will ensure that any temporary deviation does not compromise food safety.

Page 201.
Table 11A. Example of Enforcement Procedures for Raw Milk Laboratory Examinations Effective January 1, 2012

Date	**Confirmed Somatic Cell Counts per mL**	**Enforcement Action as Applied to a Standard of ~~750,000~~ 600,000 per Ml**
~~7/10/2009~~ 7/10/2012	~~500,000~~ 400,000	No Action Required
~~8/15/2009~~ 8/15/2012	~~600,000~~ 500,000	No Action Required
~~10/1/2009~~ 10/1/2012	~~800,000~~ 700,000	Violative; No Action Required
~~11/7/2009~~ 11/7/2012	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
~~11/14/2009~~ 11/14/2012	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 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.)
~~11/18/2009~~ 11/18/2012	~~700,000~~ 550,000	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 11/14/20~~09~~12.
~~11/20/2009~~ 11/20/2012	800,000	Violative; No Action Required **NOTE:** Samples collected prior to 11/18/20~~09~~12 are not used for subsequent somatic cell count enforcement purposes.
~~11/24/2009~~ 11/24/2012	~~700,000~~ 550,000	No Action Required
~~11/29/20009~~ 11/29/2012	550,000	No Action Required
~~12/3/2009~~ 12/3/2012	400,000	Permit Fully Reinstated

Page 201.
Table 12B. Example of Enforcement Procedures for Raw Milk Laboratory Examinations Effective January 1, 2013

Date	**Confirmed Somatic Cell Counts per mL**	**Enforcement Action as Applied to a Standard of 500,000 per Ml**
7/10/2013	300,000	No Action Required
8/15/2013	400,000	No Action Required
10/1/2013	600,000	Violative; No Action Required
11/7/2013	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
11/14/2013	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 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.)
11/18/2013	450,000	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 11/14/2013.
11/20/2013	800,000	Violative; No Action Required **NOTE:** Samples collected prior to 11/18/2013 are not used for subsequent somatic cell count enforcement purposes.
11/24/2013	450,000	No Action Required
11/29/2013	450,000	No Action Required
12/3/2013	400,000	Permit Fully Reinstated

Page 201.
Table 13C. Example of Enforcement Procedures for Raw Milk Laboratory Examinations Effective January 1, 2014

Date	**Confirmed Somatic Cell Counts per mL**	**Enforcement Action as Applied to a Standard of 400,000 per Ml**
7/10/2014	200,000	No Action Required
8/15/2014	300,000	No Action Required
10/1/2014	500,000	Violative; No Action Required
11/7/2014	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
11/14/2014	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 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.)
11/18/2014	350,000	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 11/14/2014.
11/20/2014	800,000	Violative; No Action Required **NOTE:** Samples collected prior to 11/18/2014 are not used for subsequent somatic cell count enforcement purposes.
11/24/2014	350,000	No Action Required
11/29/2014	350,000	No Action Required
12/3/2014	300,000	Permit Fully Reinstated

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

All criteria below must 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 ≤ 500,000, ≤ 450,000 (effective January 1, 2013), and ≤ 350,000 (effective January 1, 2014);

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

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

All criteria below must 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, >450,000 (effective January 1, 2013), and

>350,000 (effective January 1, 2014);

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	207
Committee:	Lab/Other Species

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

A. Summary of Proposal

Implement a plan to gradually reduce the somatic cell count (SCC) standard to 400,000 cell/ml by January 1, 2014 and to adopt a rolling geometric mean calculation for producer bulk milk SCC.

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

Somatic cell counts (SCC) of herd bulk milk are used worldwide as indicators of: a) herd mastitis control; b) the hygienic conditions under which the milk is produced; and c) the quality/suitability of the raw milk supply for fluid milk and manufactured dairy products. Nearly all countries have adopted SCC standard limits and such limits are used to define milk as either suitable or not suitable for human consumption. The US SCC standard is the most lenient of any of the developed countries of the world. The vast majority of dairy producing countries, and particularly those with significant international trade of milk and milk products, have adopted 400,000 cells/ml as the acceptable upper limit for herd bulk tank milk intended for human consumption.

Reducing the US standard to 400,000 cells/ml would lead to: a) improved consumer confidence of the safety and wholesomeness of the US milk supply; b) improved consumer confidence that the milk supply is produced by healthy cows; c) harmonization of standards for international trade of milk and milk products; d) improved competitive position of the US dairy industry in the global market place; e) reduced risk of residues in milk; f) reduced risk of the presence of human pathogens and their toxic products in the milk supply; and g) greater profits to producers through decreased herd level of mastitis.

Adopting the rolling geometric mean calculation for herd SCC would provide producers with a valuable management statistic and would lead to increased international harmonization of standards as nearly all major dairy producing countries use the geometric mean calculation. The geometric mean is the mathematically correct statistic to use for averaging SCC data. Adopting a geometric mean based on three consecutive monthly samples would reduce the possible volatility in herd SCC observed in some herds where one cow can have a major impact on SCC, and/or the volatility observed with season of the year and adverse weather conditions.

The technology is available to all US dairy producers to consistently produce milk less than 400,000 cells/ml. Meeting this internationally acceptable standard would not constitute a hardship for the vast majority of producers who are producing a quality product. Lowering the standard gradually will result in improvements in milk quality and safety in a manner that should avoid constituting an acute hardship on producers currently not meeting a tighter SCC standard. Reducing herd SCC would also increase producer profits as milk yield increases as SCC decreases.

This proposal is a logical, producer-friendly solution to improve the quality and suitability of the US milk supply to the benefit of US consumers. The proposal will improve the US position in the international trade of milk and milk products. The adoption of a geometric mean is logical, will not require new or sophisticated equipment, and harmonizes international methods for dealing with SCC data. The proposal allows for a one-year adjustment to monthly samples and the rolling geometric mean, and then the SCC standard is reduced over a two-year period to 400,000 cells/ml.

C. Proposed Solution

Changes to be made on page(s): 29 of the (X - one of the following):

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

Modify the 2009 PMO. Page 29, Table 1:

Somatic Cell Count*... Individual producer milk not to exceed 750,000 per mL (through December 31, 2012), 550,000 per mL (effective January 1, 2013) and 400,000 per mL (effective January 1, 2014).

Explanation of Time Table:

January 1, 2012 - Maintain the current SCC standard and means for determining compliance but phase in the adoption of a rolling geometric mean calculation for herd SCC. The new program would require SCC to be determined on all herds once during each calendar month by an FDA approved regulatory laboratory. Monthly sampling and calculation of the rolling geometric mean should be operational by all state regulatory agencies by December 31, 2012.

Calculation of the rolling geometric mean - The rolling geometric mean would be calculated based on the SCC values from the 3 most recent months. The geometric mean is calculated by converting the SCC values to Log base 10 (Log_{10}), summing the 3 Log_{10} values, dividing the sum by 3 and converting the value to the arithmetic number by finding the antilog (all calculations are easily done on hand held calculators or desk top computers). The rolling geometric mean would be expressed as cells/ml of milk to the nearest 1,000 cells, i.e. 253,225 cells/ml would be reported to the producer as a rolling geometric mean of 253,000 cells/ml.

January 1, 2013 - Lower the standard to 550,000 cells/ml based on a rolling geometric mean.

January 1, 2014 - Lower the standard to 400,000 cells/ml based on a rolling geometric mean.

Details of determining compliance should be crafted by the appropriate regulatory agencies. A suggested solution follows:

Producers would be notified monthly of their rolling geometric mean and the actual SCC value of their most recent sample. When a producer's rolling geometric mean exceeds the standard (see the time table), the producer will be notified in a warning letter that he/she was in violation and that a check sample will be taken and analyzed within the next three weeks but not before one week following receipt of the warning letter. The SCC of the check sample must be below or equal to the SCC standard for the producer to maintain his/her license. If the SCC of the check sample following a warning notification is above the standard, the producer will be notified in writing that his/her license to sell milk will be suspended by procedures in use under the current PMO. If the SCC of the check sample following warning notification is below or equal to the standard, then the producer continues to sell milk but would remain on warning as long as the rolling geometric mean is above the standard. The SCC value of the check sample would be included in the calculation of the rolling geometric mean. Therefore, the month during which the check sample was taken would contribute two, and possibly three, values to the rolling geometric mean. The producer would remain on warning status as long as the geometric mean is greater than the SCC standard. While on warning, the SCC of all samples must be below or equal to the regulatory limit or the producer's license shall be suspended. A suspended license may be reinstated by demonstrating that the SCC of a single bulk tank milk sample is below or equal to the SCC standard. Reinstatement shall not occur before two days following license suspension. A producer that is reinstated following a license suspension within the past 12 months will be on warning for the first three sample months following reinstatement and all samples analyzed during this period must be below or equal to the SCC standard; if the monthly SCC exceeds the SCC standard, the producer's license shall be suspended. The rolling geometric mean for the reinstated herd would be calculated using only the available samples (one per month for a maximum of three months) since time of reinstatement.

The rolling geometric mean for new producers would be calculated based on all available samples until the producer reaches three sample months and then the calculation would be as described above. The same rules for exceeding the SCC standard would apply to new

producers regardless of the number of samples collected and used to calculate the rolling geometric mean.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	208
Committee:	Hauling/Lab

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

A. Summary of Proposal

Add allowances in the PMO for use of an approved alternative farm bulk tank sampling system for the purpose of obtaining the farm bulk tank universal sample as required in Section 6-The Examination of Milk and Milk Products and as referenced in Appendix B-Milk Sampling, Hauling and Transportation of the Grade "A" PMO. FDA/LPET has been provided 200 of the 300 data points required and found the data to be acceptable at the time of submission of this proposal. The other data points well be submitted to FDA/LPET around the end of February for review.

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

Producers want an alternative sampling method to choose from to obtain a universal bulk tank sample when their milk is picked up and offered for sale. As bulk tanks have increased in size the method and way the universal sample is obtained has not changed. There are two approved exceptions. One is for a direct loading operation where three different sampling devices have been approved and the other is for sampling by aseptic septum needle only method. Producers have been requesting for an alternative sampling method that can be used on farm bulk tanks that is more aseptic and more representative of all the milk pumped onto the bulk milk pick-up tanker and offered for sale. This proposal is written in generic terms following the NCIMS approved direct load sampling template. A specific SOP for the method and procedure requesting approval, the QMI Alternative Aseptic Farm Bulk Tank Sampling System, is included in the proposed solution.

C. Proposed Solution

Changes to be made on page(s): Table of contents "X", 24, 26, 130, 132, 134, of the (X - one of the following):

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

Proposal: Alternative Aseptic Sampling of Farm Bulk Tank(s) Universal Sample
Areas of suggested adjustment in the 2009 PMO
Table of Contents (continued) page

(X)
APPENDIX B. MILK SAMPLING, HAULING, AND TRANSPORTATION..... 130
I. MILK SAMPLING AND HAULING PROEDURES..... 130
II. REQUIREMENTS FOR USING AN APPROVED IN-LINE SAMPLER..... 134
III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS..... 134
IV REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR OBTAINING FARM BULK TANK UNIVERSAL SAMPLES..... 135
V MILK TANK TRUCK PERMITTING and INSPECTION..... 136

Page 24 - last paragraph

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers, aseptic samplers for milk tank trucks, alternative aseptic sampler for farm bulk tank(s) universal sample(s) shall be in substantial compliance with the most current edition of the PMO.

Page 26 – LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers, aseptic samplers for milk tank trucks, alternative aseptic farm bulk tank sampler for taking universal sample(s), and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the NCIMS/FDA 2400 series Laboratory Forms and OMA.

PAGE 130 - APPNENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Training: To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler, aseptic samplers for milk tank trucks and alternative aseptic farm bulk tank sampler, all bulk milk hauler/samplers and industry plant samplers must be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples.

Page 132 – Specific items to be evaluated in determining compliance include:

Under number 2. Equipment Requirements:

Item c. Sample dipper or other sampling devices such as an alternative aseptic farm bulk tank sampler, of sanitary design and material approved by the Regulatory Agency; clean and in

good repair.

Page 132; Universal Sampling System
Add a new 5.1 or collect the universal farm bulk tank sample(s) using the Approved Alternative Aseptic Farm Bulk Tank Sampling System. Refer to the requirements for using this system in item IV on page 134.

Current page 134 -

IV. REQUIREMENTS FOR USING AN APPROVED ALTERNATIVE FARM BULK TANK SAMPLER

A protocol specific to each milk producer in which the producer or hauler utilizes an approved alternative aseptic farm bulk tank sampling system shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer the milk producer and the FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
   a. The aseptic sampler fitting must be installed according to the manufacture's recommendations and in a manner that is compatible with its intended use.
   b. The aseptic sampler septum must be installed according to the manufacturer's instructions.
   c. Transfer of milk is achieved using a Standard Operating Procedure (SOP) specific to the aseptic sampler.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the sample collection device as well as collect, identify, handle and store the milk sample.

Milk Sample Collection Evaluation Form, Form FDA-2399 (10/06)

Item 9. Raw milk for pasteurization- milk tank trucks and plant storage tanks. (Refer to Item 8 for applicable procedures).....

b. Collect sample in a sanitary manner from tank opening (manhole)

new item c. Collect sample from farm bulk tank using an approved aseptic sampler

Re-number the rest of the number 9 as appropriate.

Old item i, re-numbered item j
Sample dipper washed and sanitized after each use and replaced in sanitizing solution

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==========.

SOP for QMI
Alternative Aseptic Bulk Tank Sampling System

General Requirements:

1) The farm bulk tank(s) must have a working agitator equipped with a timer. This timer must make the bulk tank agitator run the minimum amount of time the bulk tank manufacture specifies.
2) There is no need to run the bulk tank agitator before pumping all the milk from the bulk tank using this QMI system onto the bulk milk transport tanker.
3) If the bulk tank will only be a partial pick-up, run the agitator before pumping milk from the bulk tank onto the bulk milk transport tanker as per manufacturer's specifications. Then run the QMI sampling system as normal.
4) The person(s) performing the following steps shall possess a valid bulk tank milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency

Device Requirements:

1) The QMI supplied septum sampling device can be attached to the outlet valve of the farm bulk tank so it can be cleaned-in-place (CIP) when the farm bulk tank is washed or alternatively can be removed after each use to hand clean and sanitize before the next usage.
2) Use only QMI sterile septum inserts; hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten..
3) The protective cover for the septum shall be in place at all times when the septum is not in use.
4) Wash and sanitize hands before performing the following steps.
5) When ready to pump out the milk, remove the septum protective cover.
6) Sanitize the QMI sample septum protective white cover before inserting the sampling needle. For the perimeter needle channels, slant the needle toward the center, following the angle of the channel. Be careful not to bend the lumen tip of the needle.
7) SEPTUM REPLACEMENT PROCEDURE.

   a) There are seven (7) sampling ports in each QMI septum. Use a new sampling port each time a farm bulk tank is pumped out. Replace the septum when all seven (7) sampling ports have been used.

   b) Use each QMI septum insert sampling port ONLY ONCE! "Pierced sampling ports can be easily seen. Once pierced, a port may not be used again.

   c) When all 7 QMI septum insert sampling ports are used, remove the nut that holds the QMI septum in place and remove the used QMI septum insert and discard.

d) CLEAN and SANITIZE the QMI septum insert holder area and install a new QMI septum insert, replace the nut, hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten. The protective cover should be kept over the QMI septum insert at all times when not in use.

8) Use only QMI supplied sterile sample collection bags designed to work with this system.
9) Use only the peristaltic pump recommended by QMI.
10) Volume of the milk sample obtained can be no more than approximately three quarters (¾) of the volume of the QMI sample collection bag used. Pump speed (RPM) for pump type and size of QMI aseptic sampling bag used determined and recorded.
11) The QMI sample collection bag must be placed in a portable hand carry type cooler during pumping out the milk from the bulk tank to maintain the temperature of the sample to no more than the allowable temperature in the PMO.

Sampling Procedures:

1) The person(s) performing the following steps shall possess a valid bulk tank milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.
2) The person(s) performing the following steps shall wash their hands before carrying out those steps.
3) If QMI sampling septum device is not attached to the bulk tank outlet valve and has not been CIP cleaned and sanitized with the bulk tank wash, hand WASH and SANITIZE the bulk tank outlet valve and QMI sampling septum device. (See **Device Requirements item 1)**. Use a spray bottle with approved sanitizer to best sanitize the outlet valve on the bulk tank
4) Attach the QMI sampling septum device to the bulk tank.
5) Remove the protective cover cap from the QMI sampler
6) Sanitize the white covering area over the QMI sampling septum.

7) Position the QMI peristaltic pump close enough to the bulk tank outlet valve so the QMI sampling bag can be hooked up with the needle going into an unused port on the QMI septum and the QMI sample collection bag in the portable hand carry type cooler.
8) On the QMI peristaltic pump open the sampling head by lifting up on the lip on the upper part of the pump head. Operator's manual has pictures of this step.
9) Take out a QMI sampling bag and locate the fatter section of the tubing. Place this fatter tubing section in the space created after opening the pump head lid and close the pump head lid when the tubing is positioned straight over the rollers in the pump head.

10) Take the cover off the needle attached to the one end of the QMI sample collection bag tubing and locating an unused sampling port, there are 7 on each QMI septum insert and push the needle completely into the septum. For the perimeter needle channels, slant the needle toward the center following the angle of the channel. Be careful not to bend the lumen tip of the needle.

11) Use each QMI septum insert sampling port ONLY ONCE! Pierced septum insert sampling ports can be easily seen. Once pierced, a port MAY NOT be used again. See **Septum Replacement Procedure in Device Requirements item 7**.

12) When all 7 QMI septum insert sampling ports have been used, remove the nut that holds the QMI septum in place and remove the used QMI septum insert and discard. See **Septum Replacement procedure in Device Requirements item 7**.

13) CLEAN and SANITIZE the QMI septum insert holder area and install a new QMI septum insert, replace the nut, hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten. The protective cover should be kept over the QMI septum insert at all times when not in use.

14) Open the bulk tank outlet valve, press the start button on the control pad of the peristaltic pump and turn on the pump.

15) Make sure the RPM's of the pump display match what has been determined to meet the requirements in item 10 under Device Requirements.

16) If milk is not flowing toward the pump and sampling bag press the clockwise-counterclockwise arrows on the pump display until the milk starts flowing toward the bag.

17) Place and maintain the QMI sample collection bag in the cooler during sampling so the temperature of the sample is maintained at or below PMO temperature requirements. See **Device Requirements item 11.**

18) When the bulk tank has been emptied or collection of partial pickup completed turn off the pump and remove the needle from the QMI septum. Replace the needle cover.

19) Lift the pump head lid to open it up to allow removal of the sample tubing. The reverse process as was used in step 9. Tie a knot in the QMI sample collection bag tubing close to where the tubing is attached to the bag.

20) Take the sample bag and invert with constant uninterrupted inversions 25 times. This agitates the QMI sample collection bag so that a representative sample can be taken from the milk collected in the bag.

21) Sanitize (using an approved sanitizer) a cutting device and cut the tubing from the QMI sample bag just above where the tubing attaches to the bag. Tip the bag and allow some milk to flow before positioning a properly identified sample vial (use the same identification as would be used for a conventional dip sample) into the milk stream to fill the sample vial ¾ full. (Note: QMI sample collection bags are to be used only ONCE).

22) Immediately transfer the sample vial(s), to the bulk milk pick-up tankers sample storage cooler to maintain proper temperature. A temperature control (TC) sample will also need to be taken at the first stop on the bulk milk pick-up tankers route.

23) Handle the sample(s) from this point the same as a conventionally obtained universal dip sample.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	209
Committee:	Appendix N

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

A. Summary of Proposal

This Proposal updates criterion for the Commissioner of FDA to utilize for determination that a potential problem exists with animal drug residues or other contaminants in the milk supply that would result in additional analysis for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances.

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

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE provides the basis for antibiotic residue screening requirements within the PMO. The required screening of Beta lactam drug residues has been successful in reducing the already low incidence of 0.028%, a decrease of 73% in the past 12 years. At the request of NCIMS, FDA is currently undertaking a risk analysis of APPENDIX N to determine if any change in the residue testing program is warranted.

The PMO also provides the Commissioner of FDA authority to require additional testing if a potential problem exists with animal drug residues. A determination of the Commissioner of FDA is based upon five criterion including "USDA tissue residue data from cull and veal dairy animals." Veal is a distinct livestock production process from milk production from dairy cattle that does not represent an appropriate criterion for such a determination by the Commissioner of FDA. Veal livestock have separate management systems from dairy animals and do not produce milk. Because veal livestock do not produce milk, drug residues which occur in veal livestock do not have a pathway to enter the commercial milk supply. Therefore, the National Milk Producers Federation is requesting that USDA tissue residue data from veal livestock be removed from this criterion.

C. Proposed Solution

Changes to be made on page(s):	25	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following change to the 2009 PMO.

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

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Page 25
The determination of a problem is to be based upon:
1. Sample survey results;
2. USDA tissue residue data from cull ~~and veal~~ dairy animals;
3. Animal drug disappearance and sales data;
4. State feed back; and
5. Other relevant information.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	210
Committee:	Hauling

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

A. Summary of Proposal

To allow for the location of tanker stickers on the front bulkhead of milk tank truck.

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

The area near the outlet valve is often an unsuitable area for the attachment of inspection stickers as this area on a tanker is subjected to elements on a daily basis and to cleaning chemicals and water during each wash. This environment often renders the attached stickers illegible in less than the year it needs to last.

Also, there are a variety of configurations of tankers and many do not have enclosed outlet valves other than an outlet valve cap. All tankers, regardless of the configuration, have a front bulkhead area and this area is a much more suitable area to locate a sticker.

C. Proposed Solution

Changes to be made on page(s): 135 of the (X - one of the following):

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

Change the following sentence by striking the words "near the outlet valve" and adding the words "on the front left side of the tanker bulkhead"

The affixed label shall be located near the outlet valve <u>or on the front left side of the tanker bulkhead</u>.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	211
Committee:	Hauling

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

A. Summary of Proposal

To require that milk tank trucks, that sit idle for more than four (4) hours between picking up milk, must wash the milk hose, milk pump and associated parts at a licensed / permitted Grade A facility before the resumption of picking up milk.

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

Due to economic pressures many milk tank trucks must be operated around the clock to remain profitable. An associated problem is that some samplers pick up milk in the evening (after the milk tank truck has been washed and sanitized) as they head home. Milk is again picked up in the morning as the milk tank truck heads back to the plant. The problem is that the milk hose, milk pump and associated appurtenances contain milk at ambient temperatures for greater than four (4) hours. Four hours is the generally recognized amount of time that it takes for bacteria to grow to high enough numbers to cause illness. (McSwane, Rue & Linton, "Essentials of Food Safety and Sanitation – 3rd Edition", Prentice Hall, Copyright 2003; page 37). The milk picked up in the morning sweeps the bacteria laden milk in the milk hose and milk pump into the good milk held in the insulated milk tank. The milk plant receives a load of milk that does not accurately reflect the bacteria tests of the producer samples.

The PMO states that milk may be picked up continuously within a 24 hour period, but does not directly address this situation.

C. Proposed Solution

Changes to be made on page(s):	137	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Add language to the 2009 PMO, Appendix B: Milk Sampling, Hauling and Transportation, Section IV. Milk Tank Truck Permitting and Inspection – Milk Tank Truck Standards: Number 3. Equipment Construction, Cleaning, Sanitizing and Repair, # 3-b (4) as follows:

(4) The milk tank truck appurtenances shall be cleaned and sanitized at a milk plant, receiving station, transfer station or milk tank truck cleaning facility whenever there is greater than a four (4) hour lapse of time between a pick-up of milk and subsequent milk pick-ups.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	212
Committee:	Scientific

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

A. Summary of Proposal

To establish an acceptable criteria for the onsite production and sanitization use of hypochlorous acid.

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

Hypochlorous acid is already approved, at concentrations not to exceed 200 ppm, for use as an ingredient in an antimicrobial pesticide formulation that may be applied to dairy processing equipment, and food-processing equipment and utensils (Title 40: Protection of Environment; Part 180: Tolerances and Exemptions for Pesticide Chemical Residues in Food; Subpart D: Exemptions From Tolerances).

Hypochlorous acid can be generated by the electrolysis of a dilute NaCl (brine) solution passing through an electrolytic cell consisting of anode and cathode chambers separated by a membrane. The cell allows for the migration and separation of ions through the membrane. During this process, two separate streams of activated water are produced: hypochlorous acid (HOCl) on the anode side of the cell and sodium hydroxide (NaOH) on the cathode side.

The current EPA process for registering a chemical solution as an effective sanitizer does not address those solutions that are produced and used onsite. As a result, very specific production and efficacy criteria have been proposed below under which hypochlorous acid would be considered to be effective for the sanitization of milk containers, utensils and equipment.

C. Proposed Solution

Changes to be made on page(s): Pages 202 and 210 of the (X - one of the following):

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

Modify the 2009 PMO, page 202, Appendix F. Sanitization, Section I. Methods of Sanitization, Chemical.

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in 21 CFR 178.1010 and shall be used in accordance with label directions, or equipment manufacturer instructions if produced onsite in accordance with Section III below.

Modify the 2009 PMO, Appendix F. Sanitization to include a new Section III starting on page 210.

III. ACCEPTED CRITERIA FOR THE ONSITE PRODUCTION AND SANITIZATION USE OF HYPOCHLOROUS ACID

BACKGROUND

Hypochlorous acid is already approved, at concentrations not to exceed 200 ppm, for use as an ingredient in an antimicrobial pesticide formulation that may be applied to dairy processing equipment, and food-processing equipment and utensils (Title 40: Protection of Environment; Part 180: Tolerances and Exemptions for Pesticide Chemical Residues in Food; Subpart D: Exemptions From Tolerances).

Hypochlorous acid can be generated by the electrolysis of a dilute NaCl (brine) solution passing through an electrolytic cell consisting of anode and cathode chambers separated by a membrane. The cell allows for the migration and separation of ions through the membrane. During this process, two separate streams of activated water are produced: hypochlorous acid (HOCl) on the anode side of the cell and sodium hydroxide (NaOH) on the cathode side.

The current EPA process for registering a chemical solution as an effective sanitizer does not address those solutions that are produced and used onsite. As a result, very specific production and efficacy criteria have been defined below under which hypochlorous acid is considered to be effective for the sanitization of milk containers, utensils and equipment.

CRITERIA

The following is a list of criteria that is required to accept hypochlorous acid, that was produced onsite, as an effective sanitizer of milk containers, utensils and equipment.

1. An acceptable hypochlorous acid solution is one that meets DIS/TSS-4 Jan 30, 1979 Efficacy Data Requirements, Sanitizing rinses (for previously cleaned food-contact surfaces). The applicable test requirements and performance standards are:
   a. Test requirement. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.
   b. Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.

   The manufacturer of the production machine is required to keep on file all related testing results and must make the information available to regulatory agencies upon their request.

2. The manufacturer of the machine used to produce an acceptable hypochlorous acid solution must obtain an EPA establishment number for the machine and must comply with all related machine labeling and reporting requirements.

3. The manufacturer of the machine shall provide instructions on the production and use of the acceptable hypochlorous acid solution as an effective sanitizer without post-rinse. In addition, the manufacturer shall specify: 1) the minimum acceptable Free Available Chlorine (FAC) level of the hypochlorous acid solution to be used with the maximum not to exceed 200ppm, 2) the acceptable pH range of the hypochlorous solution to be used, and 3) the maximum amount of residual NaCl in the hypochlorous solution to be used measured in terms of microsiemens. Onsite testing of the FAC level is recommended on a regular basis to ensure compliance.

4. The machine used to produce an acceptable hypochlorous acid solution must possess the capability to measure and record on a real time basis the following production parameters, and automatically stop production and trigger an alarm when operating outside of the application specifications.
   a. Softened water flow into the electrolytic cell
   b. Brine solution flow into the electrolytic cell
   c. Voltage and amperage across the electrolytic cell

5. The machine used to produce an acceptable hypochlorous acid solution must possess the capability to measure and record on a real time basis the ORP, pH and microsiemens of the generated hypochlorous acid, and automatically stop production and trigger an alarm when operating outside of the application specifications.

6. The machine used to produce an acceptable hypochlorous acid solution shall be designed with an automatic, self-cleaning capability such that the electrolytic cell and the integrated water softener are cleaned on a regular frequency and in a consistent manner to ensure that they operate within their application specifications.

7. The machine shall be constructed of materials that do not impart toxic materials into the acceptable hypochlorous acid solution either as a result of the presence of toxic

constituents in the materials of construction, or as a result of physical or chemical changes that may occur during the electrolysis process.

8. All records shall be accessible to the Regulatory Agency for inspection. Electronically generated records, if used, shall meet the criteria specified in Appendix H., V.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	213
Committee:	Scientific

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

A. Summary of Proposal

The 2009 Grade A PMO and previous PMOs made use of chemical sanitizers as a method of achieving sanitizing results that meet strict guidelines set out by the FDA and EPA – See PMO Appendix F I. Methods of Sanitization.
These chemicals are referenced in 40 CFR 180.940 and were formerly referenced in 21 CFR 178.1010. All of these referenced, registered "pesticides are generally hazardous, expensive and environmentally unsafe". In their concentrated forms, all of these registered they are "toxic", poisonous and have aggressive safety data sheet protections. Congress in fact, refers to them as "ECONOMIC POISONS" (page three short title of FIFRA).

This proposal will provide information for the implementation of a form of On-Site Pesticidal Device commonly referred to as ECA generators. "ECA" is an acronym for electro-chemical activation. The process is referred to as dilute brine electrolysis and the technology form is commonly referred to as membrane technology, whereby a dielectric membrane keeps anolyte and catholyte electrolytes separate whilst they are within the ECA cell itself. The anolyte solutions produced by these devices are not only broad spectrum efficacious, but they are non-toxic pursuant to their cyto-toxicity testing and peer reviewed publications. They present an excellent risk reduction for the environment, for workers and the public.

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

To introduce new methods for cleaning and sanitization – ECA (Electro-Chemical Activation) to be included in the 2011 PMO, known in other industries as ECA "on-site" generation.
The chemicals produced on-site can meet or exceed the sanitizing requirements for Chlorine based sanitizers and other "no-post rinse" sanitizers as set out by the U.S. FDA and U.S. EPA.

ECA on-site generated detergents and sanitizers have been used in numerous industries including the Dairy Industry. ECA has a proven track record. This area of science has become known generically as Electro-chemical Activation or "ECA". Electro-Chemical Activation (ECA) is the generation of activated solutions by passing a dilute NaCl solution through an electro-chemical cell, segregating the ions formed and producing two oppositely charged solutions with altered physical and chemical properties. Electro-Chemical Activation changes the state of the salt solution from a stable to a metastable state. The process also liberates oxygen and hydrogen from water simultaneously yielding two very unique non-toxic metastabilized electrolytes in dynamic equilibrium. One solution is a very effective sanitizer generically referred to as Anolyte; branded by Trustwater as Ecasol™. The second solution is a detergent generically called Catholyte, and branded by Trustwater as Aversol™.

ECA generated solutions offer numerous advantages over conventional chemicals and their respective cleaning procedures:

- Reduction in time required to clean and sanitize, thus reducing eventual overtime or making more time available for production activities.
- Reduction in the cost of chemicals, energy and water used and the cost of wastewater disposal associated with equipment and pipe cleaning and sanitizing processes.
- Microbiological integrity is maintained.
- Improvement in staff welfare by minimizing the handling of and/or exposure to chemical products and high temperature cleaning and sanitizing solutions.

Scientific and Technical Data attached with this proposal provides scientific evidence as proof for clarity for claims made about ECA technologies and their advantages to the Dairy industry as provided. This data pertains to Trustwater's Anolyte (branded Ecasol™) and Catholyte (branded Aversol™) solutions, however the final 2011 PMO shall be used to implement all ECA technologies.

Further data will be submitted pending availability of results.

C. Proposed Solution

Changes to be made on page(s): Page 46, 202, 270 of the (X - one of the following):

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

Modify Paragraph on page 46

2. Certain chemical compounds and methods are effective for the sanitization of milk utensils, containers, and equipment. ~~These are contained in 21 CFR 178.1010 and shall be used in accordance with label directions. (Refer to Appendix F. for further discussion of approved sanitizing procedures.)~~ Refer to Appendix F for Methods of Sanitization.

Create new Section in Appendix F

APPENDIX F. SANITIZATION

I. METHODS OF SANITIZATION

CHEMICAL

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in 40 CFR 180.940 and shall be used in accordance with label directions

ECA Technology

Electro-Chemical Activation (ECA) on-site generated Anolyte sanitizing solution is used in the milk processing industry for sanitizing milk containers, utensils and equipment – procedures can be found in Appendix H Section X.

Create New Section in Appendix H

X. Procedures for using on-site generated detergents and sanitizers

Electro-Chemical Activation (ECA) solutions are generated by passing a dilute NaCl solution through an anode, cathode and membrane resulting in a two-stream output of two oppositely charged solutions with altered physical and chemical properties.
The positively charged solution, known as Anolyte is a pH neutral sanitizer and is used in the CIP process, sanitizing of equipment and containers in place of hot water and/or chemicals as a sanitizing agent.

The negatively charged solution, known as Catholyte has detergent properties, and is produced at a pH of approximately 13.5pH, and consists predominantly of sodium hydroxide. Catholyte is a non-toxic and is used in the CIP process for cleaning of equipment and containers in place of hot water and/or chemicals as a cleaning agent.
Anolyte and Catholyte are produced on-site by an ECA Generator. The ECA generator is installed independently of the plant control system. Level switches shall be installed in both concentrate tanks and are used to start and stop the generator automatically in order to ensure that supplies of the anolyte and catholyte solutions are available when required. Level switches installed in both concentrate tanks shall provide an early warning signal to the plant control system in the event of low concentrate solution level. The ECA generator shall provide operational status signals to the plant control system. The status control signals shall include a Run Mode signal; Standby Mode and Alarm mode signals.

Before use the Anolyte and Catholyte shall be diluted to the required concentration and stored in dilute storage tanks using automative float controls whereby the device ensures appropriate levels in the storage tank at all times . During the cleaning and sanitizing process the effectiveness of the Anolyte and Catholyte depends on chemical properties of the solutions and contact time. For this reason the dilute concentration of the Anolyte Sanitizer shall be controlled using a standard pH compensated FAC (free-available chlorine) analyser and the Catholyte Detergent shall be controlled using a standard pH analyser. The FAC probe and pH probe shall be installed on the CIP return line.
Optionally conductivity can be used to control the Anolyte and Catholyte Concentrations.
Manual dosing of the Anolyte and Catholyte with manual sampling shall be used where an

automated process is not available.

Requirements for On-Site Pesticidal Devices for the Generation of Sanitizers and Cleaners

1. The Device (generator) shall be registered with the U.S. EPA as per the pesticide devices act 40 CFR 152.500 and comply with the labeling requirements outlined in 40 CFR 156.10
2. The sanitizer shall meet the Efficacy requirements for EPA DIS/TSS 4 Sanitizers Rinses (for previously cleaned food-contact surfaces). The Sanitizer it produces shall meet the Data Requirements of U.S. EPA 40 CFR Part 158, "Data Requirements for Registration", Pesticide Assessment Guidelines – Subdivision G, 91-2(f), and its test documents shall be pursuant to Good Laboratory practices (GLP's).
3. Sanitizers produced by on-site generators shall be stored in suitable containers, and shall be labeled with the contents wherein the label displays the EPA Establishment Number for the device manufacturer. The label shall also provide dilutions and use instructions along with a list of its active and inert ingredients and other required standard safety data sheet (formerly refered to as MSDS) disclosures.
4. Standard DPD titration methods shall be used to verify that the sanitizer is being applied at the required concentration for each intended use. Where test strips are permitted for spot verification, current, appropriate test strips may be used in lieu of titration methods.
5. Standard Calibrated pH probes shall be used to verify that the pH of the sanitizer and detergent are within acceptable levels. Where test strips are permitted for spot verification, current, appropriate test strips may be used in lieu of titration methods.
6. Certain materials are oxidized or otherwise corroded by at specific chloride levels which in turn correlate to free available chlorine concentrations. It is important that the needed FAC concentration given the required contact time presents a chloride concentration that is less than the corrosive index as recommended by the equipment manufacturer.
7. The generator shall be certified to the relevant ANSI Electrical, Mechanical and sanitation Safety Standards for installation in the U.S. or other appropriate relevant standard.
8. Operator training shall be provided by On-Site generator manufacturer. Basic training shall provide the operator with methods to verify that the sanitizer parameters are within specified tolerances, and that the detergent character is appropriate for the intended cleaning or biofilm control use. Basic training shall also allow the operator to maintain the device in good working condition.
9. A HMI (Human Machine Interface) shall give the operator status readout to ensure that the generator is operating within the limits that allow production of anolyte and catholyte solutions at the correct concentrations. The HMI shall not allow unauthorized entry to prevent disruption to settings and ensure solution consistency.
10. The generator shall have self-diagnostics and have the functionality to log and report an error or fault condition that has occurred to the plant central control PLC.
11. An air/gas Extraction system is installed to both concentrate tanks and the generator to remove any harmful gases. The volume of air/gas to be extracted will vary and shall meet the generator manufacturers recommendations. The extraction shall be fitted with a fault detection system such as an air flow detection switch, rotation sensor or differential pressure switch. In the event of a failure the generator shall be placed into a safe mode.
12. A standard drain is required to remove any overflow or spillage of the solutions, where a single drain point shall be used to remove both solutions.
13. The water supply to the generator shall meet the requirements of the Generator manufacturer.
14. The salt supply to the generator shall meet the specifications recommended by the Generator manufacturer.
15. FAC and pH probes shall be routinely checked and calibrated, and their offsets maintained in a continuity log. FAC and pH levels during the CIP procedures shall be event or continuously logged. Logging rates for CIP processes shall be in continuous form with a minimum of one data

sample per to provide meaningful trend data for CIP process validation.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	214
Committee:	

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

A. Summary of Proposal

This Proposal provides an update to Appendix F. Sanitization of the PMO in relationship to the Code of Federal Regulations (CFR) citation referenced under I. Methods of Sanitization, Chemical from 21 CFR 178.1010 to 40 CFR 180.940; corresponding correction to the citation in Item 11r-Utensil and Equipment – Sanitization; and also adds the updated CFR reference to Appendix L. Applicable Regulations, Standards of Identity for Milk and Milk Products and the *Federal Food, Drug, and Cosmetic Act* of the PMO. This Proposal is only an editorial correction to the appropriate CFR reference and does not expand, restrict or in any way affect what is already required under the 2009 PMO.

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

This Proposal makes an editorial correction to Appendix F. of the PMO to identify a change in Federal government agency responsibility for maintaining the most current list of chemical compounds accepted as effective for the sanitizing of milk containers, utensils and equipment from FDA to the Environmental Protection Agency (EPA). It proposes to change the 21 CFR 178.1010 citation to 40 CFR 180.940 in Appendix F. and Item 11r; and also adds the 40 CFR 180.940 citation to Appendix L. of the PMO.

C. Proposed Solution

Changes to be made on page(s): 46, 202 and 336 of the (X - one of the following):

X 2009 PMO 2009 EML

_____ _____

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

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

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

ITEM 11r. UTENSILS AND EQUIPMENT – SANITIZATION

ADMINISTRATIVE PROCEDURES

Page 46:

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in ~~21 CFR 178.1010~~ <u>40 CFR 180.940</u> and shall be used in accordance with label directions. (Refer to Appendix F. for further discussion of approved sanitizing procedures.)

APPENDIX F. SANITIZATION

I. METHODS OF SANITIZATION

CHEMICAL

Page 202:

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in ~~21 CFR 178.1010~~ <u>40 CFR 180.940</u> and shall be used in accordance with label directions.

APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT*

Page 336:

...

40 CFR PART 141 – NATIONAL PRIMARY DRINKING WATER REGULATIONS
<u>40 CFR 180.940 – Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food contact surface sanitizing solutions)</u>

FFD&CA, as amended, Sec. 402. [342] Adulterated Food and Sec. 403. [343] Misbranded Food

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	215
Committee:	Lab

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

A. Summary of Proposal

This proposal is written to update language in Appendix G. *Chemical and Bacteriological Tests Section I. Private Water supplies and Recirculated Water – Bacteriological* of the 2009 PMO.

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

Adjustments to method terminology, clarification on test procedures and grammatical changes are necessary.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 211 of the (X - one of the following):

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

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER - BACTERIOLOGICAL

Reference: Section 7, Items 8r, 18r, 7p and 17p.
Application: To private water supplies, used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and to recirculated cooling water, used in milk plants, receiving stations and dairy farms.
Frequency: Initially; after repair, modification or disinfection of the private water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and thereafter; semiannually for all milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities water supplies and at least every three (3) years on dairy farms. Recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually.
Criteria: A Most Probable Number (MPN) of coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Multiple Tube Fermentation (MTF) technique, or one of the Chromogenic Substrate ~~techniques~~ multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL ~~are~~ is tested using the MTF technique or one of the Chromogenic Substrate ~~techniques~~ procedures. The Chromogenic ~~s~~Substrate ~~techniques~~ procedures are not acceptable for recirculated cooling water. Any sample producing a bacteriological result of Too Numerous To Count (TNTC)~~, greater than 200 total bacteria colonies per 100 mL,~~ or Confluent Growth (CG)~~, bacterial growth covering the entire filtration area or a portion thereof and colonies are not discrete by the MF technique~~; or turbidity in a presumptive test with no gas production and ~~without~~ with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC)~~,~~ from the same sample or subsequent resample~~,~~ of less than 500 colonies per mL in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.
Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA 2400 Series Forms.
Corrective Action: When the laboratory report on the sample is unsatisfactory, the water supply in question shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory.

Name:	Patti Huttula and Tom Kitzmiller - NCMIS Laboratory Committee		
Agency/Organization:	Michigan Milk Producer Association/ODA		
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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	216
Committee:	MMSR

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

A. Summary of Proposal

This Proposal provides a clarification and reorganization of requirements/criteria cited in Appendix A. Guidelines for Computing Enforcement Ratings, Part I. Dairy Farms, Item 10. Permit Issuance, Suspension, Revocation, Reinstatement, Hearings, and/or Court Action Taken as Required and Part II. Milk Plants, Item 9. Permit Issuance, Suspension, Revocation, Reinstatement, Hearings, and/or Court Action Taken as Required within the 2009 MMSR.

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

This Proposal does not add any new enforcement requirements/criteria but is strictly a clarification and reorganization of the enforcement requirements/criteria cited in Appendix A. Guideline for Computing Enforcement Ratings within the 2009 MMSR.

During FDA's Special Problems in Milk Protection Courses held in FY 2009 and 2010, numerous State Rating Officers and other individuals cited how confusing the current wording of the text contained in Appendix A. Guideline for Computing Enforcement Ratings of the 2009 MMSR was. Specifically, there were concerns with the lack of any organization of the enforcement requirements/criteria as cited under Part I. Dairy Farms, Item 10. Permit Issuance, Suspension, Revocation, Reinstatement, Hearings, and/or Court Action Taken as Required and Part II. Milk Plants, Item 9. Permit Issuance, Suspension, Revocation, Reinstatement, Hearings, and/or Court Action Taken. Examples per Category were not organized in a user friendly manner. Examples per Category were located throughout the referenced text. This is FDA's attempt to reorganize the requirements/criteria per Category for those two (2) Enforcement Rating Items.

C. Proposed Solution			
Changes to be made on page(s):		30, 31, 48, 51, 52, 54, 56, 76, 77 and 82-84	of the (X - one of the following):
	2009 PMO		2009 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

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

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

G. EXAMPLES OF RATING, NCIMS HACCP LISTING FORMS

4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4).....

5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5).....

Note: *Update the FORMs cited above as indicated below:*

Page 30:

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
DAIRY FARM ENFORCEMENT
PROCEDURES
(Refer to PART I, Item 10 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) on page 9 of this Proposal.

NOTE: Also make these same changes on Pages 51, 54 and 56 of the 2009 MMSR.

Page 31:

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
MILK PLANT ENFORCEMENT
PROCEDURES
(Refer to PART II, Item 9 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) on page 10 of this Proposal.

NOTE: Also make these same changes on Pages 48 and 52 of the 2009 MMSR.

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS

PART I. DAIRY FARMS

Pages 76-77:

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

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

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. <u>**NOTE:** Use FORM FDA 2359j-MILK SANITATION</u>

RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI*)~~
b. Permit issuance based on compliance. ~~(PI*)~~

Category II: Permit Suspension

~~e~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS*)~~
~~d~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS*)~~

c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". ~~(PS*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided ....."

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR*)~~
~~f. Hearings provided for as required. (H*)~~

Category IV: Permit Reinstatement

~~g.~~ Reinstatement procedures followed. ~~(PRI*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements."

~~h. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". (PS*)~~

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk produced during suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A". ~~(PS*)~~
b. When two (2) out of the last four (4) samples exceed the standards, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS*)~~
c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for:
   i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
   ii. "Four (4) in six (6) months" positive antibiotic (not of Appendix N. origin); or
   iii. If pesticide contaminated milk is not withheld from sale. ~~(PS*)~~

Category IV: Permit Reinstatement

~~d~~a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard. ~~(PRI*)~~
~~e~~b. "Reinstating accelerated sample(s)" for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period. ~~(PRI*)~~

For Example: FORM FDA 2359j-PART I, Item 10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.): .....

PART II. MILK PLANTS

Pages 82-84:

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTIES). Prorate by enforcement action(s) in compliance. **NOTE:** A milk plant will be prorated by enforcement action(s) in compliance. Five (5) Categories will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%)

compliance. The Categories are as follows:

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

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. **NOTE:** Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section G, #5 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI)*~~
b. Permit issuance based on compliance. ~~(PI)*~~

Category II: Permit Suspension

~~c.~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS)*~~
~~d.~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for sanitation and/or uncorrected critical processing elements; or
3.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS)*~~

c. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". ~~(PS)*~~

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided ....."

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR)*~~

Category IV: Permit Reinstatement

~~f. Hearings provided for as required. (H/CA)*~~
~~g.~~ Reinstatement procedures followed. ~~(PRI)*~~

NOTE: *Grade "A" PMO*, Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

~~h. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations are not eligible for sale as Grade "A". (PS)*~~

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and milk products produced during suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A". ~~(PS)*~~
~~b. All product violations followed promptly by an inspection to determine the cause(s). (PRI)*~~
~~c.~~b. When two (2) out of the last four (4) samples exceed the limits, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS)*~~
~~d.~~c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended. ~~(PS)*~~
~~e. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues). (PRI)*~~
~~f. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period. (PRI)*~~
~~g.~~d. Violation of Vitamin Fortification Levels (Refer to M-I-92-13): Determine the cause and re-sample or withhold product from the market. ~~(PS)*~~
~~h.~~e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization it shall be corrected before further sale of milk is allowed. ~~(PS)*~~
~~i.~~f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of milk is allowed. ~~(PS)*~~
~~j.~~g. Permit suspension upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld. ~~(PS)*~~

h. All permits suspended as required by the *Grade "A" PMO.*

Category IV: Permit Reinstatement

a. All product violations followed promptly by an inspection to determine the cause(s).
b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues).
c. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.
d. All permits reinstated as required by the *Grade "A" PMO.*

~~k. All permit issuance, suspension, revocation, etc., as required by the *Grade "A" PMO.*~~

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
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MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
BTU NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES

(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of DAIRY FARM RECORDS

(Refer to PART I, ITEM 11 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection Records				25	
3	Category III-Laboratory Records				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

MILK SANITATION RATING REPORT

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
PLANT NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES

(Refer to PART II, ITEM 9 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of MILK PLANT RECORDS

(Refer to PART II, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection/Equipment Records				25	
3	Category III-Laboratory Records (Also Containers/Vitamin Volume Control)				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	217
Committee:	MMSR/HACCP

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

A. Summary of Proposal

This Proposal proposes corrections and additions to Section 11-HACCP SYSTEM TRAINING within FORM FDA 2359m, MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10). These corrections and additions are warranted to bring Section 11 within FORM FDA 22359m in conformance with the language cited in Appendix K-HACCP PROGRAM of the PMO.

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

This Proposal is needed so that FORM FDA 2359m will reflect the HACCP system training requirements cited in Appendix K of the PMO.

C. Proposed Solution

Changes to be made on page(s): 39 and 65 of the (X – one of the following):

	2009 PMO		2007 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2007 Constitution and Bylaws

Modify Section 11 of ~~the~~ **FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10)** as follows:

Pages 39 and 65:

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

~~A. Employees trained in monitoring operations.~~
~~B. HACCP Plan reassessment performed by trained individual.~~
~~C. Records review performed by trained individual.~~
~~D. Employees trained in PP operations.~~

A. PPs developed by trained personnel.
B. Hazard Analysis developed by trained personnel.
C. HACCP Plan developed by trained personnel.
D. HACCP Plan validation, modification or reassessment performed by trained personnel.
E. HACCP Plan records review performed by trained individual
F. Employees trained in monitoring operations.
G. Employees trained in PP operation

...

FORM FDA 2359m (10/12) **PAGE 2**

Name:	Jason Crafts, Chair		
Agency/Organization:	NCIMS HACCP Implementation Committee		
Address:	1105 North 1000 West		
City/State/Zip:	Logan, Utah 84321		
Telephone No.:	435 713 6158	E-mail Address:	jcrafts@gossner.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	218
Committee:	MMSR/HACCP

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

A. Summary of Proposal

This proposal offers a modification to item #2 of the **NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT** (Form FDA 2359n) to provide a location on this form to acknowledge the PMO *Appendix K. HACCP Program* requirement that State regulators auditing NCIMS HACCP listed milk plants have received training (at least once) in the auditing of milk plants under the NCIMS HACCP program.

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

The PMO *Appendix K. HACCP Program* requires that State regulators be trained to audit a milk plant that elects to be audited under the NCIMS HACCP program rather than be inspected under the traditional NCIMS inspection program. This training requirement is an important part of this program. This proposal provides State HACCP listing officers and FDA a place to acknowledge this training (or the lack of it) on the **NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT** (Form FDA 2359n).

C. Proposed Solution

Changes to be made on page(s): 41, 67 of the (X – one of the following):

	2009 PMO		2007 EML
X	2009 MMSR		2400 Forms

	2009 Procedures		2007 Constitution and Bylaws

Modify the **NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (Form FDA 2359n)** Item #2 as follows:

2. Milk plant, receiving station or transfer station audited by a trained State Regulatory auditor ~~the Regulatory Agency~~ at the minimum required frequency, and follow-ups conducted as required.

...

FORM FDA 2359n (10/12)

Name:	Jason Crafts, Chair		
Agency/Organization:	NCIMS HACCP Implementation Committee		
Address:	1105 North 1000 West		
City/State/Zip:	Logan, Utah 84321		
Telephone No.:	435 713 6158	Telephone No.:	435 713 6158

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	219
Committee:	Appendix N

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

A. Summary of Proposal

Accept a flunixin and beta-lactam test for screening under Appendix N. Approve a 2400 form and add the method to the list of allowable tank/tanker screening tests in M-a-85.

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

Flunixin is a non-steroidal anti-inflammatory drug that is found on dairy farms and detected frequently in tissues of culled cows, the FDA-Center of Veterinary Medicine developed a Flunixin screening test protocol and supplied a grant to the National Center of Food Safety and Technology (NCFST) to evaluate a flunixin screening method for milk due to concern that that current drug screening methods used to test milk would not detect the drug if it was in milk. Charm Sciences is a member of NCFST and supplied a ROSA flunixin and beta-lactam (5 drug) screening method for evaluation.

It is not a requirement to screen for flunixin in milk but it is a requirement to screen for beta-lactams in milk. Combining flunixin in combination with an approved beta-lactam screen gives the milk industry the option of adding the flunixin drug while meeting their Appendix N beta-lactam screening requirements with that same test. This provides a low cost option for adding a flunixin drug screen.

In addition FDA has started screening farm milk tanks of known tissue residue violators using a LC-MS multidrug detection method including flunixin. A screening method approved for flunixin will allow dairy authorities to more rapidly follow up positive detected samples for additional testing and producer reinstatement.

A test for flunixin detection in milk provides a tool that the dairy producer could use to monitor the drug administration and determine if it has been properly withheld prior to milk commingling or as a live animal test prior to animal slaughter and to avoid tissue residues. The milk withhold times and meat withhold times are similar with flunixin.

NCFST evaluated the Charm ROSA Flunixin and Beta-Lactam test and found it met the requirements outlined in the CVM protocol. The following is a summary abstract of the evaluation submitted for publication:

Abstract:
The Charm β-lactam and Flunixin Test is an 8 minute receptor based lateral flow Rapid One Step Assay (ROSA) that detects flunixin a non-steroidal anti-inflammatory drug and five of the β-lactam drugs approved for dairy cattle in the United States. The method is similar in principle to the SL6 β-lactam test evaluated and approved in 2003 except that an antibody for flunixin/5-hydroflunixin is substituted for the antibody for cloxacillin. The β-lactam and Flunixin Test method was tested following a CVM-FDA protocol developed with the National Center for Food Safety and Technology (NCFST). Three combined lots detected penicillin G at 2.0 ppb, ampicillin at 6.8 ppb, amoxicillin at 5.9 ppb, cephapirin at 13.4 ppb, ceftiofur (total metabolites) at 63 ppb and the flunixin marker 5-hydroxyflunixin at 1.9 ppb at least 90% of the time with 95% confidence. These detection levels are lower than the U.S. Safe Level/Tolerances and qualify the test to be used in compliance with the drug avoidance bulk tank/tanker screening program Appendix N of the PMO . Lot-to-lot repeatability was within 35% of these determined levels. The test kit was found to be suitable for testing thawed frozen samples. It was also found to respond with equal or better sensitivity for incurred samples that contained both the microbiologically active parent drug and its active metabolites. There were no interferences from somatic cells at 1.1million/mL, bacterial cells at 300,000 cfu/mL, or 32 other non-β-lactam drugs at 100ppb. Ruggedness experiments indicated the test procedure is robust. These performances meet the approval criteria of fit-for-purpose for inclusion in the National Conference for Interstate Milk Shipments milk testing program.

C. Proposed Solution

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

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

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	220
Committee:	

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

A. Summary of Proposal

This proposal requests the NCIMS chair assign a standing committee (such as the laboratory committee) or an ad hoc committee to study using the average of a producer's monthly somatic cell count in place of the single SCC count for the one pickup during the month for the required monthly quality.

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

Many, if not most dairy labs run somatic cell counts on each producer pickup, and pay their producers based upon their monthly average SCC. The average SCC more accurately reflects both the actual SCC quality of the milk and the health of the herd; and it is already calculated for those producers.

C. Proposed Solution

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

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

The proposal requests the NCIMS chair assign a standing committee (such as the laboratory committee) or an ad hoc committee to study using the average of a producer's monthly somatic cell count in place of the single SCC count for the one pickup during the month for the required monthly quality.

The committee should examine two types of averages – a simple arithmetic average and a weighted average of the SCC counts. A weighted average would have the benefit of taking care of situations such as multiple pickups in a day, multiple tanks for pickup, and multiple BTU's. The committee should also examine issues related to industry and State regulatory agency approval, technology requirements, and changes required in the PMO and related documents.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	221
Committee:	Hauling

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

A. Summary of Proposal

This proposal requests the NCIMS chairperson appoint a committee to study the need for multiple tank washings following the hauling of non-dairy allergenic food liquid prior to the loading of subsequent loads of milk – and the need for an alternative wash tag to show the nature of the previous two loads.

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

Two different sections of the PMO address the cleaning and sanitizing of over-the-road transport tankers: ITEM 12p and APPENDIX B. MILK SAMPLING, HAULING, AND TRANSPORTATION (in IV - MILK TANK TRUCK STANDARDS). Over-the-road tankers are used for hauling of many differing food liquids besides milk, principally for efficient economics. Many of these food liquids are of a different allergenic nature than dairy products.

A substantial proportion of the food recalls declared each year are attributed to cross-contamination with a given food product with a different type of allergenic agent.

Some of the soil residues from these different food liquids require a modified cleaning regimen than would be considered normal in order to completely remove all traces of any non-dairy allergenic material.

C. Proposed Solution

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

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

The NCIMS chairperson is to appoint a committee to study the need for multiple tank washings following the hauling of non-dairy allergenic food liquid prior to the loading of subsequent loads of milk – and the need for an alternative wash tag to show the nature of the previous two loads. It is recommended that the committee be chaired by the FDA. Members of the committee should include members from the hauling committee, the dairy industry, state regulatory agencies and the FDA. This committee would report its findings at the next NCIMS conference in the form of a proposal to be voted upon.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	222
Committee:	Lab

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

A. Summary of Proposal

Request the NCIMS to direct the NCIMS Laboratory Committee to form a review/study group to review SMEDP (Standard Methods for the Examination of Dairy Products) as it is referenced and referred to in the PMO and related documents. This review/study group will; report its work back to the 2013 NCIMS Conference.

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

Over the years the PMO referenced and referred usages to the SMEDP has remained relatively unchanged. Conference actions over the years have addressed and defined certain areas of these references. However since the conference actions are stated in specifics the references to SMEDP remains undefined and references whole sections or chapters of the SMEDP which contain areas not intended for use or interpretation in the PMO or related NCIMS documents.

A review/study group would help clarify the conference intended references to SMEPD in the PMO. It could also recommend areas of reference to be removed to eliminate areas of duplication from previous conference actions.

C. Proposed Solution

Changes to be made on page(s): Look at all NCIMS related documents of the (X - one of the following):

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

The NCIMS Laboratory Committee is directed to develop a review/study committee, with the direction to report back to the 2013 NCIMS Conference, to review all uses and intended uses of references to the SMEPD as they are used in the PMO and related documents. Identify areas of duplication and where specific conference actions have eliminated the need to reference the SMEDP. The review committee is also charged to identify areas where, if any, the SMEDP reference needs to remain and recommend the specific targeted areas in SMEDP for intended conference use.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	223
Committee:	Lab - 2400

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

A. Summary of Proposal

Extend the allowable time for the transportation of water samples from 30 hours to 60 hours. This will bring the transportation time requirements in line with that of milk samples.

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

See attached below.

C. Proposed Solution

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

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

Edit 2400m Dairy Waters as follows

1. Laboratory Requirements

e. Transit time does not exceed ~~30~~ 60 hours _____

f. Samples examined within ~~30~~ 60 hours of collection or within 2 hours of receipt (item 1d)

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Extending Water Sample Transportation Time from 30 Hours to 60 Hours

Background

The current 30 hour limit for water samples to be tested after collection at times necessitates special trips for water samples to be specially delivered to the laboratory. Over the last several years we have extended the time for milk samples to be in transit from 36 to 48 and now to 60 hours at the 2009 NCIMS conference.

FDA Form 2400m Dairy Waters require that samples transported more than 6 hours to be stored at 0-4.4 C with temperature control sample. The EPA drinking water program has no mandatory cooling requirement but encourages water samples in transit to be stored at 10 C or less.

Study

Round 1 Tests

(MS Water)

The initial test was performed using the laboratory's microbiologically suitable (MS) water as the matrix and seeding it with the control cultures *E. coli*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa*. Numerous counts were performed on these cultures to determine the bacterial density/ml. Appropriate dilutions were then made to achieve a goal of approximately 15 CFU's/100mL. The MS water used for the initial test contained <1 CFU/ml as determined by pour plate method using Standard Method Agar.

One flask was prepared using 2000 ml of MS water. An estimated 300 CFU's of *E. coli* was added to achieve a target of approximately 15 CFU's/100 ml. A second flask was prepared using 2000 ml of MS water. An estimated 300 CFU's of each of *E. coli*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa* was added to achieve a target of approximately 30 CFU's/100mL of coliform (15 *E. coli* and 15 *K. pneumonia*) and 15 CFU's/100mL of *P. aeruginosa*. The *P. aeruginosa* was added to see if it had an effect on the survival of the coliform bacteria.

Each flask was mixed for 10 minutes using a magnetic stirrer. The water was then aliquoted into 100 ml portions by hand pouring. The 100 ml aliquots were tested at: 0, 24, 48, 60, 72 and 96 hour intervals. The test performed was method 9221, Multiple Tube Fermentation Technique for members of the Coliform Group as described in the 2005 on-line edition of Standard Methods for the Examination of Water and Wastewater. The 10 tube format was used.

For the duration of the test, the aliquots were stored in the laboratory refrigerator between 0-4.4°C.
These results are presented in Table 1.

Round 2 Tests

(Wild Coliform)

In this test water was collected from a livestock drinking tank and diluted with MS water. Then distributed in to 100 ml samples portions that were stored in the laboratory refrigerator between0-4 .4°C. These samples were then tested were then tested with method 9221 in 5 tube of 3 dilutions (10ml, 1 ml and 0.1ml) at 0, 30, 48, 54, and 72 hours.
These results are presented in Table 2.

Round 3 Tests

(Multiple Laboratories, Multiple Methods, Multiple Matrixes')

In this round of testing well water, chill water and glycol were collected at an IMS listed Grade A dairy plant. This water was then used to create various batches listed below. In addition to samples being analyzed at MRC laboratory (29100) samples were shipped to and analyzed at the Oklahoma State Department of Agriculture laboratory (40008), Kansas State Board of Agriculture laboratory (20004) and the Arkansas Department of Health Laboratory (05001).

Well Water

One container was prepared using 7000 ml of well water. An estimated 1050 CFU's of *E. coli* was added to achieve a target of approximately 15 CFU's/100 ml. A second container was prepared using 7000 ml of well water. An estimated 1050 CFU's of each of *E. coli*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa* was added to achieve a target of approximately 30 CFU's/100mL of coliform (15 *E. coli* and 15 *K. pneumonia*) and 15 CFU's/100mL of *P. aeruginosa*. The *P. aeruginosa* was added to see if it had an effect on the survival of the coliform bacteria. The water from each container was manually agitated and distributed into 100 aliquots in water sample bottles containing sodium thiosulfate as described in form 2400m
Results are found in Tables 3 and 4.

Chill Water

One container was prepared using 5000 ml of chill water. An estimated 750 CFU's of E. coli was added to achieve a target of approximately 15 CFU's/100 ml. A second container was prepared using 5000 ml of chill water. An estimated 750 CFU's of each of *E. coli*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa* was added to achieve a target of approximately 30 CFU's/100mL of coliform (15 *E. coli* and *15 K. pneumonia*) and 15 CFU's/100mL of *P. aeruginosa*. The *P. aeruginosa* was added to see if it had an effect on the survival of the coliform bacteria. The water from each container was manually agitated and distributed into 100 aliquots in water sample bottles containing sodium thiosulfate as described in form 2400m
Results are found in Tables 5 and 6.

Glycol

One container was prepared using 5000 ml of glycol. An estimated 750 CFU's of *E. coli* was added to achieve a target of approximately 15 CFU's/100 ml. A second container was prepared using 5000 ml of glycol. An estimated 750 CFU's of each of *E. coli*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* was added to achieve a target of approximately 30 CFU's/100mL of coliform (15 *E. coli* and 15 *K. pneumonia*) and 15 CFU's/100mL of *P. aeruginosa*. The *P.*

Table 1														
	0 Hr		24 Hrs		30 Hrs		48 Hrs		60 Hrs		72 Hrs		96 Hrs	
E. Coli Count		6.9		3.6		5.1		6.9		3.6		2.2		1.1
95% Confidence Limits *	2.1	16.8	0.69	10.6	1.3	13.4	2.1	16.8	0.69	10.6	0.26	8.1	0.03	5.9
Mix (E. Coli, K. P., P.A)		23.0		23.0		12.0		>23.0		23.0		16.1		12.0
95% Confidence Limits *	8.1	59.5	8.1	59.5	4.3	27.1	13.5	infinity	8.1	59.5	5.9	36.8	4.3	27.1

aeruginosa was added to see if it had an effect on the survival of the coliform bacteria. The glycol from each container was manually agitated and distributed into 100 aliquots in water sample bottles containing sodium thiosulfate as described in form 2400m
All of the Glycol samples were negative for coliform.
Typical glycol as used as a cooling media in a dairy plant is approximately 50% propylene glycol and 50% water. The Glycol sample as collected from the dairy plant was diluted with MS water in the following ratio 10:0, 9:1, 8:2, 7:3, 6:4, 5:5, 4:6, 3:7, 2:8, 1:9 and 0:10 and tested on the Delvo 5 pack inhibitor test along with Positive negative milk controls. Only the 100% MS water and 90% MS water 10% plant glycol showed negative for inhibitor. All other dilutions showed as an inhibitor present beginning with 20% plant glycol.

Analysis

In table 7 the average count from the 30 hour test is compared to the 72 hour average results using the nearest MPN value and 95% confidence limits from the 10 tube MPN format table 9221.III from the 2005 online version of Standard Methods for the Examination of Water and Wastewater (shown as table 8). In using these criteria the 72 hour results and 30 hour results are statistically the same.

Conclusions

Based on the three rounds of test with the final round that included 4 laboratories and the results show there is no significant difference between the results at 30 hours after collection and 72 hours at collection. Results of samples tested up to 60 hours after collections protect the public heath as well as those samples that are tested within 30 hour of collection.

Table 2										
Week of August 2, 2010	0 Hr		30 Hrs		48 Hrs		54 Hrs		72 Hrs	
Wild Count		170		130		130		130		240
95% Confidence Limits **	80	140	50.0	390	50	390	50	390	100	945

Table 3 - Well Water E Coli								
	0 Hr Count	24 Hrs Count	30 Hrs Count	48 Hrs Count	54 Hrs Count	60 Hrs Count	72 Hrs Count	Avg Count
LTB 1 / Lab 1	2.2	16.1	1.1	2.2	5.1	2.2	3.6	4.6
LTB 2 / Lab 1	3.6	9.2	5.1	3.6	6.9	2.2	5.1	5.1
Colilert 1/ Lab 1	9.9	9.9	5.3	7.5	3.1	13.7	5.3	7.8
Colilert 2/ Lab 1	7.5	5.3	15.0	4.2	4.2	3.1	8.7	6.9
Colisure 1/Lab 1	11.1	5.3	7.5	8.7	8.7	5.3	3.1	7.1
Colisure 2/Lab 1	9.9	3.1	5.3	5.3	5.3	5.3	1.0	5.0
LTB 1-2 / Lab 2		12.0	2.2	5.1	3.6		5.1	5.6
MF / Lab 2		2.0	5.0	3.0	6.0		1.0	3.4
Colilert / Lab 3		8.5	6.3	4.1	2.0		3.1	4.8
MF / Lab 4		10.0	9.0	8.0	3.0		3.0	6.6
Avg Count	7.4	8.14	6.18	5.17	4.79	5.3	3.9	5.7

Table 4 - Well Water Mix								
	0 Hr Count	24 Hrs Count	30 Hrs Count	48 Hrs Count	54 Hrs Count	60 Hrs Count	72 Hrs Count	Avg Count
LTB 1 / Lab 1	16.1	23.0	16.1	23.0	16.1	16.1	12.0	17.5
LTB 2 / Lab 1	23.0	23.0	12.0	23.0	12.0	9.2	23.0	17.9
Colilert 1/ Lab 1	28.8	19.2	20.7	16.4	13.7	15.0	15.0	18.4
Colilert 2/ Lab 1	25.4	22.2	27.1	22.2	12.4	17.8	8.7	19.4
Colisure 1/Lab 1	28.8	25.4	22.2	12.4	23.8	19.2	8.7	20.1
Colisure 2/Lab 1	20.7	19.2	40.6	30.6	27.1	12.4	17.8	24.1
LTB 1-2 / Lab 2		23.0	16.1	16.1	23.0		23.0	20.2
MF / Lab 2		32.0	8.0	23.0	14.0		28	21.0
Colilert / Lab 3		5.2	4.1	5.2	2.0		9.8	5.3
MF / Lab 4		16.0	17.0	13.0	19.0		18	16.6
Avg. Count	28.6	20.8	18.4	18.5	16.3	17.9	16.4	18.0

Table 5 - Chill Water E Coli								
	0 Hr	24 Hrs	30 Hrs	48 Hrs	54 Hrs	60 Hrs	72 Hrs	Avg

	Count	Count	Count	Count	Count	Count	Count	Count
LTB 1 / Lab 1	16.1	23.0	16.1	23.0	16.1	16.1	12.0	17.5
LTB 2 / Lab 1	23.0	23.0	12.0	23.0	12.0	9.2	23.0	17.9
LTB 1-2 / Lab 2		5.1	12.0	5.1	5.1		6.9	6.8
MF / Lab 2		6.0	6.0	5.0	10.0		3.0	6.0
LTB / Lab 3		16.1	6.9	2.2	9.2		5.1	7.9
LTB PA / Lab 4		>1	>1	>1	>1		>1	
Avg Count	19.6	14.6	10.6	11.7	10.5	12.7	10.0	11.2

Table 6 - Chill Water Mix

	0 Hr Count	24 Hrs Count	30 Hrs Count	48 Hrs Count	54 Hrs Count	60 Hrs Count	72 Hrs Count	Avg Count
LTB 1 / Lab 1	23.0	23.0	23.0	16.1	23.0	23.0	23.0	22.0
LTB 2 / Lab 1	23.0	16.1	23.0	16.1	23.0	23.0	16.1	20.0
LTB 1-2 / Lab 2		16.1	23.0	16.1	23.0		23.0	20.2
MF / Lab 2		19.0	14.0	10.0	16.0		22.0	16.2
LTB / Lab 3		23.0	23.0	23.0	23.0		23.0	23.0
LTB PA / Lab 4		>1	>1	>1	>1		>1	
Avg Count	23.0	19.4	21.2	16.3	21.6	23.0	21.4	20.3

Table 7

	30 Hr. Count	72 Hr. Count	Nearest MPN 30 Hr.	95 % Confidence Limit
Well Water E. Coli	6.18	3.9	6.9	2.1 - 16.8
Well Water Mix	18.4	16.4	16.1	5.9 - 36.8
Chill Water E. Coli	10.6	10	9.2	3.1 - 21.1
Chill Water Mix	21.2	21.4	23	8.1 - 59.5

Table 8*

No. of Tubes Giving Positive Reaction Out of 10 of 10 mL ea.	MPN Index/10 mL	95% Confidence Limits (Approximate)	
		Lower	Upper
0	<1.1	0	3
1	0.1	0.03	5.9
2	2.2	0.26	8.1

3	3.6	0.69	10.6
4	5.1	1.3	13.4
5	6.9	2.1	16.8
6	9.2	3.1	21.1
7	12.0	4.3	27.1
8	16.1	5.9	36.8
9	23.0	8.1	59.5
10	>23.0	13.5	Infinite

* SMEWW 2005 online edition table 9221.III
** SMEWW 2005 online edition table 9221.IV
*** Laboratory 4 chill water samples results not included in averages.
Note: Laboratory 3's 24 hour samples were tested at 25.5 hours all others were tested ± 1 hour

Thanks to the AR, KS and OK state laboratories for participating in the sample analysis and to IDEXX for their assistance.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	224
Committee:	Lab - 2400

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

A. Summary of Proposal

Revise the 2400 form for Appendix N Bulk Milk Tanker Screening for Neogen BetaStar US to reflect the replacement of this method with the BetaStar Plus BetaLactam Test. Upon approval the BetaStar US kit will be removed from commerce.

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

The BetaStar Plus BetaLactam test will detect all six beta lactam drugs at or below the tolerance/safe levels as determined by FDA. The test has undergone the required testing protocol under Appendix N of the PMO and has been determined by FDA-CVM to have met the requirements of Appendix N of PMO. The 2400 form must be revised to reflect the changes to the kit to assure proper use.

C. Proposed Solution

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

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

Revise 2400 form Appendix N Bulk Milk Tanker Screening for Neogen BetaStar US to reflect specific changes to the new BetaStar Plus test, which has met the requirements of FDA/AOAC validation. The BetaStar Plus test will replace the BetaStar US test upon final FDA approval and the form must be revised to meet the new requirements.

Additional changes in formatting by the NCIMS Laboratory Committee to conform with new format for 2400 forms.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	225
Committee:	Lab - 2400

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

A. Summary of Proposal

Add Easygel Aerobic Plate Count Media, Pectin Gel Method, to the Milk Laboratory Evaluation Form. Amend 2400 form accordingly.

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

(Note: This is a re-submittal of Proposal #227 from the 2009 Conference. It Passed as Submitted. However, the Laboratory Committee and FDA requested additional study and data points. This study has just been completed. This re-submittal puts the proposal back on the agenda for further review and discussion.)

Amending 2400 form would harmonize recognition of this AOAC and APHA approved and widely used method.

Easygel (originally called Redigel) replaces agar in microbiological media. It uses pectin as a gelling agent. The Aerobic Plate Count (APC), Pectin Gel Method, has been an AOAC Official Method (988.18) since 1988.

It is recognized in the current edition of APHA *Standard Methods for the Examination of Dairy Products* as a Class A1 method applicable to all raw and processed and dry dairy products.

Pectin gel prepared media saves time and resources compared to traditional agar based media.

C. Proposed Solution

Changes to be made on page(s): 2400 (Rev. 1-09): 15-20 of the (X - one of the following):

_____	2007 PMO	_____	2005 EML
_____	2007 MMSR	X	2400 Forms
_____	2007 Procedures	_____	2007 Constitution and Bylaws

Add to page 15 "27. Media":

c. Easygel Aerobic Plate Count, Pectin Gel Method
1. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____

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

Add to page 20 "29.Prepared Media Storage":

e. Easygel Aerobic Plate Count plate storage
1. Store at room temperature.
2. Use before expiration date on package.
3. Store Easygel pretreated petri dishes at room temperature. Reseal unused dishes in bag.

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

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	226
Committee:	Lab - 2400

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

A. Summary of Proposal

To update the Idexx SNAP 2400 series form to eliminate the visual read language and include the instructions for how to determine if a test is invalid.

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

Labs are no longer allowed to read this test visually. All testing sites must use a reader/printer to read the testing devises. Also, the manufacturer's instructions include instructions for determining if a test is invalid. Other test kits include instructions for invalidating tests. This test should also include that language.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 4 & 5 of the (X - one of the following):

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

Starting at item 6q

q. At the end of incubation, visually inspect the control and test spot. The test is invalid and the same sample should be retested with a new SNAP device if:

1. The control spot fails to develop color.
2. Blue streaking occurs in the background or the background is the same color as the sample or control spots.
3. The sample or control spots are not uniform in color or exhibit poor spot quality.

~~q~~r. ~~Read~~ Insert only valid tests into the reader **IMMEDIATELY (no longer than 30 seconds)** ~~**after final incubation)**~~ after completion of incubation. ~~with IDEXX Reader for SNAP devices~~

s. Use the stylus to tap OK

7. Interpretation with Idexx Reader for SNAP Devices

~~a. The control spot is on the top and the test spot on the bottom of the Results Window (Correct orientation is with activator button to right and sample well to left)~~

~~b. Negative result:~~

~~1. If test spot is darker than or equal to the control spot, sample is **Negative (NF)**~~

~~c. Positive result:~~

~~1. If test spot is lighter than control spot, sample is **Initial Positive**~~

~~d~~.

a. IDEXX Reader for SNAP devices automatically prints results as **Positive** ~~(initial)~~ or **Negative (NF)**

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	227
Committee:	Lab - 2400

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

A. Summary of Proposal

Direct the NCIMS Laboratory Committee to review and clarify on all appropriate 2400 forms the intent and meaning of the phrase "Previously negative tested raw milk" currently used in the App N 2400 forms. The clarification should be stated on all appropriate 2400 forms.

Also to review the intent and meaning of the requirements for "daily performance checks" as it relates to the phrase "Previously negative tested raw milk" currently used in the 2400 App N forms. Any clarification should be stated on all appropriate 2400 form.

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

Disagreement and confusion has developed as to what the intent of the phrase "Previously negative tested raw milk" was intended to mean. This confusion has led to inconsistent enforcement and usage of this requirement in the NCIMS system. The NCIMS Laboratory Committee revisiting their intended use of this phrase and requirement should clear up the confusion.

Also review this phrase "Previously negative tested raw milk" in the context of how it shall be used in the requirement for "Daily performance checks" of the testing equipment and test as stated on the appropriate 2400 forms.

This hopefully will clarify the intent of this phrase and correct the inconsistent usage by industry and interpretation on enforcement currently happening in the program.

C. Proposed Solution

Changes to be made on page(s):		_____	of the (X - one of the following):
____	2009 PMO	____	2009 EML
____	2009 MMSR	All Appendix N	2400 Forms
____	2009 Procedures	____	2009 Constitution and Bylaws

The NCIMS Laboratory Committee shall clarify the intent, use in the App N 2400 forms and give guidance on enforcement of the phrase "Previously negative tested raw milk" that is currently used in the forms. The Laboratory Committee shall clarify the intended use and interpretation by stating the intent and interpretation on all the appropriate 2400 forms. Also review this phrase in the context of how it shall be used in the requirement for "Daily performance checks" of the testing equipment and test as stated on the appropriate 2400 forms.

This hopefully will clarify the intent of this phrase and correct the inconsistent usage by industry and interpretation on enforcement currently happening in the program.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	228
Committee:	Lab -2400

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

A. Summary of Proposal

The current requirement for Appendix N reference and test thermometers is that the graduation interval be not greater than 1.0C [NCIMS Certified Laboratories and Certified Industry Supervisor, 0.5C]. It was felt at the time that non certified labs need not meet the tighter requirements of those for certified labs.

As time passed and changes were made to the program, the 2400 forms, and safety issues surfaced, it has become apparent the requirements for a 1.0C thermometer, are no longer acceptable. One of the major reasons involves digital thermometers. They can be made to read at 1C intervals with no way of interpolating between intervals.

Amending the current paragraph to say the graduation interval for all thermometers used in Appendix N laboratories shall not be greater than 0.5C would solve this problem.

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

When this program started there was little attention given to the health hazard associated with mercury. In the past few years, this hazard has become a very real concern. Mercury thermometers are not allowed to be purchased in, or sent out of, most states. Many of the facilities using these old mercury filled thermometers, graduated at 1.0C, have had them since the beginning of the program.

To save an LEO the potential grief of dealing with digital thermometers and the 1C intervals issue is another very real problem associated with the current language. Digital thermometers are very popular these days. They are being used as replacements in current Appendix N labs,

and as new equipment in Appendix N labs coming into the program.

The language in the current 2400 form allows for the use of the digital thermometer with 1C intervals, but the thermometer doesn't allow for interpolation.

To error on the safe side an LEO that reads a digital thermometer with 1C intervals would need to mark a deviation without knowing if it were truly a deviation. An example would be checking a refrigerator that read 4C. It couldn't be determined if that 4C reading was 4.1C, 4.4C, or 4.9C. The only option available to the LEO would be to assume it was reading above 4.4C and mark it as a deviation.

By adding the proposed wording 3 problems would be addressed.

1. The safety concern with mercury.
2. Maintaining the continuity of the Appendix N General Requirements form.
3. Taking away the LEO problem of determining if a temperature was really "within range".

I believe this change is necessary and comes at a good time for upgrading the program.

C. Proposed Solution

Changes to be made on page(s): 1,2 of the (X - one of the following):

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

Appendix N Bulk Milk Tanker Screening Test Form General Requirements

3.a2 and 3.b3 Graduation/recording interval not greater than ~~1.0C~~ 0.5C [~~NCIMS CETIFIED LABORATORIES and CETIFIED INDUSTRY SUPERVISORS, 0.5~~]

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NCIMS Laboratory Committee

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	229
Committee:	Lab - 2400

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

A. Summary of Proposal

Allow manufacturers to ship antibiotic test kits unrefrigerated when it is demonstrated that the kits perform as labeled after heat stress and real-time storage to end of labeled shelf life. Modify Charm 3 SL3 Beta-lactam Test shipping requirements in the 2400 form to allow non-refrigerated shipment.

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

The requirement to ship antibiotic test kits refrigerated was implemented in 2005. Tests approved prior to 2005 were not required to ship under these conditions.

The requirement to ship antibiotic test kits refrigerated increases kit shipping costs, creates more waste, and creates additional dairy record keeping burden.

If a manufacturer of a newer approved antibiotic kit can demonstrate stability of a kit over its shelf life, including a built in worst case shipping stress, then the requirement to ship refrigerated should be waived for that kit. This will simplify kit receipt into dairies, lessen the amount of packaging waste and lower the cost of antibiotic testing.

During Charm 3 SL3 test kit submission, three test kit lots were stored refrigerated 13 months after a 37C for 72 hours heat stress. Three days at 37C was considered a worst case shipping stress based on temperatures measured during summer shipments. Each lot was tested for dose response using kit submission requirements, e.g. 30 tests at 5 drug concentrations, 5 different drugs and 60 negative samples to determine the 90% positive levels with 95% confidence (over 1000 tests per lot). The data shown in the table below demonstrate the heat stressed tests at

end of shelf life perform like the kits when they were manufactured and that they test within label claims.

Table comparing 3 lots of Charm 3 SL3 and their selectivity and sensitivity at time of manufacture and after 13 months refrigerated shelf life following 72 hours 37°C heat stress.

Drug and Labeled Sensitivity (ppb)	Lot #001 at Manufacture Sensitivity in ppb	Lot #001 after 72 hours 37C and then 13 months refrigerated Sensitivity in ppb
Amoxicillin (8.4)	8.8	7.1
Ampicillin (8.0)	8.3	6.3
Cephapirin (20.0)	17.6	15.2
Ceftiofur parent (NA)	31	25.2
Cloxacillin (8.6)	8.4	7.1
Penicillin B (3.8)	4.1	3.5
Negative (0pos. of 60)	0 positive of 60 neg.	0 positive of 60 neg.
	Lot #003 at Manufacture in ppb	Lot #003 after 72 hours 37C and then 13 months refrigerated in ppb
Amoxicillin (8.4)	7.8	8.1
Ampicillin (8.0)	6.2	7.1
Cephapirin (20.0)	16.1	15.6
Ceftiofur parent (NA)	30.9	35.2
Cloxacillin (8.6)	7.2	8.4
Penicillin B (3.8)	3.9	3.8
Negative (0pos. of 60)	0 positive of 60 neg.	0 positive of 60 neg.
	Lot #004 at Manufacture in ppb	Lot #004 after 72 hours 37C and then 13 months refrigerated in ppb
Amoxicillin (8.4)	7.8	8.3
Ampicillin (8.0)	6.5	7.6
Cephapirin (20.0)	15.4	15.6
Ceftiofur parent (NA)	32.7	35.8
Cloxacillin (8.6)	6.9	9.2
Penicillin B (3.8)	3.3	3.7
Negative (0pos. of 60)	0 positive of 60 neg.	0 positive of 60 neg.

C. Proposed Solution

Changes to be made on page(s): Charm SL, SL6 and Charm 3 SL3 2400 of the (X - one of the following):

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

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	230
Committee:	Lab - 2400

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

A. Summary of Proposal

To provide clarification to requirements at Items #3 Thermometers and #9 Sample Requirements on FDA Appendix N General Requirements form 2400n.

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

1. Some Laboratory Evaluation Officers and some Milk Laboratories are unable to reconcile the understood intent of the requirements at Items #3 and #9 of the Appendix N General Requirements form 2400n with the wording on the revision of this form dated 2/10. The proposed changes are intended to clarify the intent of the requirements for Thermometers and for Samples.

2. At Item 3a, this proposal intends to make clear that only liquid-in-glass NIST traceable thermometers are to be checked annually at the ice point, and electronic/digital NIST traceable thermometers are to be re-calibrated by authorized calibration provider per manufacturer's specifications. In most cases this must be done annually.

3. At Items 3a and 3b, this proposal intends to make clear that graduation/recording interval not greater than 1.0C or not greater than 0.5C (CIS sites) refers only to liquid-in-glass thermometers. All electronic/digital thermometers must be capable of providing a temperature to the nearest 0.1C.

4. At Item 3c1, this proposal intends to make clear that correction factors for work thermometers must be determined to nearest 0.1C.

5. This proposal seeks to delete Item 3d. This proposal contends that the intent of the requirements for compliance on equipment and samples is that temperatures be determined to the nearest 0.1C. When thermometers with 1.0C or 0.5C graduations are used, interpolation between the graduation intervals will be necessary to provide an appropriate reading.

a. As it is written now (rev 2/10), Item 3d allows liquid-in-glass thermometers to be read to nearest 1.0C. It is not relevant or accurate to determine or apply a correction factor of 0.1C accuracy for a thermometer being *read* to the nearest 1.0C or the nearest 0.5C.

b. As it is written now (rev 2/10), Item 3d allows an increase in compliance ranges for equipment and samples of nearly one whole degree Centigrade for thermometers having 1.0C graduation intervals.

1) Allows temperature down to 0.5C below the established compliance range.

2) Allows temperature up to 0.4C above the established compliance range.

6. At Item 9a2 and 9a5c, this proposal intends to make clear that records of dates, times, and temperatures related to samples and testing must be maintained.

7. At Item 9a3, this proposal intends to make clear that sample containers must not be over filled. Over filling of sample containers prevents proper mixing and could result in uneven distribution of constituents in the sample.

8. At Item 9a5b, this proposal intends to make clear that sample temperature must be 0.0-4.4C at the time of testing. Incubation times and temperatures for each method have been determined based upon sample being 0.0-4.4C at the beginning of the test procedure.

9. Outline of the form was revised as needed to accommodate changes.

10. There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 1, 2, 6 of the (X - one of the following):

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X App N GR	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Appendix N Bulk Milk Tanker Screening Test Form
General Requirements

(Unless otherwise stated all tolerances ±5%)

Items 1.-2.

3. Thermometers _____

a. National Institute of Standards and Testing (NIST) traceable thermometer or other temperature measuring device with certificate. _____

1. Must be checked annually at ice point (liquid-in-glass) _____

2. Must be re-calibrated according to manufacturer recommendation (electronic/digital) _____

~~1~~ 3. Reference temperature measuring device identity: _____

	Serial #	Date of Certificate	Ice Point Date (Liquid-in-glass)	
a:	_____	___/___/___	___/___/___	_____
b:	_____	___/___/___	___/___/___	_____

2. Graduation/recording interval not greater than 1.0C (liquid-in-glass). **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C]** Graduation/ recording interval not greater than 0.1C (electronic/digital) _____

b. Range of test temperature measuring device appropriate for designated use _____

1. Mercury-in-glass, alcohol/spirit or electronic/digital thermometers in degrees centigrade _____

2. Plastic lamination recommended for mercury thermometers _____

3. Graduation/recording interval not greater than 1.0C (liquid-in-glass). **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C]** Graduation/ recording interval not greater than 0.1C (electronic/digital) _____

c. Accuracy of all test temperature measuring devices checked before initial use and annually _____

1. Checked against NIST traceable thermometer to 0.1C _____

2. Accurate to ±1C when checked at temperature(s) of use _____

3. Results recorded/documented and individual devices tagged _____

a. Tag includes identification/location, date of check, temperature(s) checked and correction factor(s), as applicable _____

~~d. Temperature measuring devices are to be read to the nearest graduation/recording interval, optionally labs may interpolate between graduations~~ _____

~~e~~d. Temperature Monitoring Systems (wired/wireless) _____

1. The software must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency as stipulated for MIG or AIG thermometers. Optionally, set to register an alert/alarm when out of the acceptable temperature range _____

   a. When temperature(s) are out of acceptable range for greater than two hours, event must be documented and corrective action taken as necessary. Records maintained _____

2. Optionally, a minimum two-day backup power source (battery/electrical) for the temperature monitoring system and/or all required sensors/probes, remote signal device and monitor/controller may be employed in case of power failure _____

3. Temperature monitoring system records for each piece of equipment must be available/accessible for auditing as described in item 2c above _____

~~f~~e. Automatic temperature recording instruments, if used, compared weekly against an accurate thermometer, results recorded _____

~~g~~f. Temperature measuring device(s) calibrated at another location _____

1. Location calibrated: _____ _____

2. Calibrations current and acceptable _____

3. Copy of calibration record on-site _____

~~h~~g. Dial thermometers not used in the laboratory _____

Items 4.-8.

SAMPLES

9. Sample Requirements _____

a. Appendix N tanker sample(s) _____

1. Prevent contamination with disinfectants from hands or other sources _____

2. Ascertain temperature of bulk milk tanker, record maintained _____

3. Secure a representative sample for testing. Sample not over filled. If sample will not be tested without delay then a temperature control (TC) sample must be taken at the same time, transported, and maintained with the tanker sample(s) until it is tested _____

4. Transport sample(s) to the testing location promptly (preferably on ice if needed to maintain temperature) _____

5. Tanker sample(s) tested promptly upon arrival at the testing

location _____

a. Determine sample temperature by inserting a pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control

b. Sample temperature must be 0.0-4.4C at testing _____

~~b~~c. Date, time and temperature of bulk milk tanker may be used for date, time and temperature as received and tested if sample testing begins without delay, record maintained _____

b. Appendix N Producer Trace Back Samples (Sample(s) not meeting the conditions outlined below may still be tested. The certified laboratory or CIS will document the condition of the samples(s)) _____

1. Samples should be accompanied by a temperature control (TC). If no TC, aliquot sample(s) for testing and measure temperature using one of the producer samples _____

2. Sample(s) should not be leaking _____

3. Tops of samples should be protected from direct contact with ice _____

4. Unprotected samples should not be submerged in water and/or ice or slush _____

Items 10.-15.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	231
Committee:	Lab - 2400

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

A. Summary of Proposal

To provide clarification and consistency for FDA Form: 2400j Phosphatase Test – Fluorophos ALP Test System.

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

1. The proposal intends to clarify procedure steps and provide consistency in wording between items on this form and with other 2400 series forms.

2. This proposal seeks to delete some Items or parts of Items as they are either wrong, incomplete, unnecessary or understood.

3. This proposal changes the order of items to reflect actual order of the procedures for Instrument Checks, Calibration, Controls, and Test Samples.

4. This proposal adds details into sample measurement Items for both Calibration Procedure and Test Procedure, and makes the wording and order consistent between the two items.

5. Outline of the form was revised as needed to accommodate the above changes.

6. There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 1-11 of the (X - one of the following):

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

PHOSPHATASE TEST - FLUOROPHOS ALP TEST SYSTEM
[Unless otherwise stated all tolerances are ±5%]

SAMPLES

1. **Laboratory Requirements (see CP, item 33 & 34)** _____

APPARATUS

2. **See CP, items 1-32 (as necessary)** _____

3. **Cuvette Heating Block** _____

   a. Thermostatically\controlled at 38±1C _____

   ~~b. NIST-traceable thermometer, calibration checked as specified in CP item 3~~ _____

   ~~c.~~b. Temperature checked and recorded ~~daily~~ each day of use _____

4. **Pipettors, fixed volume or electronic** _____

   a. 75 µL pipettor _____

   b. 25 µL pipettor, for use with high\turbidity or high fat products (if needed) _____

   c. Calibrated as specified in CP item 6e; records maintained _____

5. **Reagent Dispenser** _____

   a. Fixed volume 2.0 mL, calibrated and checked _____

   b. Optionally, use 2.0 mL fixed volume or electronic pipettor to dispense reagent _____

   c. Calibrated as specified in CP item 6e; records maintained _____

6. **Cuvettes** _____

   a. Disposable glass 12 x 75 mm, dirt and scratch free _____

7. **Fluorometer**

   a. Air fan in the rear unobstructed _____

   b. Vents in the bottom base plate are unobstructed _____

   ~~c. Sufficient paper is on the roll in the printer~~ _____

   ~~d.~~c. User's manual available _____

8. **Water Bath, 34±1C and 63±1C, circulating (Confirmation procedures)** _____

REAGENTS

9. **Reagents, Handling and Storage** _____

   a. Test Reagent Set _____

      1. Fluorophos substrate and Substrate buffer _____

      2. Lot # _____ ~~Rcd date~~ _____ Exp date _____ _____

   b. Calibrator Set _____

      1. Calibrators A, B and C _____

      2. Lot # _____ ~~Rcd date~~ _____ Exp date _____ _____

   c. PhosphaCheck Pasteurization Controls Set _____

      1. Positive and negative control _____

      2. Lot # _____ ~~Rcd date~~ _____ Exp date _____ _____

   d. Daily Instrument Control

      1. Lot # _____ ~~Rcd date~~ _____ Exp date _____ _____

   e. Reagents stored at 0-6C _____

   ~~f. Bottles labeled with receive and open dates~~ _____

REAGENT PREPARATION

10. Working substrate _____

a. Prepare reagents as per manufacturer instructions, mix by inversion until fully dissolved _____

b. Date (mixture stable 60 days at 0-6C) _____

1. Bottle labeled with date prepared _____

2. Preparation date _____

c. Place cleaned, 2 mL reagent dispenser (item 5) on prepared reagent bottle, or cap if using 2 mL pipettor _____

INSTRUMENT AND REAGENT CHECKS

~~14.~~11. Check Procedures _____

a. Check calibration if readings are suspect (positive control value out of limits) _____

b. Press set-up button _____

c. Press left or right arrow key to get A/D option _____

d. Select A/D Mode _____

e. Zero Check _____

1. With no tube in the instrument, press "Start" key and take a reading _____

2. A/D value _____ _____

3. The reading must not exceed 314. If the reading exceeds 314, an instrument problem is indicated, call for technical assistance _____

4. Record value ~~on printout and~~ in QC record _____

f. Calibrator C/Daily Instrument Control Check _____

1. Dispense 2.0 mL of Calibrator C (item 9b) or Daily Instrument Control (item 9d) into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed Calibrator C or

Daily Instrument Control into the sample chamber and press "Start" key _____

a. The A/D value should be 602±15 (maximum allowable drift _____

b. A/D value _____ _____

c. Record Lot # and value ~~on printout and~~ in QC record _____

3. If the value does not fall within the acceptable range, then perform the following procedure (refer to manual, or contact manufacturer if unsure) _____

a. With Calibrator C or Daily Instrument Control in the sample chamber, adjust the R15 resistor until the A/D value reads 602±2 _____

b. Allow the instrument to equilibrate for 15 minutes, the A/D value should still read 602±2 _____

c. Record Lot # and value ~~on strip and~~ in QC record _____

~~4.~~ d. If the value does not fall within and stabilize at 602±2 seek technical assistance _____

~~5.~~ e. For older units requiring the instrument cover to be removed or if unsure seek technical assistance _____

g. Reconstituted Substrate/Buffer stability check _____

1. Dispense 2.0 mL of working substrate (item 10) into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed working substrate into the sample chamber and press "Start" key _____

a. The A/D value should be < 1,200 _____

b. A/D value _____ _____

c. Record Lot # and value ~~on printout and~~ in QC record _____

h. Reconstituted Substrate/Buffer contamination check _____

1. Dispense 2.0 mL of working substrate (item 10) into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed working substrate into the sample chamber _____

3. Initiate an ALP sample reading of the working substrate on an unused channel _____

4. The ALP value should be < 10 mU/L _____

   a. ALP value _____ _____

   b. Record Lot # and value ~~on printout and~~ in QC record _____

5. If the working substrate value does not fall within the acceptable range, do not use working substrate, re-check to verify, reconstitute a new set of reagents or seek technical assistance before testing samples _____

CALIBRATION
(Required at installation and after any instrument adjustments)

~~11.~~12. Calibration Procedure _____

a. Perform instrument and reagent checks (item ~~14~~ 11) prior to proceeding _____

   1. Readings from item ~~14~~ 11 are within specification, proceed with calibration _____

   2. If readings not within specification, do not proceed with calibration, make appropriate adjustments or seek technical assistance and re-check _____

   3. Record all values (initial and re-checks) ~~on tape and~~ in QC record _____

b. Check calibration ratio of Calibrators A, B and C, record Calibrator Lot # ~~on strip and~~ in QC record _____

   1. Label two (2) tubes each for Calibrators A, B and C _____

   2. Add 2 mL of each calibrator to the appropriately labeled tubes _____

   3. Heat tubes for 20 minutes to 38±1C _____

4. Find an empty channel _____

   a. Press the "Calib" key _____

   b. Locate the channel to be used, using the "<" and ">" keys _____

   c. Press the "Enter" key to select the channel _____

5. Place a tube of warmed Calibrator A (with no milk added) into the cuvette chamber, close the door and press the "Start" key _____

6. Continue as prompted until all six (6) tubes have been run _____

7. Calibration ratio should be 151±7 (when A/D mode check for Calibrator C/Daily Instrument Control is 602±6) _____

8. If ratio within specification continue, if not make adjustment and re-check calibration ratio _____

c. <u>Sample agitation</u>

   <u>1.</u> Invert retail containers 25 times, each inversion a full cycle down and up _____

d. Remove test portions (avoiding foam) within 3 min of agitation _____

e. To each calibrator, add 75 µL (or 25 µL) of the well-mixed product being tested <u>and immediately mix by vortexing</u> _____

   1. <u>For positive displacement pipettor with reusable tip</u> _____

      ~~1.~~<u>a.</u> Prior to pipetting sample, draw up MS water once and expel to waste _____

      ~~2.~~<u>b.</u> Dry exterior of piston and tip _____

      ~~3.~~<u>c.</u> Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____

      ~~4.~~<u>d.</u> Draw sample into pipettor~~, touch off to side of container~~ _____

~~5.~~e. Holding pipettor at 90° to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____

~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____

~~b.~~g. If concave, re-sample _____

~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 12e1e) _____

2. For air displacement pipettor with new tip for each Sample _____

a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____

b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

f. Add products to calibrators one tube at a time just prior to being tested _____

g. ~~Mix by vortexing~~ Run test within 20 sec of adding sample to calibrator _____

h. Place cuvette in Fluorometer, close cuvette door _____

i. Press the "CALIB" key on the Fluorometer keypad and follow the prompts on the display panel _____

j. After each reading, remove cuvette and close door immediately _____

k. Record lot #'s of the calibrators used ~~on the tape printout and~~ in the QC record book _____

l. Instrument calibrated for each product type to be tested, some products with similar fat content may share same channel _____

m. Re-calibration required if: _____

1. Controls out of limits _____

2. Adjustments made to bring A-D mode checks (item ~~14~~ 11) into specification _____

3. Any significant instrument service if performed, ex. lamp or filter replaced _____

n. Instrument checks and calibrations within specification _____

CONTROLS

~~12.~~13. Negative Control _____

a. Use PhosphaCheck negative control from set in item 9c _____

b. Or, optionally heat a sample of product to 95±1C for 1 min with stirring (temperature control [TC] used) _____

1. Cool rapidly to 0-4.4C in an ice bath _____

2. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at -15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

~~c. Add 2.0 mL of working substrate (Reagent C) to cuvettes and heat to 38±1C for 20 min (use within 4 hours)~~ _____

~~d. Add 75 µL of well mixed control to cuvette and immediately vortex~~ _____

~~e. Once control is added to reagent test within 20 sec~~ _____

~~f. Place the cuvette in the Fluorometer, close the cuvette door and press the "TEST" key on the keypad~~ _____

c. Test control as a sample (see item 15 b-k) _____

~~g.~~d. Value less than (<) 20 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

~~13.~~14. Positive Control _____

a. Use PhosphaCheck positive control from set in item 9c _____

b. Or, optionally to a portion of negative control (Item 13b), add ~~exactly~~ 0.1 mL of mixed-herd raw milk and bring up to ~~exactly~~ 100 mL with additional negative control ~~(as in item 12b)~~ _____

1. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at -15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

c. Test ~~as in items 12 c-f~~ control as a sample (see item 15 b-k) _____

d. Value between 500±150 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

TEST PROCEDURE

15. Test Procedure _____

a. Perform all instrument and reagent checks (item ~~14~~11), negative control test (item ~~12~~13) and positive control test (item ~~13~~14) prior to running analysis _____

b. Using reagent dispenser, fixed volume or electronic pipettor, dispense 2.0 mL of working substrate into labeled 12 x 75 mm glass cuvettes _____

1. Prime reagent dispenser (item 5) 3x prior to dispensing volumes to cuvettes to remove any bubbles from dispenser tubing _____

c. Warm substrate to 38±1C in the heating block for 20 min (use within 4 hours) _____

d. Sample agitation _____

1. Invert filled retail containers 25 times, each inversion a full cycle down and up _____

e. Remove test portions (avoiding foam) within 3 min of agitation _____

f. Press the "Test" key on the keypad _____

g. Select the product type channel and enter identification number _____

h. Dispense 75 µL (or 25 µL) of the well-mixed sample into the warmed substrate and immediately mix by vortexing _____

1. For positive displacement pipettor with reusable tip _____

~~1.~~a. Prior to pipetting sample, draw up MS water once and expel to waste _____

~~2.~~b. Dry exterior of piston and tip _____

~~3.~~c. Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____

~~4.~~d. Draw sample into pipettor~~, touch off to side of container~~ _____

~~5.~~e. Holding pipettor at 90° to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____

~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____

~~b.~~g. If concave, re-sample _____

~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 15h1e) _____

2. For air displacement pipettor with new tip for each

Sample _____

a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____

b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

i. Add products to substrate one tube at a time just prior to being tested _____

~~9.~~j. Run test within 20 sec of adding sample to reagent _____

~~i.~~k. Place the cuvette in the Fluorometer, close the cuvette door, and press the "START" key on the keypad _____

~~j.~~l. Results will display in 3 min., save tape print-out of results ~~in record book~~ and QC record _____

~~a.~~1. If a 25 µL sample volume was used multiply the displayed value by 3 _____

~~b.~~2. Record adjusted value on printout _____

~~k.~~m. Values of ≥ 350 mU/L or more of ALP activity are considered to contain approximately 0.1% (v/v) raw milk and must be confirmed _____

n. Record lot # of the substrate used in the QC record. _____

CONFIRMATION

16. Negative Control _____

a. Prepare separate negative control ~~for each product~~ from each suspect product _____

b. For preparation of control using the suspect product

1. Prepare by heating sample for at least 1 min after thermometer registers 95±1C, stirring or mixing as necessary (TC used) _____

~~c.~~2. Cool rapidly to 0-4.4C in an ice bath _____

~~d.~~c. This control must be less than 20 mU/L when tested _____

~~**17. Positive Control (See item 13)**~~

~~a. Must be prepared from suspect product~~

~~18.~~17. Microbial Phosphatase _____

a. To determine presence of microbial phosphatase, heat 1.0 mL of suspect milk at 63±1C for 30 min, stirring or mixing every 10 min (if fat content is >10%, heat at 66±1C) [TC used] _____

b. Cool rapidly to 0-4.4C in an ice bath _____

c. Test heated portion, unheated portion, and positive and negative controls _____

d. Interpretation _____

1. If heated and unheated portions have equal activity (within ±5%), the sample is regarded negative for residual phosphatase, the activity originally measured is microbial _____

2. If the heated portion has significantly reduced (>5%) or no activity, the sample contains milk phosphatase activity, either residual or reactivated _____

~~19.~~18. Reactivated Phosphatase _____

a. Magnesium acetate solution _____

1. Dissolve 35.4g of $Mg(C_2H_30_2)_2 \cdot 4H_20$ in 25 mL MS water warming slightly to aid solution.

2. Pour solution into 100 mL volumetric flask, rinse original container several times and add rinses to flask.

3. After cooling, make up to 100 mL (stable for 1 year at 0-4.4C) _____

b. Procedure _____

1. Place 10 mL of each milk or milk product sample to be tested in a boiling water bath and hold 1 min after temperature sample has reached 95±1C (TC used) _____

2. Cool samples rapidly to 0-4.4C in an ice bath _____

3. Place a 5 mL aliquot of sample (unheated) to be tested in a screw-cap test tube and add 0.1 mL MS water ("Blank" sample) _____

4. To a second 5 mL aliquot (unheated) in an identical tube, add 0.1 mL Mg acetate solution ("Test" sample) _____

5. Cap tubes and incubate both aliquots for 1 hr at 34±1C _____

6. Remove samples from water bath and cool rapidly to 0-4.4C in an ice bath _____

7. Dilute 1 mL of sample containing magnesium (Test) with 5 mL (1:6 dilution) of corresponding boiled milk or milk product control (items 21b 1 & 2 above) _____

8. Test undiluted sample containing no magnesium (Blank) and diluted sample containing magnesium (Test) for phosphatase activity (as described in item 16) _____

c. Interpretation _____

1. If the diluted aliquot containing magnesium (Test) has equal (±5%) or greater phosphatase activity than the undiluted aliquot containing no magnesium (Blank), the sample is regarded negative for residual phosphatase, and the phosphatase originally measured is of **reactivated** origin _____

   Dil<u>uted</u> w/Mg (Test) ≥ Undil<u>uted</u> (Blank) = Reactivated

2. If the diluted aliquot (Test) contains less activity (< 5%) than the undiluted aliquot (Blank), the sample is considered positive for **residual phosphatase** _____

   Dil<u>uted</u> w/Mg (Test) < Undil<u>uted</u> (Blank) = Residual

3. A false-positive for residual phosphatase may also be obtained if a reactivatable sample has been allowed to stand at elevated temperatures (20C) for periods of 1 hr or more before testing (SPC <20,000/mL) _____

<u>RECORDING AND</u> REPORT<u>ING</u>

~~20.~~<u>19.</u> Confirmatory Interpretation _____

a. Report as positive for residual phosphatase if microbial phosphatase, and reactivatable phosphatase are not present _____

b. ~~Report~~ <u>Record</u> all values in mU/L _____

c. Report as **Not Found** for residual phosphatase if: _____

   1. If microbial phosphatase present _____

   ~~3.~~<u>2.</u> Or, if reactivatable phosphatase present _____

   ~~4.~~<u>3.</u> Or, if there is documentation that the product was treated such that reactivatable phosphatase may be present _____

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Telephone No.:	502-564-4446 x 4462 / 512-458-7585	E-mail Address:	Lucinda.Mitchell@ky.gov / Catherine.Hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	232
Committee:	Lab - 2400

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

A. Summary of Proposal

Addition of wording the to the DMSCC 2400 Series form for how long samples may be run after initial collection.

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

Each of the ESCC forms have an item detailing how long a sample may be run after initial collection. The DMSCC form has no such instructions. This will eliminate confusion amongst the laboratories and LEOs.

There is no public health significance.

C. Proposed Solution

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

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

Addition to Item 1 on the DMSCC form:

a. Un-preserved samples may be run up to 72 hours after initial collection.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	233
Committee:	Lab/Other Species - 2400

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

A. Summary of Proposal

To allow for beta lactam drug residue testing of sheep milk by the Charm SLBL method after a quantity of such milk has been frozen for up to 60 days and properly thawed. Subsequently the samples shall be held at 0-4.4°C and analyzed within 24 hours as per the instructions for frozen controls of the Charm SLBL test method as described in the Charm SL / SL6 / SL3 2400 form.

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

Sheep by their physical size and short lactation period produce small volumes of milk. Due to this many farms and processing facilities freeze milk and store it in bags until a sufficient quantity is accumulated for processing. The frozen milk is then shipped from the farm to the processor. The frozen milk is thawed slowly under refrigerated conditions, commingled and processed.

Freezing sheep milk prior to processing has been an acceptable and most often necessary practice. The make-up of sheep milk makes this acceptable from a milk quality standpoint and there is no public health concern from the practice. The USDA "Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements" specifically addresses necessary requirements when freezing sheep milk including container type, temperature and maximum storage time.

FDA publication M-I-10-6 (Qs/As 2009) disallows the thawing and subsequent testing of sheep milk by the Charm SLBL method stating "the Charm SL drug test kit was not validated by CVM for use with frozen raw sheep milk. The raw sheep milk must be tested prior to freezing." In opposition of this statement, the validation of the test kit was in fact conducted by using

frozen raw sheep milk. During the incurred portion of the validation study, milk from treated animals was collected, divided into sample sets and shipped frozen to the independent testing laboratory. This procedure was submitted to and approved by FDA-CVM prior to the start of the validation study. In addition to this, the FDA 2400 Form "Charm SL, SL6, SL3 Beta Lactam Tests" Item 5 "Reagent Stability" specifically provides for the use of frozen control samples so long as the control samples are held at proper temperatures, thawed slowly under refrigeration and used within 24 hours. In the initial studies of the Charm SLBL, the method was validated to work with frozen controls. The frozen control samples were tested and found to be stable up to 60 days.

C. Proposed Solution

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

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

Make changes to the Form FDA 2400n-1 Charm SL / SL6 / SL3 to reflect that frozen samples of sheep milk can be officially tested using the Charm SLBL method after properly thawing using the same instructions as given for control samples.

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Telephone No.:	(802) 828-2433 / (716) 725-5080	E-mail Address:	dan.scruton@state.vt.us / Christopher.hylkema@agmkt.state.ny.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	234
Committee:	Lab - 2400

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

A. Summary of Proposal

Update to language for autoclave performance checks.

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

With the number of laboratories no longer running their autoclaves on a continual basis, there is no need to require the performance check be done weekly if the unit is not in use. This wording will allow laboratories to perform the check during weeks when testing under the NCIMS Laboratory Program requires the use of and documentation of autoclave cycles. At a minimum, quarterly performance checks will be required.

There is no public health significance.

C. Proposed Solution

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

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

Cultural Procedures – General Requirements form –

Item 13. Autoclave

i. Performance checked with full load and results recorded ~~weekly~~ quarterly at a minimum (preferably once during each week of use) using spore (G. stearothermophilus) strips or suspensions, include positive control check, results maintained _____

Name:	Patti Huttula - NCIMS Laboratory Committee		
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Telephone No.:	248-474-6672	E-mail Address:	Huttula@mimilk.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	235
Committee:	Lab - EML

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

A. Summary of Proposal

To add to the 2009 EML the option for Laboratory Evaluation Officer to send the narrative report to the laboratories electronically without the 2400 series forms.

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

All laboratories have current copies of the 2400 series forms in use on file in their facilities. By allowing the LEOs to send the narrative report electronically, the copying of completed check lists will be eliminated therefore saving supplies for the states.

There is no public health significance to making this change. The laboratories will be sent a narrative report that will be sufficiently detailed to allow the readers to determine what is cited without having to refer to the forms. This statement is already in the 2009 EML with regard to the narrative being sufficiently detailed to allow readers to understand without referring to the forms.

C. Proposed Solution

Changes to be made on page(s): 3, 22, 27, 30 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms

Page 3, paragraph 3:

~~Sets~~ A set of completed evaluation forms ~~shall~~ may be accompanied by a narrative report which describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

Page 3, paragraph 4:

Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories–/CIS must include the narrative report and may include copies of the completed FDA-2400 Series Forms ~~and a copy of the narrative report~~. Reports to FDA Regional Office and FDA/LPET should only include the narrative report.

Page 22, paragraph 1:

FDA-2400 Series Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation when the option to send them with the narrative report is used.

Page 22, paragraph 2:

Copies of the evaluation forms ~~are to~~ may be prepared for the laboratory evaluated.

Page 22, paragraph 3:

The set of completed evaluation forms for the laboratory ~~must~~ may be accompanied by ~~a~~ the narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted.

Page 22, paragraph 5:

~~A format~~ Formats suitable for narrative reports ~~appears~~ appear on pages 27 – 32.

Page 22, paragraph 6:

If choosing the option to send the narrative only via electronic submission, it will be necessary to summarize what each item is.

Pages 27 and 30:

If forms accompany the narrative report then, ~~Deviated~~ deviated items are marked with an

"X" on the evaluation forms.

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City/State/Zip:	Austin, TX 78756		
Telephone No.:	512-458-7585	E-mail Address:	Catherine.hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	236
Committee:	Lab - EML

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

A. Summary of Proposal

This Proposal seeks to add the requirement for a summary template to be submitted along with the laboratory narrative report submitted to the Laboratory Proficiency and Evaluation Team to the 2009 EML.

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

There is no public health significance. Submission of a summary template speeds IMS laboratory updates and assists in assuring the accuracy of those updates. See attached templates.

C. Proposed Solution

Changes to be made on page(s): 3, 5, 6, 7, 16, 22, 24, new 33-xx of the (X - one of the following):

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

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

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

Page 3:

SECTION 1: LABORATORY EVALUATION PROGRAMS

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS must include copies of the completed FDA-2400 Series Forms and a copy of the narrative report. Reports to FDA Regional Office and FDA/LPET ~~should~~ shall be sent electronically and shall ~~only~~ include the narrative report and appropriate, completed summary templates only (see page xx – xx). …

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Page 5:

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the milk regulatory agency, the state milk sanitation rating agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the appropriate, completed summary template and shall be submitted electronically. …

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Page 6:

Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts, or for some other reason, the Federal or State LEO shall immediately notify the milk laboratory involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be

returned to the issuing State LEO within 90 days. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed summary template and shall be submitted electronically. …

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Page 7:

When a screening facility loses its approval because of lack of approved IS or IA, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed summary template and shall be submitted by email.

Screening facilities requesting withdrawal of approval shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed summary template and shall be submitted by email. …

Page 16:

SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS

Initial certification of State LEO shall be based on meeting the following criteria:

2. The individual must submit an acceptable written report of the milk laboratory initial check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed summary template only (see page xx – xx). …

Laboratory evaluations conducted by conditionally approved State LEOs are official.

2. The individual must submit an acceptable written report of the milk laboratory check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed summary template only (see page xx – xx). …

Page 22:

SECTION 6: LABORATORY EVALUATION REPORTS

NARRATIVE REPORTS

The set of completed evaluation forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory evaluation. The copy of the narrative report submitted by email to FDA/LPET must be accompanied by the appropriate, completed summary template, both attached to the same email. The LEO must receive verification of receipt by return email and must maintain a copy of the verification in their records. State LEOs may submit reports by email~~,~~; however, they must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the evaluation, who made the evaluation, list the prior status, list the date of the last on-site evaluation, indicate the present status, what recommendations were made to correct any deviations, what test were approved, and who was certified to do them. …

Page 24:

…compliance with the facility requirements noted in the last on-site evaluation.

SUMMARY TEMPLATES

The narrative report must be accompanied by the appropriate, completed summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along with other useful information to be used by FDA/LPET. Only the current revision of the templates, authored by FDA/LPET, may be used. There are two templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS). The information captured on the template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

The appropriate summary template form must also be used for the notification of changes in accreditation and certification status, and must be submitted by email to FDA/LPET.

Directions for completing the summary template, authored by LPET, will be updated with each revision of the summary template, as necessary, and provided to the LEOs by email.

An example of a completed summary template for each application appears on pages 33-xx.

REFERENCES

New Page 33-xx:

NOTE: *At the end of the EML document, add an example of a completed summary template for each application on pages 33-xx.*

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
City/State/Zip:	College Park, MD 20740		
Telephone No.:	(708) 728-4114	E-mail Address:	Thomas.Graham@fda.hhs.gov

LPET Summary Template (USA) v-2009b

Accredited Lab Reports

For LPET use only.

(Report Type)

Lab Type: (Lab Type)

IMS No.:

Lab Status:

Evaluation Date: Month = Year =

Expiration Date: (Anniversary Date) Month = Year =

Last Two Split Samples: (Current [1] / Previous [2]) Month_1 = Year_1 = Month_2 = Year_2 =

LEO:

Laboratory Name:

Address-1:

Address-2:

City:

State: ZIP Code:

Country: USA

(Click Below for Descriptions) Approved Laboratory Procedures: 0

02-07:	☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 07
09:	☐ B2 ☐ C2 ☐ C3 ☐ C4 ☐ C9 ☐ C10 ☐ C11
09:	☐ C12 ☐ C13 ☐ C14 ☐ C15 ☐ D1 ☐ D3 ☐ I1 ☐ N1
12-27:	☐ 12 ☐ 16 ☐ 20 ☐ 21 ☐ 22 ☐ 24 ☐ 25 ☐ 26 ☐ 27
28-30:	☐ 28 ☐ 29 ☐ 30A ☐ 30D

Comments (for LPET use only):

For LPET use only.

City:

State: ZIP Code:

IMS No: 0

(Lab Type) - (Report Type)

Approved Laboratory Procedures

Analysts (Last Name, First Name)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Counts
1																0
2																0
3																0
4																0
5																0
6																0
7																0
8																0
9																0
10																0
11																0
12																0
13																0
14																0
15																0
16																0
17																0
18																0
19																0
20																0
21																0
22																0
23																0
24																0
25																0
26																0
27																0
28																0
29																0
30																0
31																0
32																0
33																0
34																0
35																0
36																0
37																0
38																0
39																0
40																0

LPET Summary Template (USA) v-2009b

CIS & Screening Reports

For LPET use only

(Report Type)

Lab Type: (Lab Type)

IMS No.:

Lab Status:

Evaluation Date: Month= Year=

Expiration Date: (Anniversary Date) Month= Year=

Last Two Split Samples: (Current [1] / Previous [2]) Month_1= Year_1= Month_2= Year_2=

LEO:

Laboratory Name:

Address-1:

Address-2:

City:

State: ZIP Code:

Country: USA

"(Click Below for Descriptions)" Approved Laboratory Procedures: 0

09:	☐ B2 ☐ C2 ☐ C3 ☐ C4 ☐ C9 ☐ C10 ☐ C11
	☐ C12 ☐ C13 ☐ C14 ☐ C15 ☐ D1 ☐ D3 ☐ I1 ☐ N1

Comments (for LPET use only):

For LPET use only

LPET Summary Template - CIS & Screening v-2009b

IMS No: 0

(Lab Type) - (Report Type)

(Type)

(Type)		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Counts
(Last Name, First Name)	Position																
1																	0
2																	0
3																	0
4																	0
5																	0
6																	0
7																	0
8																	0
9																	0
10																	0
11																	0
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15																	0
16																	0
17																	0
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27																	0
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30																	0
31																	0
32																	0
33																	0
34																	0
35																	0
36																	0
37																	0
38																	0
39																	0
40																	0

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	237
Committee:	Lab - EML

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

A. Summary of Proposal

To update the example narratives in the EML and to provide a definition of the usage of 'NOTE".

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

The EML example narrative formats have not been updated to reflect the changes in the 2400 forms and need to reflect the correct items.

The term 'note' has been used in numerous ways. LEOs are trained to use the term for items that are not deviations. The example report has a statement to use note if the item is not a deviation but that it will be called a deviation if not corrected on the next evaluation.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 28-32 of the (X - one of the following):

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

Strike the existing language and use the new examples.

~~EXAMPLE~~

~~Report of a Biennial On-Site Evaluation~~

~~of~~

~~Certified Industry Supervisor~~
~~Name~~
~~Plant Manager~~

~~Laboratory Name~~
~~Laboratory number: 00600~~
~~Laboratory Street Address~~
~~City, State 00000~~

~~On~~

~~Evaluation Date~~

~~By~~

~~LEO Name~~
~~Laboratory Evaluation Officer~~

~~Last Certified: Date~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.~~

~~Previous Laboratory Status: Fully certified for [List Procedures].~~

~~Present Laboratory Status: Fully certified for [List Procedures] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of [Date].~~

~~Other changes that need to be made to IMS list, etc: None or List Changes~~

~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.~~

~~Beta lactam Tests~~

~~DEVIATIONS AND CORRECTIONS~~

~~GENERAL REQUIREMENTS~~

~~3. Thermometers for use with Test Kits and Laboratory Equipment.~~

~~d. Calibrate your freezer thermometer against a traceable thermometer.~~

~~d2. Tag above calibrated thermometer with date, identification and correction (+0.0, if none) and record results.~~

~~6. Balance.~~

~~e. Note: Have your new balance calibrated annually by a qualified service representative.~~

~~TECHNIQUES~~

~~[Name Test]~~

~~No deviations were observed for the [Name Test].~~

~~[Name of Second Test]~~

~~15. Test Procedure.~~

~~p. Multiple tests were run at the same time. Start incubation timing immediately after the sample is added to the last test device. Analyst started timing too late.~~

~~CONCLUSIONS~~

~~[CIS Name] is certified as a Certified Industry Supervisor to perform the procedures as listed above pending correction of listed deviations and receipt of corrections in writing by the State LEO within sixty days of receipt of this evaluation. Contact me if there are questions.~~

~~Sincerely,~~

~~LEO Name~~
~~Laboratory Evaluation Officer~~

~~EXAMPLE REPORT~~

~~REPORT Of an On-Site Biennial/~~
~~Supplemental (analyst, procedure, walk-through)/~~
~~Unofficial~~

~~Certified Laboratory~~
~~NCIMS Lab ##~~

~~Certified Industry Supervisor~~

~~CIS ##~~

~~Appendix N Screening Site~~

~~NAME OF SITE~~
~~Address~~
~~Date of evaluation~~
~~By LEO's name~~

~~Previous Laboratory Status: Fully/provisionally/conditionally Certified until date~~
~~Previous Procedures: X, X, X~~

~~Present Laboratory Status: Fully/provisionally/conditionally Certified until date, pending acceptable response to this report~~
~~Procedures evaluated: X, X~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.~~

~~Other changes that need to be made to IMS list, etc: None~~

~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.~~

~~DEVIATIONS AND CORRECTIVE ACTIONS~~

~~ITEM METHOD~~

~~CULTURAL PROCEDURES FOR CERTIFIED LAB/~~
~~GENERAL REQUIREMENTS FOR APP N~~

~~CERTIFIED LAB~~

~~3d1.In the media section, calibration of thermometers was done but the calibration temperature was not always at temperature of use. Refrigerator was calibrated at 5C vs. 0.0C and hot air oven was calibrated at 65C vs. 170C. Send new/proper calibrations with response.~~

~~3d2a. The tags did not include correction factors in media area. Send verification.~~

~~APPENDIX N LAB~~

~~*1c. Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100].*~~

~~During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.~~

~~It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.~~

~~ITEM METHOD~~

~~TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.~~

~~CERTIFIED LAB~~

~~Standard Plate Count, Coliform, and Simplified Count Methods~~

~~5b1/2.Proper mixing or shaking of samples, retail must have complete inversion top over bottom and raw is to be more vigorous than observed.~~

~~6d. Analysts are to avoid the foam of sample. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.~~

~~APPENDIX N LAB~~

~~*3a1. Incubator level. Temperature checked daily (day of use), records maintained.*~~

~~The temperature is not being recorded to the tenth of a degree. Please instruct analysts to record the strip incubator to the tenth of a degree.~~

~~*10a. Reader tapes or computer printouts maintained for two years.*~~

~~Please remember that the kit number is the lot number. Please Note: Post the analyst codes in each testing area (confirmation testing area and screening testing area). This will eliminate any confusion as to which code belongs to which analyst.~~

~~Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.~~

~~PERSONNEL AND PROCEDURES CERTIFIED~~

~~LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.~~

~~**CERTIFIED LAB**~~

~~PERSONNEL AND PROCEDURES CERTIFIED~~

	SPC/PAC	COLI/PCC	PMC	D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

~~[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].~~

~~**APPENDIX N LAB**~~

Certified Industry Analysts	2004 On-Site Evaluation TEST KIT	4/2004 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2004 On-Site Evaluation TEST KIT	6/2004 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

~~CONCLUSION~~

~~Use the proper conclusion found on pages 23 & 24.~~

New example reports for the EML.

EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation

of

City Health Department Milk Laboratory

Accredited Laboratory
NCIMS LAB #####

100 South Main Street
City, State 78000

On

March 1, 2010

By

LEO Name
Laboratory Evaluation Officer
State Department of [Health, Agriculture}
100 Healthy Way
City, State 78000

Last Full Evaluation Date: March 19, 2008
Next Evaluation Due By: March 31, 2012

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28]

Present Laboratory Status: Fully certified for [5, 9C13, 9D3, 12, 16, 20 22, 24, 28] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of March 1, 2010.

Other changes that need to be made to IMS list, etc: Update Anniversary Date, drop procedure 9C14, add procedure 16.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or

procedures equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. ~~They will be marked as deviations if not corrected by the next evaluation.~~ The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

CULTURAL PROCEDURES - GENERAL REQUIREMENTS (rev. 2/10)

2. Records

2e Corrections to all records follow appropriate requirements

During the review of the autoclave records it was noticed that there were a number a items written over.

Analysts are to be reminded of the proper protocol for correcting mistakes. Cross out the error with one line, initial, date and write the correct information next to it.

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

#NOTE: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. It is suggested that a new thermometer be purchased.

The other option is to use the new NIST traceable unit that is available for use in the rest of the laboratory.

3c3 No tag was found on the freezer thermometer

Although the accuracy check was documented the unit was not tagged.

Tag the thermometer with the following: identification/location, date of check, temperature checked and the correction factor.

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

Over the past four months at least 50% of the days noted with the unit out of temperature range with no corrective action noted.

This is a serious violation and no controls or samples may be kept in the unit until it is proven that that the unit holds the proper temperature.

Send copies of the freezer temperature records for the next 4 months. If the unit cannot be maintained then a new one will need to be purchased.

Page 3 / #####
3/1/2010

13. Autoclave

13i Performance check

There were no thermometers for the incubation units for the spore check. There must be a way to check the appropriate temperature range for the test.

Please purchase thermometers for these units and send a copy of the purchase order, the temperature calibrations when received and the temperature records for the two months following.

TECHNIQUES

PETRIFILM AEROBIC AND COLIFORM COUNTS (IMS# 5,20 rev. 1/09)

No deviations noted. The analysts showed marked improvement over the last biennial on-site.

PASTEURIZED MILK CONTAINERS (IMS# 22 rev. 1/09)

10. Collection of Surface Rinse Samples

10b2 While adding the rinse solution to the container, do not touch the bottle of rinse solution to the container.
One analyst held the bottle against the container while adding the rinse solution.
Use aseptic technique when adding the rinse solution.

DELVOTEST P 5 PACK (IMS# 9D3 rev. 2/10)

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

21e Touch the slide with the tip and expel the test portion.
One analyst held the syringe above the slide and dripped the milk.
Take the syringe and hold it vertically against the slide, depress the plunger slowly allowing the milk to be expelled. Then touch off to a dry spot.

ESCC – BENTLEY 150 (IMS# 16 rev. 10/07)

No deviations noted.

FLUOROPHOS ALP (IMS# 28 rev. 6/05)

15. Instrument and Reagent Checks
Page 4 / #####
3/1/2010

15g2b Reconstituted Substrate / Buffer Stability Check A/D Value Recorded
The A/D value for this check was missing on several days of testing records during the period evaluated. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be noted with both the old *AND* new values recorded.

DAIRY WATERS (IMS# 24 rev. 1/09)

No deviations noted.

CHARM SL BETA LACTAM (IMS# 9C13 rev. 1/10)

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

Analyst	5	9C13	9D3	12	16	20	22	24	28	ON-SITE Last 2	SPLITS Last 2
Analyst 1	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 2	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 3	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 4	X	X	X	X		X	X	X	X	3/10	10/09
Analyst 5*	X	X	X	X	X	X	X	X	X	3/08, 3/06	10/09, 10/08

X = Fully Certified
* = Analyst excused – on medical leave.
5 = Petrifilm Aerobic Count
9C13 = Charm SL Beta Lactam
9D3 = Delvotest 5 Pack
12 = DMSCC
16 = ESCC (Bentley 150)
20 = Petrifilm Coliform Count
22 = Pasteurized Milk Containers
24 = Dairy Waters
28 = Advanced Fluorometer

CONCLUSION

Although the procedures, records, facilities and equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade 'A' PMO* the analyst, equipment and record deviations noted must be corrected. This laboratory is accredited until May 1, 2010 pending correction of the deviations and receipt of a letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation will be given.

Sincerely,

LEO

EXAMPLE REPORT #2

REPORT Of an Biennial On-Site/
Supplemental (analyst, procedure, walk-through)/
Unofficial/Check

Certified Laboratory
NCIMS Lab #####

Certified Industry Supervisor
CIS #####

Appendix N Screening Site

NAME OF SITE
Address
Date of Evaluation
By LEO's name

Previous Laboratory Status: Fully/provisionally/conditionally Certified until [date]
Previous Procedures: X, X, X

Present Laboratory Status: Fully/provisionally/conditionally Certified until [date], pending acceptable response to this report
Procedures evaluated: X, X

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.

Other changes that need to be made to IMS list, etc: None or addition of analysts, change in procedures, etc.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES FOR CERTIFIED LAB [rev. 2/10] /
GENERAL REQUIREMENTS FOR APPENDIX N [rev. 2/10]

CERTIFIED LAB

3. Thermometers

3c2 All test temperature measuring devices are checked at temperature of use.
The thermometers in the media section were checked for accuracy but were not always done at the temperature of use as required. The hot air oven was checked at 65C vs. 170C.
Re-check the thermometer and send with the response.

3c3a Tags include correction factors on temperature measuring devices.
The tags did not include correction factors in media area.
Send copies of the tags.

APPENDIX N LAB

1c Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100)].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

ITEM METHOD

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods (IMS#2 rev. 1/09)

5. Sample Agitation
5b1 Shake samples raw samples 25 times in 7 sec with 1 ft movement
All analysts did not shake quickly enough. Raw samples need to be shaken more vigorously.

Page 3 / #####
Date

5b2 Invert filled retail container 25 times, each inversion a complete down and up motion
All analysts did not complete the inversions.

6d Avoid foam if possible when pipet is inserted into sample.
All analysts did not avoid the foam. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

CHARM SL BETA LACTAM (IMS# 9C13 rev 2/10)

3a1 Incubator level. Temperature checked daily (day of use), records maintained.
The temperature is not being recorded to the tenth of a degree.
Please instruct analysts to record the strip incubator to the tenth of a degree.
Send copies of the temperature record for the next two months.

14d Reader tapes or computer printouts maintained for two years.
It would be best to keep the printouts with the daily sheets as it is more difficult to look through separate stacks to match.the tankers tested.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/PACCOLI/PCCPMC			D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

Certified Industry Analysts	2010 On-Site Evaluation TEST KIT	4/2010 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2010 On-Site Evaluation TEST KIT	6/2010 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

CONCLUSION

Use the proper conclusion found on pages 23 & 24.

Name:	Catherine Hall		
Agency/Organization:	NCIMS Laboratory Committee		
Address:	1100 West 49th Street		
City/State/Zip:	Austin, TX 78756		
Telephone No.:	512-458-7585	E-mail Address:	Catherine.hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	238
Committee:	Lab - EML

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

A. Summary of Proposal

To allow State LEO the same time frame as the Federal LEO for the supplemental surveys.

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

The EML now states for State LEO to make a date within 30 days of the receipt of the request for an evaluation of a new analyst, new methods or facilities. The FDA/LPET has 60 days for these requests. State LEO cannot always accommodate facilities in the 30 day time period especially when a state has only one LEO.

C. Proposed Solution

Changes to be made on page(s): 3 of the (X - one of the following):

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

2. Evaluations of milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the State LEO. The State LEO shall schedule a mutually agreeable date or

a date within ~~30~~ 60 days of the receipt of the request for an evaluation.

Name:	Catherine Hall		
Agency/Organization:	NCIMS Laboratory Committee		
Address:	1100 West 49th Street		
City/State/Zip:	Austin, TX 78756		
Telephone No.:	512-458-7585	E-mail Address:	Catherine.hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	239
Committee:	Lab - EML

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

A. Summary of Proposal

Addition of missing word in the EML.

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

To add the needed word.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 23 of the (X - one of the following):

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

Page 23

2. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade 'A' PMO* the analyst/facility/equipment/records deviations noted must be corrected. This laboratory is accredited/approved for 30 - 60 days pending correction of the deviations and receipt of a

letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation/approval will be given.

Name:	Catherine Hall		
Agency/Organization:	NCIMS Laboratory Committee		
Address:	1100 West 49th Street		
City/State/Zip:	Austin, TX 78756		
Telephone No.:	512-458-7585	E-mail Address:	Catherine.hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	240
Committee:	Lab - EML

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

A. Summary of Proposal

Addition to the EML regarding the issuance of the 2400 Series Forms.

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

During the past year a number of 2400 forms were sent to the FDA/LPET after NCIMS Executive Board approval and have not been released within the stated 90 day time frame in the EML. This option gives the NCIMS Laboratory Committee the authorization to release the forms for use in the laboratories.

C. Proposed Solution

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

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

Page 1:

Add the following to the 2nd paragraph:

FDA memoranda shall be issued with the forms within 90 days of NCIMS Executive Board approval. If the FDA fails to issue the forms within the 90 days as required, then the NCIMS Laboratory Committee shall then issue them.

Name:	Catherine Hall		
Agency/Organization:	Texas Department of State Health Services		
Address:	1100 West 49th Street		
City/State/Zip:	Austin, TX 78756		
Telephone No.:	512-458-7585	E-mail Address:	Catherine.hall@dshs.state.tx.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	241
Committee:	Lab - EML

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

A. Summary of Proposal

To remove references to SMEDP in the EML where they are not applicable.

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

There is no public health significance.

A number of items in the Standard Methods do not reflect what the NCIMS does and need to be removed.

C. Proposed Solution

Changes to be made on page(s): 3, 4, 16, 18, of the (X - one of the following):

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

Page 3:

The Federal or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms. ~~and where~~

~~appropriate the latest edition of *Standard Methods for the Examination of Dairy Products*[1] (SMEDP).~~

Page 4:

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms~~, and where appropriate SMEDP,~~ as determined by an on-site evaluation.

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA-2400 Series Forms~~,~~ **and the PMO**~~, and where appropriate SMEDP~~.

Page 16:

1. The individual must be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms~~, and where appropriate, as described in SMEDP~~ when accompanied by a representative of the FDA/-LPET on a check laboratory evaluation.

Page 18:

8. Reference books ~~– other than SMEDP~~. (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater)

Page 24:

~~1. Available from the American Public Health Association, 800 I St., N.W., Washington, D.C. 20001-3710, USA. {http://www.apha.org}~~

~~2~~ 1. Copies of the FDA-2400 Series Forms can be downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	242
Committee:	Lab - EML

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

A. Summary of Proposal

Update the 2009 EML with the addition of the Federal LEOs to reflect the cooperative program.

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

The EML has only stated the duties of the State LEOs with the assumption that all LEOs, both State and Federal shall follow the document. This would bring the document to reflect the way the program does and should work.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 1, 2, 5, 16, 17, 18, 19, 20, 21, 22, of the (X - one of the following):

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

Page 1:

The State Laboratory Evaluation Office (State LEO) will use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. The Federal Laboratory Evaluation Office (Federal LEO) will use the appropriate FDA-2400 Series Forms when evaluating state central laboratories and State LEO).

Page 2:

The Federal LEO will accompany the State LEO on no more than two check surveys for certification purposes.

Page 5:

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager must notify the State/Federal LEO immediately....

Page 16:

Initial certification of State or Federal LEO shall be based on meeting the following criteria:

1. The individual must a State or Federal government employee....

3. Add to end of paragraph:

It is also a prerequisite that the individual either attend the Laboratory Examination of Dairy Products course or have experience with the procedures used in a milk testing laboratory prior to step 1 above or step 3.

Laboratory evaluations conducted by conditionally approved State/Federal LEOs are official.

Conditional certification of State/Federal LEO can occur following the initial check evaluation described above. Full certification will be granted after the State/Federal LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified

State/Federal LEO to attend the next scheduled Workshop, unless excused with cause by FDA/LPET, will require that the State/Federal LEO must restart the process. The State/Federal LEO candidate would then be required to participate in another check evaluation with a representative of the FDA/LPET, and then attend the next scheduled Workshop.

Page 17:

Once an individual has become a State/Federal LEO and is therefore considered fully certified, is he/she fails to submit acceptable written reports of milk laboratory evaluations within 60 days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the State/Federal will have their certification status downgraded from full to provisional. In addition, an action plan will be established that is mutually agreeable to the FDA/LPET and the state. The State/Federal LEO would have to meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved State/Federal LEOs are official.

State/Federal LEOs who lose certification cannot be re-certified for a period of 60 days from the date of loss of certification.

Page 18:

While conducting laboratory evaluations, the State/Federal LEO may find it.....

Page 19:

The evaluations of laboratories by a State/Federal LEO should be systematic.

Upon initial evaluation and/or renewal, the laboratory, must make application for an evaluation provided by the State/Federal LEO.

Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory the State/Federal LEO to permit observations of counting procedures.

After entering the laboratory, the State/Federal LEO should note the names of all analysts in the laboratory as/or after they are introduced and record procedures performed by each.

Before beginning the survey, the State/Federal LEO should discuss the "ground rules" for the survey.

Page 20:

By frequent referral to the noted items, the State/Federal LEO will be reminded to observe all laboratory procedures....

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the State/Federal LEO:

However, the State/Federal LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors.

Page 21:

The State/Federal LEO should make suggestions concerning any needed improvement of laboratory techniques.

In addition to a regularly scheduled visit, some State/Federal find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check surveys) must be evaluated by the State/Federal LEO and used to determine compliance to the NCIMS Milk Laboratory Program.

If at any time during any evaluation there is interference with or willful refusal to permit

evaluation, the State/Federal LEO will serve notice that the laboratory will not be certified or will be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals will result in non-certification or decertification for thirty days (30). Or, if at any time before or during any evaluation the State/Federal LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the evaluation. The State/Federal LEO must indicate to the laboratory management why the evaluation was terminated and must indicate what steps must be taken before a re-evaluation will be scheduled. The laboratory may make reapplication by addressing the concerns that led to the termination of the evaluation and by completing the application form and stipulating that the safety concerns and/or non compliance issues have been addressed.

Page 22:

The State/Federal LEO must maintain a complete copy of the evaluation report, including forms. The laboratory/facility and State/Federal LEO must maintain, at minimum, copies of the last two biennial/triennial evaluations, subject to verification by the State LEO and the FDA/LPET.

The set of completed evaluation forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State/Federal LEO as to whether or not the laboratory is doing acceptable work.

Page 23:

Explanation: A qualified acceptance where the State/Federal LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken will be sufficient to ensure compliance.

Page 24:

A new on-site evaluation shall be made when the State/Federal LEO has reason to believe that a rating would result in an acceptable rating.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	243
Committee:	Lab - EML

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

A. Summary of Proposal

Addition to the EML to specify that the NCIMS Laboratory Committee shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval if the FDA has been unable to issue the form by the 90 day time frame.

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

During the past year a number of 2400 forms were sent to the FDA/LPET after NCIMS Executive Board approval and have not been released within the 90 day time frame required in the EML. This has meant that laboratories have not been able to use new equipment or new protocols while waiting for the forms.

If the FDA is unable to issue the forms in the 90 day time frame, this change would authorize the NCIMS Laboratory Committee to release the forms for use in the laboratories.

C. Proposed Solution

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

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

EML Introduction Page 1 Second Paragraph

The State Laboratory Evaluation Officer (State LEO) will use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the FDA and the NCIMS executive board, and are effective 90 days after executive board approval. FDA memoranda with the approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, the NCIMS Lab Committee shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	244
Committee:	Lab - EML

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

A. Summary of Proposal

To allow for the State Laboratory Evaluation Officers to input information for the IMS List through the website as the State Rating Officers are currently doing.

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

To streamline the process and keep the laboratory portion of the IMS List updated at the monthly minimum requirement as stated in the 'Procedures' document. This is not currently as up to date as is required and this is a way to keep a better flow for the process. The State LEOs would follow the same process that the SROs are currently using. By utilizing the same process, the IMS List will be as up to date as possible for the SROs during ratings.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 3 of the (X - one of the following):

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

Section 1 (Page 3)

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories /CIS must include copies of the completed FDA-2400 Series Forms and a copy of the narrative report. Reports to FDA Regional Office and FDA/LPET should only include the narrative report.

Once a State LEO has completed a survey report, he/she has the option of updating the IMS List through the use of the website or by using the template provided by the FDA LPET.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	245
Committee:	Lab - EML

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

A. Summary of Proposal

To allow for the State Laboratory Evaluation Officers to follow the same process for input to the IMS List that the State Rating Officers are currently doing.

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

To streamline the process and keep the laboratory portion of the IMS List updated at the monthly minimum requirement as stated in the 'Procedures' document. This is not currently as up to date as is required and this is a way to keep a better flow for the process. The State LEOs would follow the same process that the SROs are currently using. By utilizing the same process, the IMS List will be as up to date as possible for the SROs during ratings.

There is no public health significance.

C. Proposed Solution

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

_____ 2009 PMO _____ 2009 EML

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

Once a fully certified State LEO has performed an on-site survey, he/she has the option of updating the IMS List.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	246
Committee:	Lab - EML

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

A. Summary of Proposal

Include the prerequisite for FD373 State Milk Laboratory Evaluation Officers Workshop (LEO) that was listed in the FDA Course catalogue

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

If this is listed as a prerequisite in the catalogue, then it should be listed in the EML as well.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 16 of the (X - one of the following):

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

3. The individual must attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET in conjunction with the Food and Drug Administration, State Training Team. <u>If the individual does not have experience in the examination of dairy products, they must attend Course FD374 (formerly STT 300)</u>

"Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

Note: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	247
Committee:	Lab - EML

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

A. Summary of Proposal

To remove the website listed in the references as a source of the 2400 series forms. Instead directing the reader to contact the federal or state LEO.

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

The website does not contain the most current 2400 series forms.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 24 of the (X - one of the following):

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

2. Copies of the FDA-2400 Series Forms can be ~~downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}~~ obtained from your federal or state LEO.

A list of federal or state LEO's can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm.

Once at that website:

For federal LEO's click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team

For state LEO's click on the link State Grade A Milk Regulatory, Rating and Laboratory Personnel and them click on your state. The table is organized Regulatory, Rating, then Laboratory. Scroll down to the laboratory section to find the contact information for your state's LEO(s).

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