# Proposal # 201

## Committee:

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## COUNCIL ACTION

## FINAL ACTION

## A. Summary of Proposal

This proposal affirms that products labeled as milk or milk products shall be produced according to the standards contained in the *PMO*.

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

The milk sanitation program of the United States Public Health Service (USPHS) is one of its oldest and most respected activities. The model milk regulations upon which the current PMO is based have a nearly 100-year history, which is directly responsible for the renowned food safety success of the industry and the “dairy halo” – pasteurized milk and fluid milk products continue to be associated with less than one percent (<1%) of such reported outbreaks (2015 PMO).

Through the continuous efforts by the dairy industry and public health agencies to improve the food safety of the milk supply, US consumers readily recognize milk and other milk products to be among the safest foods available.
C. Proposed Solution

Changes to be made on page(s): 7 of the (X - one of the following):

X 2015 PMO 2015 EML

2015 MMSR 2400 Forms

2015 Procedures 2015 Constitution and Bylaws

GG. MILK PRODUCTS:

Grade "A" Milk and Milk Products shall be produced according to the sanitary standards of this Ordinance.

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, or that are labeled as such.

Name: NMPF NCIMS Committee
Agency/Organization: National Milk Producers Federation
Address: 2107 Wilson Blvd, Suite 600
City/State/Zip: Arlington, VA 22201
Telephone No.: 703-243-6111 E-mail Address: bbrczinski@nmpf.org
A. Summary of Proposal

This proposal clarifies that the words “Grade “A”” that are required to appear on the exterior surface of a package do not need to appear on a secondary container.

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

The PMO references a number of labeling requirements for all bottles, containers and packages containing milk or milk products, including the words “Grade “A”” on the exterior surface. This proposal clarifies the intent of this requirement is to inform consumers that the product is a Grade “A” dairy product, not to inform people engaged in logistics and distribution.

By adding the definition of “package” (consistent with 21 CFR 1.20) to the PMO, as well as by adding this term to the description of the labeling requirement, it limits this required wording to the primary packaging of the food (on either the principal display panel, the secondary or informational panel, and the cap/cover) and not to secondary packaging (i.e., corrugated boxes, shipping containers, wrappings, etc.) that is used for transportation throughout the distribution chain.

While a manufacturer may voluntarily add the “Grade “A”” wording to a secondary package, this is outside of the scope of the requirement that is currently in the PMO. As this proposal does not change the labeling requirement on the package that is presented to the consumer, there would be no impact on public health.
C. Proposed Solution

Changes to be made on page(s): 10, 19 of the (X - one of the following):

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

SECTION 1. DEFINITIONS

Page 10:

**OO. PACKAGE:** Any container or wrapping in which any food, any device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;
(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or
(d) Containers used for tray pack displays in retail establishments.
(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part. (21 CFR 1.20)

SECTION 4. LABELING

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with: ....

Page 19:

4. The words “Grade “A”” on the exterior surface of the package. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.
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<td>National Milk Producers Federation</td>
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<tr>
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<tr>
<td>Telephone No.:</td>
<td>703-243-6111</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:bbriczinski@nmpf.org">bbriczinski@nmpf.org</a></td>
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A. Summary of Proposal

To provide a labeling option for aseptically processed milk products to both preserve the food safety of the opened container as well as to preserve the freshness of the container prior to opening. (Reference Section 4: Labeling page 18.). This proposal provides an option to label the bottle “keep refrigerated”, leaving off the text “after opening”.

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

Processors may choose to both preserve and improve the quality and freshness of aseptically processed milk products by utilizing a refrigerated route-to-market, sometimes referred to as ‘cold chain’. As the beverage transfers to the end-use consumer, the proposed label statement of ‘keep refrigerated’ is intended to guide the unconsumed aseptic beverage to the consumer’s refrigerator rather than to an ambient storage location.

For aseptically produced milk products, this is not an issue of food safety and has no public health significance.

For aseptic milk, the current PMO language “keep refrigerated after opening” is absolutely necessary on the label from a food safety perspective due to consumers who may not understand that once the bottle is opened, the beverage is no longer aseptic. This proposal provides processors an option to substitute the language “keep refrigerated” and thus extends the refrigeration requirement to both the unopened and the opened bottle.
SECTION 4. LABELING

All bottles, containers and packages containing milk or milk products defined in Section 1. of this Ordinance shall be labeled in accordance with the applicable requirements of the FFD&CA, the Nutrition Labeling and Education Act (NLEA) of 1990, and regulations developed there under, the CFR, and in addition, shall comply with applicable requirements of this Section as follows:

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, condensed and/or dried.
2. The Either the words “keep refrigerated” or “keep refrigerated after opening” in the case of aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products.

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A. Summary of Proposal

This proposal corrects some spelling and grammar issues in the Grade “A” Pasteurized Milk Ordinance 2015 revision (PMO).

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

Proper spelling, grammar and punctuation helps a document clearly convey the information enclosed within. With the vast quantity of information in the PMO it is doubly important for the spelling, grammar and punctuation to be correct.

C. Proposed Solution

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MAKE THE FOLLOWING CHANGES TO THE 2015 PMO

Strike through text to be deleted and underlined text to be added
SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-line-sampler or aseptic sampler, that…

Page 367:

1. Presumptive Positive: A presumptive positive test is a positive result from…

Page 368:

5. Individual On-Farm Producer/Processor’s Raw Milk Supply: An individual on-farm producer/processor’s raw milk supply may be transported in bulk milk pickup tankers; and/or their raw milk supply may be stored in a farm bulk milk tank(s)/silo(s) on the dairy farm that directly feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system or piped from the a farm bulk milk tank(s)/silo(s) to a raw milk tank(s) and/or silo(s) in the milk plant that

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Telephone No.: 231-357-3541 E-mail Address: Dankertp@michigan.gov
A. Summary of Proposal

This modification to Section VI clarifies that certain milk producer compliance testing shall not result in action against milk offered for sale prior to completion and notification to the milk producer of the test results.

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

Section VI of the PMO establishes testing protocols to determine dairy farm compliance with the PMO. It is not intended to assess the safety of the milk supply. Appendix N testing requirements requires that a milk sample be obtained from every truckload of raw milk arriving at a dairy plant. The sample must be tested for the presence of at least four of six specific Beta-lactam drugs. Positive test results lead to the mandatory testing of raw milk samples from each farm which supplied raw milk for that truckload.

The FDA’s Questions and Answers: 2012 Milk Drug Residue Sampling Survey provides the following statement in regards to positive drug residue samples from individual dairy farms: “Because milk from many different dairy farms is pooled together during processing, the levels of drug residues that might be present in the milk from an individual dairy producer are unlikely to result in residue levels in the pooled milk that would pose a health threat to the consumer.”
SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

Page 30:

5. Drug Testing: Beta lactam test methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current target testing or tolerance levels, shall be used for each Beta lactam drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam test methods available. (Refer to M-a-85, latest revision, for the approved Beta lactam test methods and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved Beta lactam test methods available.) Enforcement action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N. of this Ordinance.) The commingled milk of the producer of the confirmed positive shall be presumed not violative unless such commingled milk is screened and confirmed positive for the same drug residue or any other drug residue as part of the receiving plant’s compliance with Appendix N and/or the Appendix N pilot program. A result shall be considered confirmed positive for Beta lactams if it has been obtained by using a test method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV. of Appendix N. of this Ordinance.

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Telephone No.: 816-801-6366 E-mail Address: callen@dfamilk.com
## A. Summary of Proposal

To revise the PMO (2015 Revision) Section 6 to include the BactoCount IBC (BCC) and the BactoCount IBCm (BCMC) as alternate methods to enumerate bacteria in raw milk.

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

The BactoCount IBC and the BactoCount IBCm can produce bacterial counts with an accuracy, repeatability and reproducibility that is equal to or greater than traditional agar based methods and at the same time eliminate the need for serial dilutions, cut the time-to-result from 48 hours to 10 minutes, and minimize the effect of human error.
C. Proposed Solution

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p.30

2. Alternate methods, for bacterial counts at 32°C (Plate Loop Count (PLC), Spiral Plate Count (SPLC), BactoScan FC (BSC), BactoCount IBC/IBCm (BCC/BCMC), TEMPO AC-Aerobic Count (TAC), and Peel Plate AC-Aerobic Count (PPAC) methods). (Refer to M-a-98, latest revision, for the specific milk and/or milk products for which these tests are approved.)

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E-mail Address: dterrell@bentleyinstruments.com
**A. Summary of Proposal**

This Proposal will update the definitions of “Bulk Milk Hauler/Sampler”, “Dairy Plant Sampler” and “Industry Plant Sampler” within Section I-Definitions of the PMO to be more up-to-date with the sampling activities that these samplers are allowed to conduct within the PMO. It will also provide consistency in wording of the three (3) definitions. Corresponding corrections have also been incorporated into Appendix B-Milk Sampling, Hauling, and Transportation of the PMO, including to the “Universal Sampling System”.

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

By adding the proposed new wording in the definitions it will bring the definitions more up-to-date with the sampling activities that these samplers are allowed to conduct within the PMO and will also provide consistency in wording of the three (3) definitions. The proposed new wording to Appendix B. of the PMO is warranted to be in alignment with the new definitions.
### C. Proposed Solution

Changes to be made on page(s): 2, 3, 6, 26, 139 and 141 of the (X - one of the following):

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

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### SECTION 1-DEFINITIONS ... 

**Page 2:**

**E. BULK MILK HAULER/SAMPER:** A bulk milk hauler/sampler is any person who collects responsible for the collection of official “Universal” samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this Ordinance, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or raw milk products. This person is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

**Page 3:**

**O. 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 of the Regulatory Agency and is evaluated at least once every two (2) year twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Dairy plant samplers that are also Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSOs) are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

**Page 6:**

**V. INDUSTRY PLANT SAMPLER:** A person responsible for the collection of official “Universal” samples that are related to samples collected from direct loaded milk tank trucks, if acceptable to the Regulatory Agency; and/or the collection of Appendix N samples for
regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section 6. and/or Appendix N. of this Ordinance. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

SEC. 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative official “Universal” sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-line-sampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk milk tank and/or silo, 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.

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of a representative official “Universal” sample related to samples collected from direct loaded milk tank trucks either at the dairy farm or receiving milk plant, receiving station or transfer station, if acceptable to the Regulatory Agency.

APPENDIX B. MILK SAMPLING, HAULING, AND TRANSPORTATION

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 employees of the Regulatory Agency and are evaluated at least once each two (2) year every twenty-four (24) month period by a SSO or a properly delegated Sampling Surveillance Regulatory Official (dSSO). These individuals are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of SMEDP. (Refer to Appendix M. of this Ordinance.) Dairy plant samplers that are also SSOs or dSSOs are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

NOTE: For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.
The bulk milk hauler/sampler is any a person who collects responsible for the collection of official “Universal” samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this Ordinance, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or milk products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk receiver, the operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies. Section 3. of this Ordinance requires that Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once each two (2) year every twenty-four (24) month period by a SSO or dSSO using FORM FDA 2399a - BULK MILK HAULER/SAMPLER REPORT. (Refer to Appendix M. of this Ordinance.)

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official “Universal” samples that are related to samples collected from direct loaded milk tank trucks, if acceptable to the Regulatory Agency; and/or the collection of Appendix N. samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Section 6. and/or Appendix N. of this Ordinance. These industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once each two (2) year every twenty-four (24) month period by a SSO or dSSO. These industry plant samplers are evaluated using FORM FDA 2399 - MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of SMEDP when collecting Appendix N. samples and FORM FDA 2399a when collecting official “Universal” samples from direct loaded milk tank trucks at a milk plant, receiving station or transfer station. (Refer to Appendix M. of this Ordinance.) …

NOTE: For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.

Page 141:

5. Universal Sampling System: When bulk milk hauler/samplers collect raw milk samples, the “universal sampling system” shall be employed, whereby samples are collected every time milk is picked up at the dairy farm. This “universal sampling system” shall also be employed whenever industry plant samplers are authorized by the Regulatory Agency to collect samples from direct loaded milk tank trucks at a milk plant, receiving station or transfer station. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler and/or industry plant sampler, respectively. The use of the “universal sample” puts more validity and faith in samples collected by industry personnel. The following are sampling procedures: …. 
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</tr>
<tr>
<td>Address</td>
<td>5001 Campus Drive</td>
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<td>E-mail Address</td>
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36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 208
Committee: Hauling

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A. Summary of Proposal

This proposal seeks to add the requirement that industry plant samplers must be evaluated by the regulatory agency prior to collection of official samples into Appendix B of the Grade “A” Pasteurized Milk Ordinance 2015 revision (PMO).

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

2015 PMO, Appendix B clearly states that both bulk milk hauler/samplers and industry plant samplers are required to be trained and evaluated and states that the bulk milk hauler/sampler must hold a valid permit prior to the collection of official samples. There is no mention that the industry plant sampler must be evaluated prior to collection of official samples. This may lead to uncertainty of whether the industry plant sampler may collect official samples prior to being evaluated by the regulatory agency.

C. Proposed Solution

Changes to be made on page(s): 139 of the (X - one of the following):

X 2015 PMO
2015 EML
2015 MMSR
2400 Forms
2015 Procedures
2015 Constitution and Bylaws
MAKE THE FOLLOWING CHANGES TO THE 2015 PMO

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

Page 139

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Appendix N. of this Ordinance. These industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once each two (2) year period by a SSO or a dSSO. These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of SMEDP-(Refer to Appendix M. of this Ordinance.) prior to the collection of official samples.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Paula Dankert, State Laboratory Evaluation Officer</th>
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<tr>
<td>Agency/Organization:</td>
<td>Michigan Department of Agriculture &amp; Rural Development</td>
</tr>
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A. Summary of Proposal

Appendix B of the 2015 PMO prescribes specific FDA forms that are required to be used when inspecting milk tank trucks, bulk milk haulers/samplers and industry plant samplers. This restricts all member states and international participants from developing forms that are more conducive to their work flow or regional law requirements. This proposal would allow members to develop equivalent forms for use in their programs.

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

Each NCIMS member state and international member/partner are currently required to use the FORM FDA 2399, FORM FDA 2399a and/or FORM FDA 2399b to complete inspections of milk tank trucks, bulk milk hauler/samplers and industry plant samplers according to Appendix B of the 2015 PMO. This restriction prevents member organizations from creating forms that work best within their inspection framework while still satisfying the PMO requirements. This restriction impedes LEAN process initiatives and reduces the efficiency of some organizations. Allowing the creation of equivalent forms does not pose a public health hazard and can increase the productivity and efficiency of member organizations.
C. Proposed Solution

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Pg 139: The dairy plant sampler … These individuals are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of SMEDP, or an equivalent form. (Refer to Appendix M. of this Ordinance.)

Pg 139: These individuals are evaluated at least once each two (2) year period using FORM FDA 2399a-BULK MILK HAULER/SAMPLER REPORT, or an equivalent form. (Refer to Appendix M. of this Ordinance.)

Pg 139: These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of SMEDP, or an equivalent form. (Refer to Appendix M. of this Ordinance.)

Pg 145: Milk tank trucks shall be evaluated every twenty-four (24) months plus the remaining days of the month in which the inspection is due using the requirements established in Section 3. And 5. Of this Ordinance using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT, or an equivalent form. (Refer to Appendix M. of this Ordinance.)

Pg 146: All Items of FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT fall into the categories of “Compliance”, “Non-Compliance” or “Not Applicable” (NA) as determined during the inspection. The following Items relate to FORM FDA 2399b: Any equivalent form must also cover all of these items. (Refer to Appendix M. of this Ordinance.)

Pg 146: Items a. through l. on FORM FDA 2399b or an equivalent form shall be evaluated according to the following criteria:

Pg 147: Defects and damage that would adversely affect products contained in the milk tank truck are pointed out on FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT or an equivalent form and corrective actions are prescribed.
Name: Shawn Lee, State Laboratory Evaluation Officer
Agency/Organization: Michigan Department of Agriculture & Rural Development
Address: 525 W. Allegan Street
City/State/Zip: Lansing, MI 48909
Telephone No.: 231-349-6906  E-mail Address: Lees8@michigan.gov
A. Summary of Proposal

This proposal corrects wording that is confusing concerning the training required for industry plant samplers in Appendix B of the Grade “A” Pasteurized Milk Ordinance 2015 revision (PMO).

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

Confusion in implementation of the training requirement may occur when within Section I-TRAINING of Appendix B, it states that the industry plant samplers shall be trained and then near the end of the same section it states that appropriate training should be provided.

C. Proposed Solution

Changes to be made on page(s): 140 of the (X - one of the following):

X  2015 PMO
_____ 2015 EML
_____ 2015 MMSR
_____ 2400 Forms
_____ 2015 Procedures
_____ 2015 Constitution and Bylaws
MAKE THE FOLLOWING CHANGES TO THE 2015 PMO

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

Page 140

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

Regularly scheduled refresher short courses by the regulatory agents and officials administering weights and measures would assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler. Appropriate training Regularly scheduled refresher short courses should also be provided to industry plant samplers, with regularly scheduled refresher short courses.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Paula Dankert, State Laboratory Evaluation Officer</th>
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</thead>
<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Michigan Department of Agriculture &amp; Rural Development</td>
</tr>
<tr>
<td>Address:</td>
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<td>City/State/Zip:</td>
<td>Lansing, MI 48909</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>231-357-3514</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Dankertp@michigan.gov">Dankertp@michigan.gov</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

To require training for all bulk milk haulers/samplers and industry plant samplers at least once every twenty-four (24) months.

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

It is imperative that the dairy industry have available accurate and representative samples from each farm and tanker of milk. Many hauler/samplers and receivers are trained upon starting the job but there is no method or requirement of ongoing training. The industry is best served when those doing the sampling are trained properly upon starting and continue to receive ongoing training.
C. Proposed Solution

<table>
<thead>
<tr>
<th>Changes to be made on page(s):</th>
<th>140</th>
<th>of the (X - one of the following):</th>
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<td>2015 EML</td>
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<tr>
<td>_____ 2015 MMSR</td>
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<td>2400 Forms</td>
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<tr>
<td>_____ 2015 Procedures</td>
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<td>2015 Constitution and Bylaws</td>
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</tbody>
</table>

Page 140:

**TRAINING:** To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, all bulk milk hauler/samplers and industry plant samplers shall be instructed in the importance of proper sampling and in the proper procedures for picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet the requirements can conduct this training.

...

Regularly scheduled refresher short training courses by the regulatory agents, qualified industry personnel, and/or officials administering weights and measures would assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler shall be offered. All permitted bulk milk haulers/samplers shall attend at least one (1) course at least once every twenty-four (24) months. Appropriate training shall also be provided to industry plant samplers with regularly scheduled refresher short training courses at least once every twenty-four (24) months.

Name: NMPF NCIMS Committee

Agency/Organization: National Milk Producers Federation

Address: 2107 Wilson Blvd, Suite 600

City/State/Zip: Arlington, VA 22201

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

This proposal broadens the requirement of using a watch to assure proper agitation time as stated in Appendix B of the Grade “A” Pasteurized Milk Ordinance 2015 revision (PMO).

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

Due to advances in technology and/or preference, timing devices other than a watch, such as a clock, stopwatch or a cell phone app should be allowed to be used by the hauler/sampler to assure proper agitation time of a bulk milk tank.

C. Proposed Solution

Changes to be made on page(s): _______ 141 _______ of the (X - one of the following):

X  2015 PMO  2015 EML
_______ 2015 MMSR  2400 Forms
_______ 2015 Procedures  2015 Constitution and Bylaws
MAKE THE FOLLOWING CHANGES TO THE 2015 PMO

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

Page 141:

2. Equipment Requirements: a. Sample rack and compartment to hold all samples collected.
b. Refrigerant to hold temperature of milk samples between 0°C- 4.5°C (32°F- 40°F).
c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
d. Single use sample containers; properly stored.
e. Calibrated pocket thermometer; certified for accuracy every six (6) months; accuracy ±1°C (2°F).
f. Approved sanitizing agent and sample dipper container.
g. Watch An electronic device for timing milk agitation.

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<th>Paula Dankert, State Laboratory Evaluation Officer</th>
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<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Dankertp@michigan.gov">Dankertp@michigan.gov</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

Change the wording in the Hauler section, Appendix B, from rinsing the dipper to cleaning the dipper to make the language consistent with the requirements for the sampling equipment in the PMO and with the Bulk Milk Hauler/Sampler Evaluation Report (Form 2399a).

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

The PMO and the Bulk Milk Hauler/Sampler Evaluation Report (Form 2399a) both require the sample dipper to be cleaned and sanitized. The requirement in the PMO (p 141, Equipment Requirements, item c) is that the “Sample dipper or other approved aseptic sampling devices...” be “clean and in good repair”. Similarly, the Bulk Milk Hauler/Sampler Evaluation Report (Form 2399a, Bulk Tank Sampling Procedures, item 10a) requires that the sample transfer instrument be “Clean, sanitized or sterilized and of proper construction and repair”.

While both instances note that the sample dipper should be “clean” and Form 2399a also references “sanitized”, this cannot be achieved with the protocol in the PMO which requires the sample dipper be “rinsed free of milk and placed in its carrying container” after a sample is taken.

The changes below seek to align the requirements and clarify the sampling protocols of the PMO and Form 2399a.
C. Proposed Solution

Changes to be made on page(s): 142 of the (X - one of the following):

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

PMO, Appendix B, Section I. Milk Sampling and Hauling Procedures, p 141-142

Page 141:

2. Equipment Requirements:

  ...
  
c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
  ...

5. Universal Sampling System: When bulk milk hauler/samplers collect raw milk samples, the “universal sampling system” shall be employed, whereby samples are collected every time milk is picked up at the farm. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler. The use of the “universal sample” puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:

  ....
  
e. Collect a representative sample or samples from the farm bulk milk tank and/or silo by using a sample dipper or other approved aseptic sampling device. (Refer to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B. of this Ordinance for the specific protocol for the use of approved aseptic sampling devices.) When transferring milk from the sampling equipment, caution should be used to assure that milk is not spilled back into the farm bulk milk tank and/or silo. Do not fill the sampling container more than three-quarters (¾) full. Close the cover on the sample container.

  
f. The sample dipper shall be rinsed free of milk cleaned and placed in its carrying container.

  g. Close the cover or lid of the farm bulk milk tank.
BULK TANK SAMPLING PROCEDURES

10. Sample Transfer Instrument
   a. Clean, sanitized or sterilized and of proper construction and repair

14. Sample Collection – Precautions and Procedures
   w. Rinse Clean then rinse sample dipper in safe tap water, return to storage container, open tank valve, start milk transfer pump

Name: NMPF NCIMS Committee
Agency/Organization: National Milk Producers Federation
Address: 2107 Wilson Blvd, Suite 600
City/State/Zip: Arlington, VA 22201
Telephone No.: 703-243-6111  E-mail Address: bbriczinski@nmpf.org
A. Summary of Proposal

Allow for the use of pulsed light as a method of sanitizing single service containers as required in Section 7 Item 12p.

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

There is desire within industry to utilize additional technologies in addressing this PMO requirement. In this case, it is our goal to add pulsed light as an additional means to meet PMO requirement for sanitizing single service glass containers.

Currently only single service glass containers must be sanitized at the plant of use while Appendix J requires like any other single service container to be manufactured in an sanitary environment, transported under sanitary conditions and sampled and tested in accordance with Appendix J Part C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES

Pulsed Light is an acceptable food additive in 21 CFR 179.41 for the microbial destruction in food. FDA considers food contact packaging material to be food this is based on “case law interpreting the definition makes clear that many substances that meet the definition of food contact substances section 409(h)(6) of the FD&C Act also meet the definition
of food (see, e.g., Natick Paperboard v. Weinberger, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food); U.S. v. Articles of Food 688 Cases of Pottery (Cathy Rose), 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food))” (Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74233)

EPA Guidelines for Food Contact Sanitizers efficacy look for a 5 log10 reduction or a kill of 99.999% of bacteria utilizing Escherichia coli, Staphylococcus aureus or Salmonella sp. dependent upon the sanitize agent. This is consistent with historical requirements found the in the PMO for the evaluation of sanitizing agents.

Food Additive Petition 4M4417 by Foodco Corporation that led to the adoption of 21 CFR 179.41 shows significant log reductions of many vegetative organisms of public health concern.

At the Fluence Treatment of 1 J/cm2 the following log reductions were achieved

<table>
<thead>
<tr>
<th>Organism</th>
<th>Log Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli ATCC 25932</td>
<td>&gt;5 log</td>
</tr>
<tr>
<td>E. coli NFPA 12</td>
<td>&gt;6 log with no recoverable organisms</td>
</tr>
<tr>
<td>Enterococcus faecium ATCC 19434</td>
<td>&gt;7 log</td>
</tr>
<tr>
<td>Staph aureus ATCC 27661</td>
<td>&gt;6 log</td>
</tr>
<tr>
<td>Staph aureus CAMP Test Strain</td>
<td>&gt;5 log</td>
</tr>
<tr>
<td>Klebsiella pneumonia</td>
<td>~6 log</td>
</tr>
<tr>
<td>Listeria innocua ATCC 33090</td>
<td>&gt;5 log</td>
</tr>
<tr>
<td>Salmonella typhimurium</td>
<td>&gt; 5 log</td>
</tr>
<tr>
<td>Salmonella enteriditis KGF Strain</td>
<td>&gt;6 log</td>
</tr>
<tr>
<td>Shigella flexneri ATCC 29903</td>
<td>&gt;7 log with no recoverable organisms</td>
</tr>
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</table>
## C. Proposed Solution

Changes to be made on page(s): 212 of the (X - one of the following):

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

Insert the following language in Appendix F I. METHODS OF SANITIZATION after the description under the heading HOT WATER:

**LIGHT**

Pulsed Light as described in 21 CFR 179.41 is an acceptable method to sanitize single service glass containers provide the following provision are met:

1. The interior surface of Single Service Glass Containers shall be treated to a minimum fluence of 2 J/cm²
2. Daily the pulse light treatment system shall be check by a calibrated sensor to ensure the minimum treatment of each container as stated is sub item 1.

Name: R. Lynn Young

Agency/Organization: Milk Regulatory Consultants, LLC

Address: 56820 Highway A

City/State/Zip: Russellville, MO 65074

Telephone No.: 573-338-1785  E-mail Address: rlynnyoung@cs.com
A. Summary of Proposal

This Proposal clarifies the bacteriological sampling and testing requirements within Appendix G. of the PMO for individual water supplies and Category I water that is used for potable water purposes, which has been reclaimed from milk and milk product and from heat exchangers or compressors in a milk plant as defined in Appendix D. of the PMO. This Proposal attempts to clarify the inspection and corrective action responsibilities, associated with invalidated and unsatisfactory individual water supplies and Category I reclaimed water systems as addressed in Appendix G. In addition this Proposal corrects inconsistencies and lack of uniformity in text within Items 8r, 18r, 7p, 17p, Appendix D. and Appendix J. of the PMO, specifically relating to the terms “semi-annually”, “semiannually”, “each six (6) months”, etc. sampling and testing language.

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

Category I water reclaimed from milk and milk products and from heat exchangers or compressors in a milk plant as defined in Appendix D. of the PMO can be used for all potable purposes including source water for pasteurized equivalent water. This Proposal would align the bacteriological testing requirements for Category I water with those for an individual water supply as cited in Appendix G. of the PMO.

FDA’s Milk Safety Team (MST) has received numerous questions relating to the new E. coli testing requirements for an individual water supply. MST has also been asked who has the responsibility to inspect and correct the water system when test results indicate the water supply is invalidated or unsatisfactory and whether or not this inspection has to be documented. The proposed new wording in Appendix G., Section I., Frequency provides guidance to these questions.
### C. Proposed Solution

Changes to be made on page(s): xii, 48, 60, 69, 87, 118, 184, 186, 187, 222, 223, and 341 of the (X - one of the following):

<table>
<thead>
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<th>X</th>
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<th>xii, 48, 60, 69, 87, 118, 184, 186, 187, 222, 223, and 341</th>
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</tbody>
</table>

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

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

### TABLE OF CONTENTS

*Page xii:*

**APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS**

I. INDIVIDUAL WATER SUPPLIES AND CATEGORY I. WATER THAT IS USED FOR POTABLE WATER PURPOSES, WHICH HAS BEEN RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN A MILK PLANT AS DEFINED IN APPENDIX D. OF THIS **ORDINANCE** – BACTERIOLOGICAL

II. RECLAIMED WATER AND RECIRCULATED COOLING WATER – BACTERIOLOGICAL

III. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST

**STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING**

**ITEM 8r. WATER SUPPLY**

**ADMINISTRATIVE PROCEDURES**

*Page 48:*

7. Samples for bacteriological examination of individual water supplies and reclaimed water from heat exchanger processes or compressors on dairy farms as defined in Appendix D. of this **Ordinance** are taken upon the initial approval of the physical structure or water system, based upon the requirements of this **Ordinance**; when any repair or alteration of the water supply system has been made; and at least once every three (3) years for individual water supplies and at least once every six (6) month period for reclaimed water,
thereafter. Provided, that individual water supplies with buried well casing seals, installed prior to the adoption of this Section, shall be tested at intervals no greater than least once every six (6) months month period apart. Whenever such samples indicate either the presence of E. coli bacteria or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this Section. Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) months month period. Bacteriological examinations shall be conducted in a laboratory acceptable to the Regulatory Agency. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated three (3) year or six (6) month period, respectively, plus the remaining days of the month in which the sample is due. …

ITEM 18r. RAW MILK COOLING …

ADMINISTRATIVE PROCEDURES …

Page 60:

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

STANDARDS FOR GRADE “A” PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING LOW-ACID MILK AND/OR MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGING LOW-ACID MILK AND/OR MILK PRODUCTS …

ITEM 7p. WATER SUPPLY …

ADMINISTRATIVE PROCEDURES8 …

Page 69:

8. Samples for bacteriological testing of individual water supplies and Category I and II, when required, water that has been reclaimed from milk and milk products and from heat exchangers
of compressors in milk plants as defined in Appendix D. of this Ordinance are taken upon the initial approval of the physical structure or water system; each at least once every six (6) months month period thereafter; and when any repair or alteration of the water supply system has been made. Provided, that when water is hauled to the milk plant, such water shall be sampled for bacteriological examination at the point of use and submitted to an official laboratory at least four (4) times in separate months during any consecutive six (6) months month period. Samples shall be taken by the Regulatory Agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

ITEM 15p. PROTECTION FROM CONTAMINATION ...

ADMINISTRATIVE PROCEDURES ...

15p.(B) ...

Page 87:

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

In the case of water that comes in contact with pasteurized milk and/or milk products it shall:
   a. Meet at least the minimum times and temperatures provided for in the definition of Pasteurization in equipment that may not meet Item 16p; or
   b. Meet the requirements found in Appendix H., Section IX. of this Ordinance; or
   c. Have undergone an equivalent process found acceptable by FDA and the Regulatory Agency; or
   d. Have undergone a hazard evaluation and safety assessment of the specific milk plant’s water supply, which may come from an individual water supply, municipal water system or Category I. water that is used for potable water purposes, which has been reclaimed from milk and milk products and from heat exchangers or compressors in the milk plant as defined in Appendix D. of this Ordinance, and application involved and has undergone an additional treatment to destroy or remove bacteria acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product. Supporting information shall be submitted to and approved by the Regulatory Agency. The supporting information may include, but is not limited to the following:
      (1) Statement of proposal;
      (2) Intended use;
      (3) Review of equipment to be used in the process;
      (4) Diagram of the process of interest;
      (5) Documentation that the specific milk plant’s source water supply shall meet or exceed meets or exceeds the EPA Safe Drinking Water Bacteriological Standards. The
Safety Assessment safety assessment shall include a comparison of samples from the facility’s specific milk plant’s water source supply, pasteurized water, and proposed pasteurized equivalent water. Water samples of the pasteurized equivalent water shall be collected daily for two (2) weeks following approval of the initial installation and at least once every six (6) month period thereafter; and (6) Protocol for the continued monitoring of criteria and procedures. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. 

**ITEM 17p. WATER SUPPLY ...**

**ADMINISTRATIVE PROCEDURES ...**

*Page 118:*

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

**APPENDIX D. STANDARDS FOR WATER SOURCES ...**

*Page 184:*

**V. WATER RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN MILK PLANTS**

Water reclaimed from Grade “A” milk and milk products may be reused in a milk plant. Water reclaimed from non-Grade “A” milk and milk products may also be reused in a milk plant provided that the design and operation of the equipment used to reclaim water meets the requirements of this Ordinance. Water utilized for heat exchanger purposes in plate or other type heat exchangers or compressors, except those utilizing gaskets to separate oil and water, in Grade “A” milk plants may be reclaimed for milk plant operations. The three (3) general categories for reclaimed water use are:

**CATEGORY I. USED FOR POTABLE WATER PURPOSES**

Reclaimed water to be used for potable water purposes, including the production of culinary steam, shall meet the following requirements and shall be documented:
1. Water shall comply with the Bacteriological Standards of Appendix G. of this Ordinance, and, in addition, shall not exceed a total plate count of 500 per milliliter (500/mL).
2. Samples shall be collected daily for two (2) weeks following initial approval of the installation and semi-annually at least once every six (6) month period thereafter. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. …

Page 186:

**CATEGORY II. USED FOR LIMITED PURPOSES**

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

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

1. There is no carry-over of water from one (1) day to the next, and any water collected is used promptly; or
   a. The temperature of all water in the storage and distribution system is maintained either at 7°C (45°F) or below, or at 63°C (145°F) or higher by automatic means; or
   b. The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, or UV disinfection that complies with the criteria in Appendix D. of this Ordinance, prior to the water entering the storage tank; or
   c. The water shall comply with the Bacteriological Standards of Appendix G. of this Ordinance and, in addition, shall not exceed a total plate count of 500 per milliliter (500/mL). Samples shall be collected daily for two (2) weeks following initial approval of the installation and semi-annually at least once every six (6) month period thereafter. Provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system. All physical, chemical and microbiological tests shall be conducted in accordance with the latest edition of SMEWW; and that,
2. Distribution lines and hose stations are clearly identified as “limited use reclaimed water”; and ….

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**VI. WATER RECLAIMED FROM HEAT EXCHANGER PROCESSES OR COMPRESSORS ON GRADE “A” DAIRY FARMS**

Potable water utilized for heat exchange purposes in plate or other type heat exchangers or compressors on Grade “A” dairy farms may be salvaged for the milking operation if the following criteria are met: …

6. The water shall comply with the Bacteriological Standards of Appendix G. of this Ordinance.
7. Samples shall be collected and analyzed prior to initial approval and semi-annually at least
once every six (6) month period thereafter.

8. Approved chemicals, such as chlorine, with a suitable retention period, or UV disinfection that complies with the criteria in Appendix D. of this Ordinance may be used to suppress the development of bacterial growth and prevent the development of tastes and odors. …

Page 222:

**APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS**

1. INDIVIDUAL WATER SUPPLIES AND CATEGORY I. WATER THAT IS USED FOR POTABLE WATER PURPOSES, WHICH HAS BEEN RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN A MILK PLANT AS DEFINED IN APPENDIX D. OF THIS ORDINANCE - BACTERIOLOGICAL

**Reference:** Section 7., Items 8r, 7p, and 15p; and Appendix J, Section D., Item 7 of this Ordinance.

**Application:** To individual water supplies, used by dairy farms, milk plants, receiving stations, transfer stations, and milk tank truck cleaning facilities and single-service containers and/or closures fabrication plants; and to Category I water used in milk plants.

**Frequency:** Initially, water shall be tested for the presence of total coliform and if positive for total coliforms the water shall be tested for E. coli initially; after any repair, modification or disinfection of the individual water supplies of dairy farms, milk plants, receiving stations, transfer stations, and milk tank truck cleaning facilities and single-service containers and/or closures fabrication plants; and thereafter, semiannually at least once every six (6) month period for all milk plants’ individual water supplies and Category I water use in milk plants, at least once every twelve (12) month period for single-service containers and/or closures fabrication plants, and at least once every three (3) years on dairy farms thereafter. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month, twelve (12) month, or three (3) year period, respectively, plus the remaining days of the month in which the sample is due.

**Criteria:** The water shall be tested for the presence of total coliform initially and if positive for total coliform the same sample shall be tested for E. coli. A MPN of total 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 (1) of the Chromogenic Substrate 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 (1) vessel containing 100 mL is tested using the MTF technique or one (1) of the Chromogenic Substrate multiple tube procedures. A MPN of E. coli 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 Fluorogenic Substrate multiple tube procedures; a direct count of less than 1 per 100 mL using the MF Fluorogenic Substrate multiple tube technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one (1) vessel containing 100 mL is tested using the Fluorogenic Substrate. Any sample producing a bacteriological result of Too Numerous To Count (TNTC) or Confluent Growth
(CG) by the MF technique; or turbidity in a presumptive test with no gas production and 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 colony forming units (CFU) 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/NCIMS 2400 Forms. (Refer to M-a-98, latest revision.)

**Corrective Action:** When the laboratory report on for the water sample indicates that the sample is positive for total coliform but negative for the presence of E. coli or indicates a HPC of greater than 500 CFU per mL on a sample that had previously been invalidated, the water system in question shall be considered at risk for pathogenic contamination and shall be physically inspected by the facility and necessary corrections made by the facility until subsequent samples are bacteriologically satisfactory. This inspection shall be documented and completed within thirty (30) days of the date of the positive test result. If this initial inspection and corrective action are completed, but the water in question is still testing positive for total coliform but negative for E. coli, the facility Regulatory Agency shall continue to investigate conduct a physical inspection of the water supply in question and the facility shall correct any problems identified until a subsequent samples are sample is bacteriologically satisfactory. When the laboratory report on for the water sample indicates that the sample is positive for both total coliform and E. coli, or the facility has failed to complete the water system inspection within thirty (30) days of the initial positive test result, the water is considered unsatisfactory. The water system in question shall be physically inspected by the Regulatory Agency and necessary corrections made by the facility until a subsequent sample is bacteriologically satisfactory.

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**II. RECLAIMED WATER AND RECIRCULATED COOLING WATER – BACTERIOLOGICAL**

**Reference:** Section 7., Items 8r, 18r, 7p and 17p; and Appendix J, Section D., Item 7 of this Ordinance.

**Application:** To reclaimed water and recirculated cooling water, used in milk plants, receiving stations, transfer stations, single-service containers and/or closures fabrication plants (water baths) and on dairy farms.

**Frequency:** Initially; after any repair, modification or disinfection of the reclaimed water and/or recirculated cooling water supplies of dairy farms, milk plants, receiving stations, and transfer stations and single-service containers and/or closures fabrication plants (water baths); and reclaimed water and recirculated cooling water used in milk plants, receiving stations, transfer stations, single-service containers and/or closures fabrication plants (water baths) and on dairy farms shall be tested semiannually at least once every six (6) month period thereafter. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

**Criteria:** The reclaimed water and recirculated cooling water shall be tested for the presence of total coliform. An MPN of total coliform organisms of less than 1.1 per 100 mL, when
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/NCIMS 2400 Forms. (Refer to M-a-98, latest revision.)

Corrective Action: When the laboratory report on for the reclaimed water or recirculated cooling water sample is indicates that the sample is unsatisfactory, the reclaimed water or recirculated cooling water supply in question shall again be physically inspected by the Regulatory Agency and necessary corrections made by the facility until a subsequent sample is bacteriologically satisfactory. …

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

D. FABRICATION PLANT STANDARDS …

Page 341:

7. WATER SUPPLY …

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each at least once every twelve (12) months thereafter; and when any repair or alteration of the individual water supply system has been made. The examination of the sample shall be conducted in an Officially Designated Laboratory. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated twelve (12) month period plus the remaining days of the month in which the sample is due.

d. Water baths utilizing recirculated water for cooling product-contact surfaces shall comply with the bacteriological standards outlined in Appendix G. of this Ordinance and shall be tested semi-annually at least once every six (6) month period. To determine if water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

e. Records of all required water tests shall be maintained at a location acceptable to the Rating/Regulatory Agency for a period of two (2) years. …
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<th>CAPT Robert F. Hennes</th>
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<tr>
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</tr>
<tr>
<td>Telephone No.:</td>
<td>(240) 402-2175</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Robert.Hennes@fda.hhs.gov">Robert.Hennes@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>
### A. Summary of Proposal

This proposal seeks to obtain approval (addition to M-a-98 latest revision) for the use of the AccuPoint® Advanced Alkaline Phosphatase electronic test for the detection of alkaline phosphatase in pasteurized fluid dairy products (all matrices defined within M-a-98). The test demonstrates the ability to detect alkaline phosphatase at the minimum sensitivity requirement of 350 mU/L (III. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST, page 223 of the 2015 PMO). The AccuPoint Advanced Alkaline Phosphatase test is used to verify proper pasteurization of the HTST process on fluid products and to detect inadvertent contamination with raw milk post-pasteurization.

### REACTION MECHANISM

AccuPoint Advanced Alkaline Phosphatase is a chemiluminescence-based test which enables the user to determine whether a milk sample has been properly pasteurized or is contaminated with raw milk. A sample of milk to be tested is collected using the AccuPoint sampler and exposed to the substrate solution contained within the sampler body. After a brief incubation, the amount of light generated by the interaction of the substrate with alkaline phosphatase naturally present in raw milk is detected by the AccuPoint Advanced reader and reported in mU/L.
B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Additional approved methods for the detection of alkaline phosphatase will provide the dairy industry additional methods to determine adequate pasteurization. Guidance for experiments was obtained from the FDA Laboratory Proficiency and Evaluation Team (LPET) using the document entitled “FDA Center for Veterinary Medicine New Method/Equipment Evaluation Criteria”.

Additional information is available upon request.

C. Proposed Solution

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This proposal seeks to obtain approval (addition to M-a-98 latest revision) for the use of the AccuPoint® Advanced Alkaline Phosphatase electronic test for the detection of alkaline phosphatase in pasteurized fluid dairy products (all matrices defined within M-a-98). The test demonstrates the ability to detect alkaline phosphatase at the minimum sensitivity requirement of 350 mU/L (III. PASTEURIZATION EFFICIENCY – FIELD PHOSPHATASE TEST, page 223 of the 2015 PMO). The AccuPoint Advanced Alkaline Phosphatase test is used to verify proper pasteurization of the HTST process on fluid products and to detect inadvertent contamination with raw milk post-pasteurization.

Page 223:

III. PASTEURIZATION EFFICIENCY - FIELD PHOSPHATASE TEST

Reference: Section 6. of this Ordinance.

Frequency: When any laboratory phosphatase test is positive, or any doubt arises as to the adequacy of pasteurization due to noncompliance with equipment, or requirements of Item 16p.

Criteria: Less than 350 mU/L by an electronic phosphatase procedure.

Apparatus: Fluorophos (Advanced Instruments), Paslite and Fast Alkaline Phosphatase (Charm Sciences, Inc.), AccuPoint Advanced Alkaline Phosphatase (Neogen Corporation), approved/validated standards and accessories.
<table>
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<tr>
<th>Name</th>
<th>Melissa Herbert, VP Regulatory Affairs / Nate Banner, Product Manager</th>
</tr>
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<tr>
<td>Agency/Organization</td>
<td>Neogen Corporation</td>
</tr>
<tr>
<td>Address</td>
<td>620 Lesher Place</td>
</tr>
<tr>
<td>City/State/Zip</td>
<td>Lansing, MI 48912</td>
</tr>
<tr>
<td>Telephone No.</td>
<td>(517) 372-9200</td>
</tr>
<tr>
<td>E-mail Address</td>
<td><a href="mailto:mherbert@neogen.com">mherbert@neogen.com</a>, <a href="mailto:nbanner@neogen.com">nbanner@neogen.com</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

Appendix N section VI, pertaining to testing for non-beta-lactam antibiotics with test methods that have not been evaluated by FDA and accepted by the NCIMS, is moved into a new appendix (Appendix T). This clearly delineates testing that is required by Appendix N (currently Beta-lactams) from voluntary testing that is performed for business-to-business purposes (e.g., customer specifications, export requirements) using test methods that have not been evaluated by FDA and accepted by the NCIMS.

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

This proposal separates testing that is mandated by the Grade “A” PMO (currently the Beta-lactams) from testing that is beyond the scope of Appendix N. This voluntary testing for business-to-business purposes (e.g., customer specifications, export requirements) is performed using test methods that have not been evaluated by FDA and accepted by the NCIMS.

This proposal does not change current drug residue testing requirements and responsibilities of the Beta-lactam program.
## C. Proposed Solution

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**Page 362:**

**APPENDIX N. BETA LACTAM DRUG RESIDUE TESTING AND FARM SURVEILLANCE**

**I. INDUSTRY RESPONSIBILITIES**

...

**Page 376:**

**APPENDIX T. NON-BETA LACTAM DRUG RESIDUE TESTING AND FARM SURVEILLANCE**

**IV. I. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS**

Provided, that until at least two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer’s data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.

**UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):**

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier,
and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

1. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both of these duplicate retests give a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test method from M-a-85, latest revision, and M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker’s confirmation. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker’s Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this Appendix N shall occur.

2. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. The initial positive M-a-85 and M-I-92-11 test is found to be a presumptive positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be conducted in an Official Laboratory, Officially Designated Laboratory
or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all prior
testing shall be provided to the analyst performing the load and/or raw milk supply that has not
been transported in bulk milk pickup tanker’s confirmation. The presumptive positive load
and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-
sampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest
revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-)
controls. If either or both of the duplicate samples are positive and the positive (+) and
negative (-) controls give the proper results, the sample is deemed a Screening Test Positive
(Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker’s
Confirmation). A written copy of the test results shall be provided to the Regulatory Agency.
The milk, which that sample represents, is no longer available for sale or processing into
human food. Producer trace back, reporting, and enforcement as defined in this Appendix N
shall occur.

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UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY
FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND
DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK
SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP
TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY
FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS
NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening
and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been
transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the
documented permission of the Regulatory Agency(ies). In advance of using such a test
method, a prior documented agreement shall be obtained among the user of the test method,
the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be
used to verify the presence of a non-Beta lactam drug residue.

If the initial test result from a drug test method that has not been evaluated by FDA and
accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a
facility identified in the prior documented agreement using the same drug test method. The
initial positive test is found to be a verified screening positive by promptly repeating in
duplicate with positive (+) and negative (-) controls that give the proper results, using the same
test, on the same sample, with one (1) or both of these duplicate retests giving a positive result.
The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate
Regulatory Agency may take control of the verified screening positive load and/or raw milk
supply that has not been transported in bulk milk pickup tankers. A written copy of the verified
screening positive test results shall follow the initial Regulatory Agency notification. The
verified screening positive load and/or raw milk supply that has not been transported in bulk
milk pickup tankers shall be disposed of to remove it from the human or animal food chain.
Producer trace back shall be conducted by industry using the same drug test method at the
direction of the Regulatory Agency as cited in the prior documented agreement. If the initial
producer test result from the drug test method is found to be positive, the sample shall
promptly be retested in a facility identified in the prior documented agreement using the same
drug test method. The initial positive test is found to be a verified producer screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups and/or use of the violative individual producer’s milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is verified screening positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant’s raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive for drug residues using an approved test method or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Name:  NMPF NCIMS Committee
Agency/Organization: National Milk Producers Federation
Address: 2107 Wilson Blvd, Suite 600
City/State/Zip: Arlington, VA 22201
Telephone No.: 703-243-6111  E-mail Address: bbriczinski@nmpf.org
A. Summary of Proposal

This proposal clarifies that industry participation in an Appendix N Pilot Program is not mandatory.

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

This proposal offers clarity around the question of whether or not a pilot program to expand testing for drug residues is mandatory for industry.
C. Proposed Solution

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Page 362:

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be tested for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. of this Ordinance. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling and testing program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling and testing program shall be analyzed as specified by FDA. (Refer to Section 6. of this Ordinance.) Testing for drug residues may also occur as part of a drug residue pilot program. Industry participation through sampling and testing in drug residue pilot programs is not mandatory. The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Bulk milk pickup tanker samples confirmed positive for drug residues using approved test methods and/or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained as determined necessary by the Regulatory Agency.

Note: This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA’s concurrence with the NCIMS Executive Board.
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<td>Address:</td>
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<td>Arlington, VA  22201</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>703-243-6111</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:bbriczinski@nmpf.org">bbriczinski@nmpf.org</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

This proposal seeks to obtain approval (addition to m-a-85 latest revision) for BetaStar® Advanced for Beta-lactams for the use of detecting beta-lactam drug residues in raw, commingled bovine milk. The test demonstrates the ability to detect all six recognized beta-lactam drug residues at the minimum sensitivity requirement and the 50% detection level of the tolerance level rule in section “V. APPROVED TEST METHODS”, on page 376 of the 2015 PMO.

REACTION MECHANISM
BetaStar® Advanced for Beta-lactams is a single step lateral flow immunochromatographic assay based on a competitive immunoassay format. Milk is wicked through a reagent zone, which contains antibodies and receptors conjugated to colloidal gold particles. If beta-lactams or desfuroylceftiofur are present, they will be captured by their particle-antibody complex. The drug-antibody-particle complex then is wicked onto a membrane. The membrane contains two separate and independent test lines, with one consisting of a drug conjugated to a protein carrier designed to capture the beta-lactams and the other test line consisting of a drug-protein conjugate designed to capture desfuroylceftiofur. These independent test lines capture any antibody gold particle complex or receptor gold particle complexes (in absence of antibiotics) to concentrate and form a visible line. As the level of a particular drug in the sample increases, free drug molecules will complex with the antibody gold particles or receptor gold particles. This allows less antibody-gold or receptor gold to be captured into the test lines. Therefore, as the concentration of a drug in the sample increases, the test line density decreases. The membrane also contains a control line where an immune complex present in the reagent zone is captured by an antibody, forming a visible line. The control line will always form regardless of the presence of the drug, ensuring the strip is functioning properly. The intensity of each test line and control line is analyzed by a reader providing a calculated ratio of the test line compared to the control line. The ratio between the intensity of the test line compared to the control line will determine a positive or negative result.
B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission

Neogen Corporation is actively involved with NCIMS and seeks to gain approval of an easier
to use next generation technology which will provide the dairy industry another approved
testing option. BetaStar Advanced for Beta-lactams detects all six Beta-lactams identified by
FDA for their use in treating disease in lactating dairy cattle and are the most likely to cause a
residue in milk if misused. This new BetaStar Advanced for Beta-lactams test will replace the
currently approved BetaStar Plus test.

Additional information is available upon request.

C. Proposed Solution

Changes to be made on page(s): 376* of the (X - one of the following):

X 2017 PMO
2011 EML
2017 MMSR
2400 Forms
2017 Procedures
2013 Constitution and Bylaws

This proposal seeks to obtain approval (addition to m-a-85 latest revision) for BetaStar®
Advanced for Beta-lactams for the use of detecting beta-lactam drug residues in raw,
commingled bovine milk. The test demonstrates the ability to detect all six recognized beta-
lactam drug residues at the minimum sensitivity requirement and the 50% detection level of
the tolerance level rule in section “V. APPROVED TEST METHODS”, on page 376 of the
2015 PMO.

*Criteria for method approval referenced on page 376 of the 2015 PMO, no amendments to
PMO are being requested in this proposal.

Name: Melissa Herbert, VP Regulatory Affairs / Nate Banner, Product Manager
Agency/Organization: Neogen Corporation
Address: 620 Lesher Place
City/State/Zip: Lansing, MI 48912
Telephone No.: (517) 372-9200 E-mail Address: mherbert@neogen.com, nbanner@neogen.com
A. Summary of Proposal

This proposal seeks to obtain approval (addition to m-a-85 latest revision) for the use of the BetaStar® Advanced for Tetracyclines test to detect tetracycline drug residues in raw, commingled bovine milk. The test demonstrates the ability to detect tetracycline drug residues at the tolerance levels, and as stated in section “V. APPROVED TEST METHODS”, on page 376 of the 2015 PMO, sensitivity levels are greater than 150ppb for Chlortetracycline, 119ppb for Oxytetracycline, and 67ppb for Tetracycline.

REACTION MECHANISM
BetaStar® Advanced for Tetracyclines is a single step lateral flow immunochromatographic assay based on a competitive immunoassay format. Milk is wicked through a reagent zone, which contains antibodies conjugated to colloidal gold particles. If tetracycline, chlortetracycline or oxytetracycline is present, they will be captured by their particle-antibody complex. The drug-antibody-particle complex then is wicked onto a membrane. The membrane contains one test line, consisting of a drug conjugated to a protein carrier designed to capture the tetracyclines. This test line captures any antibody gold particle complexes (in absence of antibiotics) to concentrate and form a visible line. As the level of a particular drug in the sample increases, free drug molecules will complex with the antibody gold particles. This allows less antibody-gold to be captured into the test lines. Therefore, as the concentration of a drug in the sample increases, the test line density decreases. The membrane also contains a control line where an immune complex present in the reagent zone is captured by an antibody, forming a visible line. The control line will always form regardless of the presence of the drug, ensuring the strip is functioning properly. The intensity of the test line and control line is analyzed by a reader providing a calculated ratio of the test line compared to the control line. The ratio between the intensity of the test line compared to the control line will determine a positive or negative result.
B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The Charm® II radio receptor assay under M-a-85 is presently the only approved confirmatory method for Tetracyclines in milk. BetaStar® Advanced for Tetracyclines provides the dairy industry a lateral flow format that can be used by more industry and regulatory stakeholders for screening and confirmation.

Additional information is available upon request.

C. Proposed Solution

Changes to be made on page(s): 376* of the (X - one of the following):

- X 2017 PMO
- 2011 EML
- 2017 MMSR
- 2017 Procedures
- 2400 Forms
- 2013 Constitution and Bylaws

This proposal seeks to obtain approval (addition to m-a-85 latest revision) for the use of the BetaStar® Advanced for Tetracyclines test to detect tetracycline drug residues in raw, commingled bovine milk. The test demonstrates the ability to detect tetracycline drug residues at the tolerance levels, and as stated in section “V. APPROVED TEST METHODS”, on page 376 of the 2015 PMO, sensitivity levels are greater than 150ppb for Chlortetracycline, 119ppb for Oxytetracycline, and 67ppb for Tetracycline.

*Criteria for method approval referenced on page 376 of the 2015 PMO, no amendments to PMO are being requested in this proposal.

Name: Melissa Herbert, VP Regulatory Affairs / Nate Banner, Product Manager
Agency/Organization: Neogen Corporation
Address: 620 Lesher Place
City/State/Zip: Lansing, MI 48912
Telephone No.: (517) 372-9200
E-mail Address: mherbert@neogen.com, nbanner@neogen.com
A. Summary of Proposal

To provide both the Regulatory Agencies and the dairy industry better defined guidance on proper testing protocols and handling of positive drug residue test results, this proposal revises specific non-beta lactam drug residue testing to adhere to well-understood standards of the beta lactam testing program.

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

This proposal seeks to provide both industry and regulatory better defined guidance on proper testing protocols and handling of positive drug residue test results.

Several proposals were submitted during the 2015 NCIMS conference related to drug residue testing outside of, and in addition to, the beta-lactam required testing. The outcome of these proposals created confusing protocols and expectations for both Regulatory Agencies and the dairy industry in the proper methods for testing non-beta-lactam drug residues and the appropriate response to test results.

This proposal revises specific non-beta lactam drug residue testing to adhere to the well-understood standards of the beta-lactam testing program.
C. Proposed Solution

Changes to be made on page(s): 14, 362, 367, 375-378 of the (X - one of the following):

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not
been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam, Tetracycline, and Sulfonamide drug residues (herein referred to as “Required Testing Drugs”). Additionally, other drug residues shall be tested for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. of this Ordinance…

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III. REQUIRED TESTING PROGRAM FOR DRUG RESIDUES

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V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use test methods from M-a-85, latest revision, for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactam Required Testing Drug residues, following the testing procedures specified in Section III. of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. of this Ordinance. Enforcement action based on each test method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6. of this Ordinance.

One (1) year after two (2) or more drug test methods have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug Required Testing Drug or drug family of a non-Required Testing Drug, other unevaluated drug test methods for that particular non-Beta lactam drug Required Testing Drug or drug family of a non-Required Testing Drug are not acceptable for determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug test methods by FDA and the NCIMS for drugs other than Beta lactam Required Testing Drug does not mandate any additional screening by industry or Regulatory Agencies with the evaluated drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N. and other drug testing:
1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

VI. TEST METHODS FOR NON-BETA LACTAMS

REQUIRED TESTING DRUGS

RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND
ACCEPTED BY THE NCIMS

Provided, that until at least two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta-lactams Required Testing Drugs, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactams Required Testing Drug screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer’s data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERминING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactams Required Testing Drug drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactams Required Testing Drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

1. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both
UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactams. Required Testing Drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam Drug residue.

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</tr>
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<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Dairy Farmers of America</td>
</tr>
<tr>
<td>Address:</td>
<td>10220 N. Ambassador Drive</td>
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<tr>
<td>City/State/Zip:</td>
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Proposal #: 222
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A. Summary of Proposal

To provide both the Regulatory Agencies and the dairy industry better defined guidance on proper testing protocols and handling of positive drug residue test results, this proposal revises language related to specific non-beta lactam drug residue testing to adhere to well-understood standards of the beta lactam testing program.

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

This proposal seeks to provide both industry and regulatory better defined guidance on proper testing protocols and handling of positive drug residue test results.

Several proposals were submitted during the 2015 NCIMS conference related to drug residue testing outside of, and in addition to, the beta-lactam required testing. The outcome of these proposals created confusing protocols and expectations for both Regulatory Agencies and the dairy industry in the proper methods for testing non-beta-lactam drug residues and the appropriate response to test results.

This proposal revises specific non-beta lactam drug residue testing to adhere to the well-understood standards of the beta-lactam testing program.
C. Proposed Solution

Changes to be made on page(s): 14, 362, 367, 375-378 of the (X - one of the following):

X  2015 PMO  2015 EML

2015 MMSR  2400 Forms

2015 Procedures  2015 Constitution and Bylaws

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not
been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam and Tetracycline drug residues (herein referred to as “Required Testing Drugs”). Additionally, other drug residues shall be tested for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. of this Ordinance…

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III. REQUIRED TESTING PROGRAM FOR DRUG RESIDUES

ESTABLISHED DEFINITIONS:

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V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use test methods from M-a-85, latest revision, for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk tankers for Beta lactam Required Testing Drug residues, following the testing procedures specified in Section III. of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. of this Ordinance. Enforcement action based on each test method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6. of this Ordinance.

One (1) year after two (2) or more drug test methods have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam Required Testing Drug or drug family of a non-Required Testing Drug, other unevaluated drug test methods for that particular non-Beta lactam Required Testing Drug or drug family of a non-Required Testing Drug are not acceptable for determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug test methods by FDA and the NCIMS for drugs other than Beta lactam Required Testing Drug does not mandate any additional screening by industry or Regulatory Agencies with the evaluated drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N. and other drug testing:
1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

VI. TEST METHODS FOR NON-BETA LACTAMS REQUIRED TESTING DRUGS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

Provided, that until at least two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta-lactams Required Testing Drugs, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta-lactams Required Testing Drug screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer’s data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta-lactams Required Testing Drug drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta-lactams Required Testing Drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

1. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both
UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-β-lactams. Required Testing Drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-β-lactams Required Testing Drug residue.

Name: Chris Allen
Agency/Organization: Dairy Farmers of America
Address: 10220 N. Ambassador Drive
City/State/Zip: Kansas City, MO 64153
Telephone No.: 816-801-6366  E-mail Address: callen@dfamilk.com
A. Summary of Proposal

To provide both the Regulatory Agencies and the dairy industry better defined guidance on actions following positive drug residue test results, this proposal clarifies the use of “future farm pickups”, “further farm pickups” and “future pickups”.

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

Several proposals were submitted during the 2015 NCIMS conference related to drug residue testing outside of and in addition to the beta-lactam required testing. The outcome of these proposals created confusing protocols and expectations for both Regulatory Agencies and the dairy industry in the appropriate response to drug residue test results.

FDA’s 2015 Multi-Criteria Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products resulted in a change in the screening strategy from requiring 100% screening of tankers for only beta lactams to a statistical-selection screening program that proposes eventually including several non-beta lactam drug families. The statistical-selection screening strategy only requires screening for a statistical-selected number of tankers (e.g. 1 in 15 for tetracycline). The 2015 NCIMS created the Appendix-N Pilot Program to establish protocols to statistically-select tankers to be screened for non-beta lactams. Tetracycline is the first non-beta lactam drug chosen to be included in this pilot program.

Because of the distance milk travels and due to the size of many producers, a situation can
easily occur as follows: at the time of notification to the violative producer and regulatory agency, enough time may have passed since the farm pickup (that resulted in a violative producer action) that the violative producer may have already had additional farm shipments that are in-transit to a plant and/or may have additional farm shipments that have already been received at a plant. Not requiring 100% screening for tetracycline (or other non-beta lactam drug families in the future) will create uncertainty for milk handlers and plant managers in how to manage these in-transit or previously received tankers. To eliminate this uncertainty, the following language needs to be added to the PMO.

### C. Proposed Solution

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**Note:** This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA’s concurrence with the NCIMS Executive Board.

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**APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE**

**I. INDUSTRY RESPONSIBILITIES**

*Page 363:*

**REPORTING AND FARM TRACE BACK:**

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues
using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant’s raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Upon official notification to the Regulatory Agency and milk producer of a violative individual producer’s milk, further farm pickups (future farm pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer’s milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues. Milk from the violative producer that is in-transit and/or previously received at a plant prior to official notification to the Regulatory Agency and milk producer of the confirmed positive shall be presumed not violative unless such milk is screened and confirmed positive for the same drug residue or any other drug residue as part of the receiving plant’s compliance with Appendix N and/or the Appendix N pilot program.

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**Permit Suspension and the Prevention of the Sale of Milk:** Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer’s Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups (future farm pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer’s milk are prohibited until subsequent testing reveals the milk is free of drug residue. Milk from the violative producer that is in-transit and/or previously received at a plant prior to official notification to the Regulatory Agency and milk producer of the confirmed positive shall be presumed not violative unless such milk is screened and confirmed positive for the same drug residue or any other drug residue as part of the receiving plant’s compliance with Appendix N and/or the Appendix N pilot program.

Page 378:

**UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY**
FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers…

… The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups (future pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) and/or use of the violative individual producer’s milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Milk from the violative producer that is in-transit and/or previously received at a plant prior to official notification to the Regulatory Agency and milk producer of the confirmed positive shall be presumed not violative unless such milk is screened and confirmed positive for the same drug residue or any other drug residue as part of the receiving plant’s compliance with Appendix N and/or the Appendix N pilot program. Whenever a drug residue test is verified screening positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

Name: Chris Allen

Agency/Organization: Dairy Farmers of America

Address: 10220 N. Ambassador Drive

City/State/Zip: Kansas City, MO 64153

Telephone No.: 816-801-6366 E-mail Address: callen@dfamilk.com
A. Summary of Proposal

Clarify language in Appendix N section VI pertaining to unapproved test sensitivity requirement.

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

Section VI of Appendix N includes requirements for unapproved drug residue testing (for non-Beta lactams). One such requirement is that the test method manufacturer’s data indicate that testing sensitivity is at or below US target testing or tolerance levels.

Some drugs have zero tolerance levels and do not have an established target testing level. This proposal clarifies that test kits may still be used to test for these drugs, as it is not possible for a commercially available test method to have a detection limit less than zero.
C. Proposed Solution

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VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

Provided, that until at least two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer’s data indicates that testing sensitivity is at or below U.S. target testing or non-zero tolerance levels, when available.

Name: Appendix N Modification Committee
Agency/Organization: Appendix N Modification Committee
Address: 2711 North Haskell Avenue
City/State/Zip: Dallas, Texas 75204
Telephone No.: (214) 721-1101 E-mail Address: Roger_Hooi@DeanFoods.Com
A. Summary of Proposal

Clarify language related to the documented agreement when using non-Beta lactam test kits that have not been evaluated by FDA and accepted by the NCIMS.

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

Clarify language related to the documented agreement when using non-Beta lactam test kits that have not been evaluated by FDA and accepted by the NCIMS. This proposal better reflects the intent of the three-way agreement as proposed by the NCIMS Appendix N Modification Committee.
### C. Proposed Solution

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**Page 376**

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

...

**UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):**

...

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation. Whenever the facility and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed.

....

**Page 378:**
UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

...

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue. Whenever the facility and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed.

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<td>NCIMS Appendix N Modification Committee</td>
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</tr>
<tr>
<td>City/State/Zip:</td>
<td>Dallas, Texas 75204</td>
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<tr>
<td>Telephone No.:</td>
<td>(214) 721-1101</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:roger_hooi@deanfoods.com">roger_hooi@deanfoods.com</a></td>
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36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 226
Committee: Appendix N

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A. Summary of Proposal

Correct conflicting language in Appendix N section VI pertaining to testing for non-Beta lactam drug residues.

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

Clarify options for verifying initial screening test positive results using methods that have not been evaluated by FDA or accepted by NCIMS. This proposal addresses conflicting language in Appendix N section VI pertaining to testing for non-Beta lactam drug residues.
C. Proposed Solution

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V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use test methods from M-a-85, latest revision, for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactams residues, following the testing procedures specified in Section III. of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. of this Ordinance. Enforcement action based on each test method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6. of this Ordinance.

One (1) year after two (2) or more drug test methods have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated drug test methods for that particular non-Beta lactam drug or drug family are not acceptable for determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug test methods by FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or Regulatory Agencies with the evaluated drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N. and other drug testing:

1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

Page 376:

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT
HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

Provided, that until at least two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer’s data indicates that testing sensitivity is at or below U.S. target testing or tolerance levels.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies), provided that the test method manufacturer’s data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels. In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, one (1) of the following two (2) options (1 or 2) shall be used for confirmation:

Option 1:

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both of these duplicate retests give a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test method from M-a-85, latest revision, and M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a
location acceptable to the Regulatory Agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker’s confirmation. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be resampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker’s Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

Option 2:

2. If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. The initial positive M-a-85 and M-I-92-11 test is found to be a presumptive positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker’s confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be resampled, at the direction of the Regulatory Agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker’s Confirmation). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

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UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP
TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies) provided that the test method manufacturer’s data indicate that testing sensitivity is at or below U.S. target testing or tolerance levels. In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue.

One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, Option 3 shall not be used for non-Beta lactam screening or verification.

Option 3:

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency may take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be disposed of to remove it from the human or animal food chain. Producer trace back shall be conducted by industry using the same drug test method at the direction of the Regulatory Agency as cited in the prior documented agreement. If the initial producer test result from the drug test method is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified producer screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups and/or use of the violative individual producer’s milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is verified screening
positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

**NOTE:** When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant’s raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be confirmed positive for drug residues using an approved test method or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Name: Appendix N Modification Committee
Agency/Organization: NCIMS Appendix N Modification Committee
Address: 2711 North Haskell Avenue
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Telephone No.: (214) 721-1101 E-mail Address: roger_hooi@deanfoods.com
36th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 227
Committee: Appendix N/Lab

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COUNCIL ACTION

FINAL ACTION

A. Summary of Proposal

Create a third exemption for a new drug test method’s acceptable detection level(s) to accommodate inhibition tests and multi-antibiotic family detection kits.

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

The 50% rule implemented in 1999 into beta-lactam test validation protocol and subsequently incorporated into the 2015 PMO states that drug test methods shall not detect drug residues at less than 50% of tolerance levels or 25% of the target testing level for individual drugs with exceptions for 1) Penicillin G (2 ppb) and 2) Tetracyclines [Oxytetracycline (119 ppb) and Tetracycline (67 ppb)]. These sensitivity criterion are technically limiting to multi-antibiotic family detection methods like inhibition tests. Since the rule in 1999, no new inhibition tests have been evaluated or approved even though they are a simple and low cost method for screening a variety of antibiotic families. New multi-antibiotic family methods like Delvo T, Cowside II, TRIO have been recently developed and are commonly used worldwide to screen raw milk for antibiotics other than beta-lactams. This proposal creates an exemption for multi-family antibiotic methods if the methods can be brought into substantial compliance with the detection acceptance criteria using confirmatory methods. A recent example of a method that did not initially meet the 50% rule sensitivity requirement, but then substantially complied with the sensitivity requirements after confirmation protocol is with Charm-SL tetracycline method being evaluated and approved for the 2015 proposal 211 pilot program.
C. Proposed Solution

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Page 376:

drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N. and other drug testing:

1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.
3. Multi-family antibiotic screening methods brought into substantial compliance with detectable level acceptance criteria using confirmation protocol(s).

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

Name: Bob Salter
Agency/Organization: Charm Sciences, Inc
Address: 659 Andover St.
City/State/Zip: Lawrence, MA 01843
Telephone No.: 978-687-9200 E-mail Address: bobs@charm.com
A. Summary of Proposal

This Proposal clarifies the sampling frequency requirements for Grade “A” raw milk and Grade “A” milk and/or milk products that are not produced on a continuous monthly basis, i.e., intermittently, seasonal, lactating dairy animals are dried off, etc. as required within Section 6-The Examination of Milk and/or Milk Products of the PMO.

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

This Proposal provides guidance to the Regulatory Agency when samples of Grade “A” raw milk and Grade “A” milk and/or milk products are to be collected and they are not produced on a continuous monthly basis, i.e., intermittently, seasonal, lactating dairy animals are dried off, etc., to be in compliance with the sampling frequency required in Section 6 of the PMO. It will also provide guidance to Milk Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) when evaluating samples of Grade “A” raw milk and a milk plant’s Grade “A” milk and/or milk products collected at the required frequency and all necessary laboratory examinations made when calculating an Enforcement Rating during a rating or check rating, respectively.
C. Proposed Solution

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MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS …

Page 27:

NOTE: If the production of Grade “A” raw milk or any Grade “A” condensed or dry milk or milk product, as defined in this Ordinance, is not on a continuous yearly monthly basis, at least five (5) samples shall be taken within a continuous production period and; therefore, cannot meet this Section’s sampling frequency requirement that during any consecutive six (6) months, at least four (4) samples of the Grade “A” raw milk milk or Grade “A” milk or milk product 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, then a sample of the Grade “A” raw milk or Grade “A” milk or milk product shall be collected during each month of production. …

MAKE THE FOLLOWING CHANGES TO THE 2015 METHODS:

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

APPENDIX A

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS
(FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)) …

PART I. DAIRY FARMS

Page 95:

8. At least four (4) samples collected in at least four (4) separate months from each dairy farm’s milk supply, during any consecutive six (6) months, except when three (3) months
show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (Grade “A” PMO, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

a. Four (4) samples taken from each dairy farm during any consecutive six (6) month period. However, if the production of Grade “A” raw milk is not on a continuous monthly basis and; therefore, cannot meet the PMO sampling frequency as cited, then a sample of the Grade “A” raw milk shall be collected during each month of production for any consecutive six (6) month period. (Use MMSR, Page 10 as a guide.)

**NOTE:** Use MMSR, Section B., 2., e.2.), as a guide for frequency determination.

b. Required bacterial counts, somatic cell counts, drug residue and cooling temperature checks performed on each sample in an official or officially designated laboratory. ...

**PART II. MILK PLANT**

Page 102:

7. Samples of each milk plant’s milk and/or 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 the number of milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.) …

b. During any consecutive six (6) months, at least four (4) samples of each Grade “A” milk and/or 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 or milk product, as defined in the Grade “A” PMO, is not on a continuous yearly monthly basis, at least five (5) samples shall be taken within a continuous production period and; therefore, cannot meet the PMO sampling frequency requirement as cited, then a sample of the Grade “A” milk or milk product shall be collected during each month of production. …

**Note:** This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA’s concurrence with the NCIMS Executive Board.
Name: CAPT Robert F. Hennes
Agency/Organization: FDA/CFSAN
Address: 5001 Campus Drive
City/State/Zip: College Park, MD 20740
Telephone No.: (240) 402-2175   E-mail Address: Robert.Hennes@fda.hhs.gov
A. Summary of Proposal

This Proposal clarifies that transferring Grade “A” raw milk on Grade “A” dairy farms directly from a milk can(s) to a milk tank truck is not permitted within the PMO. It also clarifies that milk plants shall not receive Grade “A” raw milk from Grade “A” dairy farms in milk cans.

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

Regulatory Agencies are asking if it is acceptable to transfer Grade “A” raw milk being stored in milk cans on a Grade “A” dairy farm directly to a milk tank truck. Recently, this situation was observed whereby a bulk milk hauler was transferring Grade “A” raw milk stored in milk cans directly to a milk tank truck on multiple dairy farms within an IMS listed BTU. This practice has been considered not acceptable and creates the potential for milk to become contaminated during this collection, sampling and transferring process. The PMO implies that this practice is not permitted; however, the PMO currently does not contain language that would specifically prohibit this practice.

Regulatory Agencies are also asking if a milk plant can receive Grade “A” raw milk in milk cans.

This Proposal would clarify that both of these practices are not permitted within the PMO.
C. Proposed Solution

Changes to be made on page(s): PMO-18, 19, 26, 32, 43, 53, 62, 66, 129 and 139 of the (X - one of the following):

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

MAKE THE FOLLOWING CHANGES TO THE 2015 PMO:

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

Page 18:

SECTION 4. LABELING …

All bottles, containers and packages containing Grade “A” milk and/or milk products defined in Section 1. of this Ordinance shall be labeled in accordance with the applicable requirements of the FFD&CA, the Nutrition Labeling and Education Act (NLEA) of 1990, and regulations developed there under, the CFR, and in addition, shall comply with applicable requirements of this Section as follows:

All bottles, containers and packages containing Grade “A” milk and/or milk products, except milk tank trucks, and storage tanks/silos and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, condensed and/or dried. …

Page 19:

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. …

Page 26:

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-
line-sampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk milk tank and/or silo, or milk tank truck or other container. The transferring of Grade “A” raw milk on a Grade “A” dairy farm from a milk can(s) directly to a milk tank truck is prohibited. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency. …

Page 32:

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

All Grade “A” raw milk and/or milk products for pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging and all Grade “A” pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, aseptically processed and packaged, or retort processed after packaged to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section. The transferring of Grade “A” raw milk on a Grade “A” dairy farm from a milk can(s) directly to a milk tank truck is prohibited. Milk plants shall not receive Grade “A” raw milk in milk cans from Grade “A” dairy farms. …

ITEM 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES …

ADMINISTRATIVE PROCEDURES …

Page 43:

15. The transfer of milk from a bulk milk tank and/or silo to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The hose port shall be fitted with have a tight-fitting door, which shall be in good repair. It shall be kept closed except when the hose port is in use. An easily clean-able surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination.

Provided, milk can be transferred from a bulk milk tank to a bulk milk pickup tanker by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall, provided: …

   g. At all times, the bulk milk pickup tanker manhole openings(s) shall remain closed, except for brief periods for sampling and examination when environmental conditions permit. The transferring of Grade “A” raw milk from a milk can(s) directly to a milk tank truck is prohibited. …

ITEM 12r. UTENSIL AND EQUIPMENT – STORAGE …

ADMINISTRATIVE PROCEDURES …
Page 53:

4. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

§ 4. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet, in a location convenient to their use, and protected against contamination. …

Page 62:

STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED, ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS

Milk plants shall comply with all Items of this Section and shall not receive Grade “A” raw milk in milk cans from Grade “A” dairy farms. The Grade “A” PMO, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant’s food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. Provided, in the case of milk plants or portions of milk plants that are IMS Listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products, the APPS or RPPS, respectively, as defined by this Ordinance, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this Ordinance and shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. Those Items, contained within the APPS and RPPS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA. …

ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for:

1. The pasteurizing, processing, cooling, reconstitution, condensing, drying and packaging of milk and milk products. …

Page 66:

6. Receiving cans of milk and milk products from other milk plants in milk plants receiving such cans. …

Page 129:

SECTION 10. TRANSFERRING; DELIVERY CONTAINERS; AND COOLING

Except as permitted in this Section, no milk producer, bulk milk hauler/sampler or distributor
shall transfer milk or milk products from one (1) container or milk tank truck to another on the
street, in any vehicle, store or in any place except a milk plant, receiving station, transfer
station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid
milk products is prohibited.
The transferring of Grade “A” raw milk on a Grade “A” dairy farm from a milk can(s) directly
to a milk tank truck is prohibited. Milk plants shall not receive Grade “A” raw milk in milk
cans from Grade “A” dairy farms.
It shall be unlawful to sell or offer for sale any pasteurized milk or milk products that have not
been maintained at the temperature set forth in Section 7. of this Ordinance. If containers of
pasteurized milk or milk products are stored in ice, the storage container shall be properly
drained.

ADMINISTRATIVE PROCEDURES

TRANSFERRING: The transferring of Grade “A” raw milk on a Grade “A” dairy farm from
a milk can(s) directly to a milk tank truck is prohibited. Milk plants shall not receive Grade
“A” raw milk in milk cans from Grade “A” dairy farms.
The dipping or ladling of milk and fluid milk products is expressly prohibited, except for
immediate cooking purposes. Milk and milk product containers, which have been filled and
sealed at a milk plant, shall be used for the delivery of milk or milk products. Caps, closures or
labels shall not be removed or replaced during transportation. …

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Milk sampling, hauling, and transport are integral parts of a modern dairy industry. Hauling,
sampling and transport can be categorized into three (3) separate functions: Dairy or Industry
Plant Samplers, Bulk Milk Hauling and Sampling and Milk Transport from one (1) milk
handling facility to another.

I. MILK SAMPLING AND HAULING PROCEDURES …

The bulk milk hauler/sampler is any person who collects official samples and may transport
raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or
transfer station and has in their possession a permit from any Regulatory Agency to sample
such products. The bulk milk hauler/sampler occupies a unique position making this individual
a critical factor in the current structure of milk marketing. As a weigher and sampler, they
stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk
receiver, the operating habits directly affect the quality and safety of milk committed to their
care. When the obligations include the collection and delivery of samples for laboratory
analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and
regulatory programs affecting producer dairies. Section 3. of this Ordinance requires that
Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These
individuals are evaluated at least once each two (2) year period using FORM FDA 2399a-
BULK MILK HAULER/SAMPLER REPORT. (Refer to Appendix M. of this Ordinance.)
The bulk milk hauler shall not transfer Grade “A” raw milk directly from a milk can(s) to a milk tank truck. …

MAKE THE FOLLOWING CHANGES TO THE 2015 MMSR:

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

PART III. INDIVIDUAL SHIPPER RATING …

Page 107:

3. All milk and/or milk products properly labeled (Grade “A” PMO, Section 4. LABELING).

b. Include in Label Review: …

1.) A representative label(s) for all milk and/milk products produced, including raw. Milk and/or milk products are labeled according to the Grade “A” PMO definition(s) and requirements and applicable CFRs.
2.) Vehicles hauling milk shall be properly identified with the name and address of the milk plant or hauler. (Include under raw milk.)
3.) Milk cans from dairy farms properly identified. (Include under raw milk.)
4.) Bills-of-lading and dairy farm weight tickets contain all the required information, including BTU #. (Include under raw milk where applicable.) …

Note: This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA’s concurrence with the NCIMS Executive Board.

<table>
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<tr>
<th>Name:</th>
<th>CAPT Robert F. Hennes</th>
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<td>FDA/CFSAN</td>
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<tr>
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</tr>
<tr>
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<td>College Park, MD 20740</td>
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<tr>
<td>Telephone No.:</td>
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<tr>
<td>E-mail Address:</td>
<td><a href="mailto:Robert.Hennes@fda.hhs.gov">Robert.Hennes@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

This Proposal provides clarity, consistency and uniformity to the text contained within the MMSR. It requires that a BTU shall obtain a Sanitation Compliance Rating (SCR) of ninety (90) or above to be IMS listing, which will align BTU IMS listings with milk plants, receiving stations and transfer stations. Clarifies milk and/or milk product test results and pasteurization equipment testing results from the Regulatory Agency’s official records that are to be reviewed and the actions to be taken if not in compliance on ratings and check ratings. Clarifies preceding six (6) months of a rating or check rating and the time period for the Regulatory Agency’s official records review for Enforcement Rating (ER) calculations following ratings and check ratings. It also clarifies the items that can be pro-rated on ratings and check ratings for a consistent and uniform approach.

This Proposal also requests that the Chair assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA to conduct a comprehensive and thorough review of the MMSR and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide editorial clarity, consistency and uniformity to text contained throughout the MMSR.

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

FDA Milk Safety Team (MST) conducted a thorough and comprehensive review of the MMSR to identify inconsistencies and lack of uniformity in text throughout the document and to provide clarity to text throughout the document where warranted related to the items addressed in A. above. It also reviewed the document for rating and listing practices that are no longer being utilized, or utilized by a few States; or have been modified over the course of many
years and the MMSR may not have been updated to reflect all of those modifications or current practices. This MST review was partially triggered by numerous questions obtained from newly FDA certified Milk Sanitation Rating Officers (SROs), newly appointed Grade “A” Milk Safety Program managers; and an extremely long period of time since the last time that the MST conducted a thorough and comprehensive review of the MMSR related to the items addressed in A. above.

By requiring that a BTU shall obtain a Sanitation Compliance Rating (SCR) of ninety (90) or above to be IMS listed will align BTU IMS listings with milk plants, receiving stations and transfer stations for consistency and uniformity purposes. Currently, this proposed requirement that a BTU shall obtain a SCR of ninety (90) or above to obtain an IMS listing is not cited in the Procedures document. The practice of allowing representatives of a BTU (area or individual milk shipper) to sign a “Permission to Publish” for a rating with a SCR of less than ninety (<90) is being practiced by a few States; however, the majority of the States do not offer or allow this practice at all. Even if a State provides for a BTU (area or milk individual shipper) to sign a “Permission to Publish” on a rating with a SCR of less than ninety (<90) the BTU (area or milk individual shipper) still cannot ship the raw milk to an IMS listed milk plant, receiving station or transfer station. An IMS listed milk plant, receiving station or transfer station that receives raw milk from an IMS listed source with a SCR of less than ninety (<90) will be immediately withdrawn from the IMS List. By making this change it brings BTUs in alignment with the IMS listing requirements for milk plants, receiving stations and transfer stations and eliminates the confusion that if a BTU is IMS listed they still cannot ship raw milk to an IMS listed milk plant, receiving station or transfer station with a SCR of less than ninety (<90).

Also, for consistency and uniformity purposes the term “New Rating” applies for the rating conducted after an IMS listing is withdrawn following a rating or check rating.

### C. Proposed Solution

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<th>Changes to be made on page(s):</th>
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<th>of the (X - one of the following):</th>
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**MAKE THE FOLLOWING CHANGES TO THE 2015 MMSR:**

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

*Page ii:*
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### B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

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### C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS

2. **Collection of Data**

   c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being IMS Listed Under the NCIMS Voluntary HACCP Program Listing Procedure

### D. CERTIFICATION/LISTING METHODS FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS.

### H. PUBLICATION OF THE INTERSTATE MILK SHIPPER’s REPORT”

2. **Preparation of the “INTERSTATE MILK SHIPPER’s REPORT”**

   a. Individual Shipper of Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging

### ABBREVIATIONS AND ACRONYMS

- EML (Evaluation of Milk Laboratories)
- EPA (Environmental Protection Agency)
- ER (Enforcement Rating)
- HACCP (Hazard Analysis Critical Control Point)
- HHST (Higher-Heat-Shorter-Time)
- HTST (High-Temperature-Short-Time)
- LOU (Letter of Understanding)
- LPET (Laboratory Proficiency and Evaluation Team)
- RMS (Regional Milk Specialist)
- RPPS (Retort Processed after Packaging System)
SCR (Sanitation Compliance Rating)
SMEDP (Standard Methods for the Examination of Dairy Products) ...

UP (Ultra-Pasteurization)
USDA (United State Department of Agriculture)

Page 1:

A. DEFINITIONS …

1. AREA RATING: An area rating, if used, shall apply to Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. An individual dairy farm shall only be included in one (1) IMS Listing …

Page 2:

6. BULK TANK UNIT (BTU): A dairy farm or group of dairy farms from which Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and which is rated as a single entity and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. An individual dairy farm shall only be included in one (1) IMS Listing …

Page 3:

16. IMS LISTED MILK SHIPPER: An interstate milk shipper (BTU, receiving station, transfer station, milk plant or a milk plant, receiving station or transfer station with an attached supply of Grade “A” raw milk), which has been certified by a Rating Agency as having attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. The ratings are based on compliance with the requirements of the Grade “A” PMO and were made in accordance with the procedures set forth in the Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR). For milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program, respectively, the Regulatory Agency’s regulatory and Rating Agency’s rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program. An individual dairy farm shall only be included in one (1) IMS listing.
17. **INDIVIDUAL RATING**: An individual rating is the rating of a single producer group, dairy farm, milk plant, receiving station, and/or transfer station or a milk plant, receiving station or transfer station with an attached supply of Grade “A” raw milk under the supervision of a single Regulatory Agency and has attained an acceptable Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) necessary for inclusion on the IMS List. Milk plants producing Grade “A” condensed and/or dried milk and/or milk products and/or Grade “A” condensed and/or dry whey and/or whey products may be rated separately from the same milk plant producing other Grade “A” milk and/or milk products, provided each IMS listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products, and/or retort processed after packaged Grade “A” low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant IMS listing for milk plants that produces aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products shall have only an NCIMS HACCP IMS listing. An individual dairy farm shall only be included in one (1) IMS Listing listing. …

*Note: Renumber remaining definitions accordingly.*

**Page 7:**

**B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING**

1. **DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING BTU OR ATTACHED SUPPLY OF GRADE “A” RAW MILK COMPLIANCE WITH APPENDIX N. OF THE GRADE “A” PMO**

During an Interstate Milk Shippers’ (IMS) rating or FDA check rating, it is necessary to determine compliance of the BTU or attached supply of Grade “A” raw milk with the requirements of Appendix N. of the *Grade “A” PMO*. The following criteria are to be used in making that determination. If the BTU or attached supply of Grade “A” raw milk is not in substantial compliance, a rating or check rating is not to be completed and the Rating Agency shall immediately notify the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the IMS certification listing.

a. **Record Review**

Determine from records that are stored in a manner acceptable to the Rating Agency that all milk pick-up tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, are screened daily, prior to processing, for Beta lactams with an approved test method. As necessary, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. of the *Grade “A” PMO*.

Compliance with the above Item would be satisfied in the following manner:
1.) Records indicating that raw milk was always shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers was always being received by an IMS listed milk shipper shall suffice for actual test results.

2.) If raw milk is shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers is to received by a non-IMS listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) may at their discretion request records on the testing of loads of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, that are sent to received by non-IMS listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO or FDA RMS should choose and request to review records for no more than fifteen (15) days, unless these selected records show indicate a problem.

b. Regulatory Notification and Disposition

If a sample from a milk tank truck load of milk; and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup; or a sample of raw milk from an individual dairy farm is positive for a drug residue, determine if the Regulatory Agency was immediately notified, including the method of proper disposition to keep the contaminated milk out of the food chain. …

Page 8:

2. COLLECTION OF DATA …

Data from which the ratings and check ratings are determined are obtained by the SRO SROs or FDA RMSs, respectively, from the Regulatory Agency’s official records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the dairy farms. It is not necessary, except on very small BTUs or attached supplies of Grade “A” raw milk, to inspect every dairy farm, since a sufficiently accurate determination of the percentage compliance with the sanitation requirements can be determined by rating statistically selected dairy farms.

a. Number of Dairy Farms to be Rated

1.) The minimum number of dairy farms to be included in the rating depends upon the number in the area BTU or attached supply of Grade “A” raw milk to be rated and the accuracy desired. To attain accuracy such that the probable error in the individual percentages of compliance with the various Items of sanitation will be less than five percent (5%), the minimum number of dairy farms selected at random for inspection during the rating shall be determined from TABLE 1. …

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b. Random Selection of Dairy Farms to be Rated
The individual dairy farms included in the rating or check rating shall be representative to reflect conditions throughout the BTU or attached supply of Grade “A” raw milk. It is important that the selection method excludes elements of pre-selection and provides a truly random sample. The selection of dairy farms for a rating should be made from a current listing of dairy farms making up the BTU or attached supply of Grade “A” raw milk and may be compared to a list for the previous sixty (60) days to determine if an appreciable shifting of dairy farms has taken place. Random selections, once made, should be deviated from only in cases of emergencies. Replacements, where necessary, should also be selected at random. Whenever possible, random selection or announcements of such selections for only one (1) day's work at a time should be made.

Examples of methods, which are satisfactory for the random selection for dairy farms, include the following:

1.) The name of each dairy farm in the BTU or attached supply of Grade “A” raw milk is written on a small card, one (1) name per card. These cards are then thoroughly shuffled and the number of dairy farms to be included in the rating, as determined from TABLE 1, are selected.

2.) The selection of dairy farms is made at intervals from a complete card index, ledger record, or other list. When this method is used, the sequence interval chosen shall be such that the entire card index, ledger record, or other list is subject to the sampling method. The sequence interval may be determined by dividing the total number of dairy farms by the number needed for the rating or check rating.

**For Example:** If there were 280 dairy farms in the BTU or attached supply of Grade “A” raw milk, TABLE 1 indicates that forty (40) shall be included in the rating and the sequence interval in this case would be every seventh (7th) dairy farm. The first dairy farm in sequence is picked at random from the complete card index, ledger record or other list in order that chance alone determines the selection of individual dairy farms.

3.) Immediately prior to the initial random drawing of dairy farms to be selected for inclusion in a rating, every dairy farm, which produces forty percent (40%) or more of the volume of milk in a BTU, which consists of five (5) dairy farms or more, shall become a separate BTU. Random generated number table.

**NOTE:** Immediately prior to the initial random drawing of dairy farms to be selected for inclusion in a rating, every dairy farm, which produces forty percent (40%) or more of the volume of milk in a BTU or attached supply of Grade “A” raw milk, which consists of five (5) dairy farms or more, shall be removed from the existing BTU or attached supply of Grade “A” raw milk and rated as a separate BTU. …

*d. Recording of Inspection Data*

1.) During a rating or check rating, inspection data are recorded on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT, the Items of which correspond to the Items
e. Recording of Laboratory and Other Test Data

1.) The Regulatory Agency’s official records are used to determine compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or FDA RMS to determine from the official Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the Grade "A" PMO and Evaluation of Milk Laboratories (EML), respectively. Ratings and check ratings shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests and the Rating Agency shall immediately notify the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the IMS listing.

2.) Compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements is based on whether, at the time of the rating or check rating, a dairy farm meets the standards of Section 7. of the Grade "A" PMO. Credit for bacterial, drug residue, somatic cell and cooling temperature requirements shall be given if no more than two (2) of the last four (4) sample results exceed the limits limit(s). Provided, that the last sample result is within the limit limit(s). Individual dairy farms that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample exceeds the limit(s) shall not be given credit (debited) for the specific bacterial, drug residue, somatic cell and/or cooling temperature limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial, drug residue, somatic cell and cooling temperature requirements shall be given when less than the required number of samples have been examined during the preceding six (6) months. For rating or check rating purposes, the preceding six (6) months is considered to be the elapsed period of the month prior to the earliest rating date in which the rating or check rating is made conducted and the preceding six (6) months. Dairy farms, which have had a permit for less than six (6) months at the time of the rating or check rating and for which the Regulatory Agency has not yet examined the required number of samples, shall be given credit. Provided, that the last sample result is within the limits limit(s). Individual dairy farms that have had a permit for less than six (6) months and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial, drug residue, somatic cell and/or cooling temperature limit(s) that was exceeded.

3.) The SRO or FDA RMS shall utilize the Regulatory Agency’s official records in determining compliance with those Items of sanitation which require laboratory tests to complete the evaluation rating or check rating, respectively.

NOTE: All Grade “A” raw milk required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the
NCIMS. Grade “A” raw milk that does not have validated and accepted test methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific Grade “A” milk and/or milk products that have FDA validated and NCIMS accepted test methods.) …

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS …

a. Rating or check rating results are transferred to FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEP TIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings or check ratings of area or individual IMS listed milk shippers.

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c. The Sanitation Compliance Rating SCR is Derived from the Following Formula:

\[
\text{Rating SCR} = 100 - \left( \text{The Sum of the "Pounds Sold Daily (100# Units) X Total Debits" column} \right) \div \left( \text{The Sum of the "Pounds Sold Daily (100# Units)" column} \right)
\]

This rating figure SCR calculation is entered in the appropriate space in the upper right hand corner of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEP TIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. It is also entered on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1) and FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT, in the appropriate location. …

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING MILK PLANT, RECEIVING STATION AND TRANSFER STATION COMPLIANCE WITH APPENDIX N. OF THE GRADE “A” PMO

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During an IMS rating/NCIMS HACCP listing audit or FDA check rating/FDA NCIMS HACCP audit, it is necessary to determine compliance of the milk plant, receiving station and/or transfer station with the requirements of Appendix N. of the Grade “A” PMO. The following criteria are to be used in making that determination. If the milk plant, receiving station or transfer station is not in substantial compliance, a rating/NCIMS HACCP listing audit or FDA check rating/FDA NCIMS HACCP audit is not to be completed and the Rating Agency shall immediately notify the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the IMS certification listing.
a. Record Review

Determine from records that are stored in a manner acceptable to the Rating/NCIMS HACCP Listing Agency that all milk pick-up tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, are screened daily, prior to processing, for Beta lactams with an approved test method. As necessary If an attached supply of Grade “A” raw milk, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. of the Grade “A” PMO.

Milk plants, receiving stations and transfer stations having an attached supply of Grade “A” raw milk with raw milk tank truck loads that occasionally are diverted by direct dairy farm shipment to a milk plant, receiving station or transfer station shall be deemed in compliance if the following criteria are met:

1.) Records indicating that raw milk was always shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers was always being received by to an IMS listed milk shipper shall suffice for actual test results.
2.) If raw milk is shipped in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers is to be received by a non-IMS listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs and FDA RMSs may at their discretion request records on the testing of loads of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers that are sent to be received by non-IMS listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO or FDA RMS should choose and request to review records for no not more than fifteen (15) days, unless these selected records show indicate a problem.

b. Regulatory Notification

If a sample from a milk tank truck load of milk and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup tankers was found to have a is positive for a drug residue, determine if the Regulatory Agency was properly immediately notified.

c. Industry Notification

If a sample from a milk tank truck load of milk and/or a sample from all raw milk supplies that have not been transported in bulk milk pickup tankers was found to have a is positive for a drug residue, determine if the permit holder a representative of the BTU or attached supply of Grade “A” raw milk that the dairy farms are attached to, was properly notified.

2. COLLECTION OF DATA …

Data from which ratings and check ratings are determined are obtained by SROs or FDA RMSs, respectively, from the Regulatory Agency’s official records on file with the Regulatory
Agency and from the evaluation of sanitary practices and facilities at the milk plants, receiving stations and transfer stations. For Receiving stations and/or transfer stations operated by the milk plant and under the same routine supervision of the milk plant and shipping to the milk plant they may be considered as an integral part of the milk plant to which milk is shipped and may be IMS listed with the milk plant. Therefore, all such receiving stations and/or transfer stations not having an individual ratings rating and supplying milk to the milk plant selected for the rating shall be included in the milk plant's IMS listing. Receiving stations and/or transfer stations, which are not an integral part of a milk plant or are not IMS listed with the milk plant, shall have an individual ratings rating and may be rated separate from their BTUs.

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a. Recording of Inspection Data

1.) During a rating or check rating, inspection data are recorded on FORM FDA 2359-MILK PLANT INSPECTION REPORT, the Items of which correspond to the Items of sanitation in Section 7. of the Grade “A” PMO. ...

3.) The average number of pounds of Grade “A” milk and milk products processed daily is needed required for computing the rating SCR and is entered in the appropriate place at the top of FORM FDA 2359-MILK PLANT INSPECTION REPORT. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, high-temperature-short-time (HTST), or higher-heat-shorter-time (HHST) or ultra-pasteurization (UP); or Grade “A” milk and/or milk product(s) that has not been pasteurized at minimum pasteurization times and temperatures; only the quantity of all Grade “A” milk and/or milk products affected by the deficiency, rather than the entire milk plant’s Grade “A” milk and/or milk products production, is recorded for use in the computation of the milk plant’s Sanitation Compliance Rating SCR. Only violations of Items 16p, 18p and 19p of the Grade “A” PMO are to receive partial debits. Provided, that bacterial count, coliform count, phosphatase, drug residue and cooling temperature may be partially debited for the particular Grade “A” milk and/or milk product involved. All other violations should be considered as affecting the entire Grade “A” milk and/or milk products production of the milk plant.

b. Recording of Laboratory and Other Test Data

1.) The Regulatory Agency’s official records are used utilized in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or FDA RMS to determine from the official Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the Grade “A” PMO and EML, respectively. Ratings and NCIMS HACCP listing audits shall not be
conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests and the Rating Agency shall immediately notify the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the IMS listing.

2.) Compliance with bacterial, coliform, phosphatase, drug residue and cooling temperature requirements is based on whether, at the time of the rating or check rating, a milk plant’s Grade “A” milk and/or milk products meet the standards of Section 7. of the Grade "A" PMO. Credit for bacterial, coliform, phosphatase, drug residue and cooling temperature requirements for each each Grade “A” milk and/or milk product, including bacterial and cooling temperature requirements for commingled raw milk prior to pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging, for each of the above applicable requirements, shall be debited if no more than two (2) of the last four (4) sample results exceed the limit(s); and the last sample result is in violation. Provided, that the last sample result is within the limit(s). Individual Grade “A” milk and/or milk products that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample exceeds the limit(s) shall not be given credit (debited) for the specific bacterial, coliform, phosphatase, drug residue and/or cooling temperature limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial, coliform, phosphatase, drug residue and cooling temperature requirements shall be given when less than the required number of samples has been examined during the preceding six (6) months. For rating or check rating purposes, the preceding six (6) months is considered to be the elapsed period for of the month prior to the earliest rating date in which the rating or check rating is made conducted and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the rating or check rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited be given credit. Provided, that the last sample result is within the limit(s). Milk plants that have had a permit for less than six (6) months and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial, coliform, phosphatase, drug residue and/or cooling temperature limit(s) that was exceeded.

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3.) The SRO or FDA RMS shall utilize the Regulatory Agency’s official records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation rating or check rating, respectively. Official The Regulatory Agency’s official records of Equipment pasteurization equipment Tests tests may also be used in lieu of performing such Equipment pasteurization equipment Tests tests during the rating or check rating. Provided, that the SRO or FDA RMS is satisfied as to the competency of the Regulatory Agency’s personnel to perform these Equipment pasteurization equipment Tests tests as described in Appendix I. of the Grade "A" PMO. …

c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being IMS Listed Under the NCIMS Voluntary HACCP Program Listing Procedure …
4.) Criteria and Procedures for Denial or Withdrawal of an IMS Listing

A.) An IMS listing under the NCIMS voluntary HACCP Program may be denied or withdrawn when CLEs have been noted indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies) indicating: …

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(iv) Milk is received from a supply other than a NCIMS IMS listed source or from a listed source with a Sanitation Compliance Rating below 90 percent (90%).

B.) Significant deficiencies involving one (1) or more CLEs constitute grounds for denial or withdrawal of a milk plant’s, receiving station’s or transfer station’s NCIMS HACCP listing. …

CLEs are noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT with a double star (**) and cover the following areas of the NCIMS voluntary HACCP Program: …

(vii) OTHER NCIMS REQUIREMENTS: Incoming milk supply from a NCIMS IMS listed source(s) with a Sanitation Compliance Rating(s) of 90 percent (90%) or above and a drug residue control program implemented. …

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3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

The criteria and procedures for actions following a NCIMS HACCP listing audit are found in Section C., 2., c. of this document. Sanitation Compliance Ratings SCRs shall be made of dairy farms that are attached supplies of Grade “A” raw milk of milk plants, receiving stations, or transfer stations IMS listed under the NCIMS voluntary HACCP Program listing procedure. …

b. The name of the milk plant and the total pounds of milk and/or milk products processed daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Plant", and second, "Pounds Processed Daily (100# Units)", columns, respectively, of FORM FDA 2359L-STATUS OF MILK PLANTS. …

If the milk plant's daily output varies, the recorded quantity is the daily average, based on actual operating days, for the week preceding the rating. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers, etc.; or capping of these containers; or individual pasteurization unit used, i.e., vat, HTST, HHST or UP; or Grade
“A” milk and/or milk product(s) that has not been pasteurized at minimum pasteurization times and temperatures, the number of pounds of all Grade “A” milk and/or milk products so packaged, capped, not pasteurized at minimum pasteurization times and temperatures or pasteurized individual pasteurization unit used are debited. In such cases, entries are made on separate lines below the name of the milk plant. The name or names of the milk and/or milk product(s) identity of the individual packaging and/or capping machine(s) affected by the violation(s) of Items 16p, 18p, and/or 19p; or bacterial, coliform or cooling temperature standards of the Grade “A” PMO; the identity of the individual pasteurization unit(s) used, i.e., vat, HTST, HHST or UP affected by the violation(s) of Item 16p is entered in the “Name of Plant” column, together with a parenthetic entry of the total volume in 100 pound units (cwt.) of the Grade “A” milk and/or milk product(s) involved. The name or names of the Grade “A” milk and/or milk product(s) affected by the violation(s) of bacterial, coliform, phosphatase, drug residue or cooling temperature standards of the Grade “A” PMO; or not pasteurized at minimum pasteurization times and temperatures affected by the violation(s) of Items 16p is entered in the "Name of Plant" column, together with a parenthetic entry of the total volume in 100 pound units (cwt.) of the Grade “A” milk and/or milk product(s) involved. Care shall be taken not to enter this quantity in the "Pounds Processed Daily (100# Units)" column where it would again be included in the total pounds of Grade “A” milk and/or milk products processed daily. (Refer to Section K. #s 14 and 15 for examples.) …

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d. The SCR computation procedure for a milk plant is similar to that for dairy farms, except that a modified procedure is necessary in computing debits for violations involving only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or capping of these containers; or individual pasteurization unit used, i.e., vat, HTST, HHST or UP); or Grade “A” milk and/or milk product(s) that has not been pasteurized at minimum pasteurization times and temperatures; or individual Grade “A” milk and/or milk product(s) violating the bacterial, coliform, phosphatase, drug residue or cooling temperature standards; and for violations involving receiving or transfer stations that are IMS listed with the milk plant. The latter is explained in the preceding paragraph. For such violations, the entry in the "Total Debits" column is multiplied by the actual number of pounds of Grade “A” milk and/or milk product involved, as entered parenthetically in the "Name of Plant" column, rather than by the milk plant’s entire Grade “A” milk and/or milk products production from the "Pounds Processed Daily (100# Units)" column. This figure is entered in the "Pounds Processed Daily (100# Units) X Total Debits" column.

The formula for determining the Sanitation Compliance Rating SCR for the milk plant is as follows derived from the following formula:

\[
\text{Rating SCR} = 100 - \left( \frac{\text{The Sum of the “Pounds Processed Daily (100# Units) X Total Debits” column}}{\text{The Sum of the “Pounds Processed Daily (100# Units)” column}} \right)
\]

This rating figure SCR calculation is entered in the appropriate space in the upper right hand corner of FORM FDA 2359L-STATUS OF MILK PLANTS. It is also entered on
c. The name(s) of the BTU(s), receiving station(s) and/or transfer station(s) shipping milk to the milk plant, which are separately rated and listed, are also entered in the "Name of Plant" column, below the name of the plant but the quantity of milk supplied daily is entered parenthetically in the same manner as for locally supervised receiving and/or transfer stations. The poundage is not recorded in the "Pounds Processed Daily (100# Units)" column, since this quantity is already accounted for in the milk plant figures. If the rating for the receiving station(s) and/or transfer station(s) is equal to, or greater than, that of the milk plant, the plant rating is considered as being inclusive of the receiving station's and/or transfer station's violations; therefore, no entry is made in the "Total Debits" column. However, if the receiving station's and/or transfer station's rating(s) is less than ninety percent (90%) and lower than that of the milk plant, the difference is entered in the "Total Debits" column. For the station(s), this difference is then multiplied by the number of pounds of milk shipped daily by the receiving station(s) and/or transfer station(s) to the milk plant and entered in the "Pounds Processed Daily (100# Units) X Total Debits" column. If milk plants, receiving stations or transfer stations are rated with an attached supply of Grade "A" raw milk, then both the dairy farm(s) and the individual milk plant, receiving station or transfer station, respectively shall achieve a SCR of ninety percent (90%) or higher in order to be eligible for a listing on the IMS List.

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f. If, upon receipt, one (1) or more shipper(s) of unattached raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging violates the bacterial and/or cooling temperature standards, the violations are debited against the rating of the receiving station(s) and/or transfer station(s) shipping the milk, prior to combining the ratings in accordance with the methods described above.

D. CERTIFICATION/LISTING METHODS FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS ...

1. COLLECTION OF DATA

Data from which certifications certification listings for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by State Rating Agency SROs or FDA RMS from the Regulatory Agency’s official records on file with the Regulatory Agency or single-service containers and/or closures manufacturer, respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

Data from which certifications certification listings for foreign manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by a TPC’s SRO or a SSC from the Regulatory Agency’s official records on file with the Regulatory Agency, SSC or single-service containers and/or closures manufacturer,
respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

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b. Recording of Laboratory and Other Test Data

1.) As applicable, the Regulatory Agency’s official records from the Regulatory Agency, and records from the SSC and/or single-service containers and/or closures manufacturers are used utilized in determining compliance with bacterial, coliform and chemical, as applicable, requirements. The acceptance of data from Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO or FDA RMS to determine from the official Milk Laboratory Control Agency or for the SSC that certified and listed the single-service containers and/or closures manufacturer that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the Grade “A” PMO and EML, respectively. Certification listings shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency, SSC or single-service containers and/or closures manufacturers, as applicable, for the necessary tests and the Rating Agency or SCC, respectively, shall immediately notify the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs to withdraw the IMS certification listing.

2.) Compliance with bacterial and coliform requirements is based on whether, at the time of the certification listing, a single-service manufacturer’s containers and/or closures meet the standards of Appendix J. of the Grade "A" PMO. Each manufacturing line of containers and/or closures for each of the above applicable requirements, credit shall be debited given if no more than two (2) of the last four (4) sample set results exceed the limit(s), and the last sample set result is in violation. Provided that the last sample set result is within the limit(s). Individual sample sets that are in violation of having two (2) of the last four (4) sample results exceeding the limit(s) and the last sample set exceeds the limit(s) shall not be given credit (debited) for the specific bacterial and/or coliform limit(s) that was exceeded. No credit shall be given (debited) for compliance with bacterial or coliform requirements when less than the required number of sample sets has been examined during the preceding six (6) months. For certification listing purposes, the preceding six (6) months is considered to be the elapsed period for of the month prior to the earliest certification listing date in which the certification listing was made conducted and the preceding six (6) months. Single-service containers and/or closures manufacturers which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year round basis and for which the Regulatory Agency, SSC and/or single-service containers and/or closures manufacturer, as applicable, has not yet examined the required number of sample sets shall not be debited given credit. Provided, that the last sample set result is within the limit(s). Single-service containers and/or closures manufacturers that have had a permit, if applicable, for less than six (6) months or do not operate on a year round basis and their last sample results exceed the limit(s) shall not be given credit (debited) for the specific bacterial and/or coliform limit(s) that was exceeded. …
E. COMPUTATION OF ENFORCEMENT RATINGS ...

1. PURPOSE ...

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b. Appraisal of Items is based on the SRO’s observations made during the rating or check rating, respectively, and their review of the Regulatory Agency's official records for the lesser of one (1) of the following periods:

1.) The period since Back to the beginning of the month in which the last previous rating, but not less than six (6) months was conducted; or

For Example: The previous rating was conducted 10/21/2014 and the earliest rating date for the next rating or check rating was 6/14/2016. The period for the Regulatory Agency’s official records review for this rating or check rating, respectively, would cover 10/1/2014 to 6/13/2016.

2.) The two (2) years preceding the date of the current rating. Back to the beginning of the month in which the previous rating was conducted. If the last rating was conducted within the preceding six (6) months, for rating or check rating purposes, the preceding six (6) months is considered to be the elapsed period of the month prior to the earliest rating date in which the rating or check rating was conducted and the preceding six (6) months.

For Example: The previous rating was conducted 12/21/2015 and the earliest rating date for the next rating or check rating was 5/14/2016. The period for the Regulatory Agency’s official record review for this rating or check rating, respectively, would cover 11/1/2015 to 5/13/2016.

NOTE: When determining compliance of the Regulatory Agency’s official records, adequate records shall be reviewed to determine that all requirements within the applicable time period addressed above have been met. Therefore, all of the Regulatory Agency’s official records contained with the applicable time period cited above shall be in compliance with all PMO frequency, testing, sampling, enforcement, etc. requirements to be given credit.

c. Enforcement Rating scores ERs shall be computed utilizing the GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS, contained in Appendix A. of this document.

d. The Enforcement Rating ER applies directly to the individual Regulatory Agency; therefore, there are no provisions for combining the Enforcement Ratings ERs of two (2) or more Regulatory Agencies. Enforcement Ratings ERs shall be made in accordance with the procedures in the following Sections.

e. For ER purposes, to determine if inspections (dairy farms and transfer stations at least once every six (6) month period and milk plants and receiving stations at least
once every three (3) month period); pasteurization equipment tests (at least once every three (3) month period and the holding time testing at least once every six (6) month period); Grade “A” milk and/or milk product sampling and testing (during any consecutive six (6) months, at least four (4) samples of each Grade “A” milk and milk product, 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; individual water supplies (dairy farms at least once every three (3) year period and milk plants, receiving stations and transfer stations at least once every six (6) month period), reclaimed water and recirculated cooling water samples (at least once every six (6) month period); and sampler evaluations (at least once every twenty-four (24) month period) have been made at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the inspection, test(s), milk and/or milk product sampling and testing, water sampling and/or evaluation, respectively, is due.

2. RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ONLY …

b. When an Item requires separate action on the part of the Regulatory Agency with respect to each dairy farm, compliance is prorated on the proportion of dairy farms included in the rating or check rating for which official the Regulatory Agency’s official records that were reviewed during the appropriate time period back to the previous rating indicate show the Item to have been satisfied. …

d. For rating purposes, to determine if tests have been made at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the test(s) is due.

e. For dairy farms inspected under the provisions of Appendix P. of the Grade “A” PMO, the following rating criteria applies: …

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H. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’s REPORT”

1. PURPOSE

a. The IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List) is an electronic publication of CFSAN’s Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway 5001 Campus Drive, College Park, MD 20740-3835. This is a part of the activities of the PHS/FDA in cooperation with the Regulatory Agencies in the cooperative program for the certification IMS listing of interstate milk shippers.
b. Triplicate copies or PHS/FDA’s electronic version (transmitted via computer) of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT shall be submitted by the SRO to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for milk shippers who desire to be listed on the IMS List. (Refer to Section J. #s 8 and 9 for a copy of the Form.)

A signed copy of a written FORM FDA 2359o PERMISSION FOR PUBLICATION—INTERSTATE MILK SHIPPER’s LISTING shall accompany each triplicate set of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT, submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication on the IMS List. For the submission of PHS/FDA’s electronic version, a signed copy of the written FORM FDA 2359o PERMISSION FOR PUBLICATION—INTERSTATE MILK SHIPPER’s LISTING shall be maintained on file by the Rating Agency for publication on the IMS List and shall be reviewed as part of the check rating and/or Regulatory/Rating Agency Program Evaluation. Once a milk shipper has been IMS listed, all ratings, re-ratings and new ratings and NCIMS HACCP listing audits, re-audits and new audits shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs even though the milk shipper has refused to sign a written FORM FDA 2359o PERMISSION FOR PUBLICATION—INTERSTATE MILK SHIPPER’s LISTING. Supporting sampling and laboratory certification accreditation reports, as specified in the Procedures, are also necessary for inclusion and retention of the milk shipper on the IMS List. (Refer to Section J. #12 for a copy of the Form.)

The Sanitation Compliance Rating SCR of a milk shipper is not published on the IMS List unless the written and signed FORM FDA 2359o PERMISSION FOR PUBLICATION—INTERSTATE MILK SHIPPER’s LISTING is signed by an authorized representative of the milk shipper concerned included in the IMS listing and has been obtained received by and the Rating Agency. BTUs, Milk milk plants, receiving stations and transfer stations shall achieve a Sanitation Compliance Rating SCR of ninety percent (90%) or greater in order to be eligible for a listing on the IMS List. The Sanitation Compliance Rating SCR for milk plants, receiving stations and transfer stations will not be printed on the IMS List.

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

a. Individual Shipper of Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging

This milk shipper is commonly referred to as a BTU. Following the computation of the Sanitation Compliance Rating SCR on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING and the ER from Part I of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date shall be the date of the first day of the BTU rating. (Refer to Section K. #s 16 and 17 for examples.)
NOTE: If the Enforcement Rating (ER) for the IMS Listed Shipper listed milk shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

Page 32:

b. Receiving Station or Transfer Station

1.) Attached Grade “A” Raw Milk Supply Only:

A receiving station or transfer station with a single source of Grade “A” raw milk, both under the jurisdiction of the same Regulatory Agency.

Following the computation of the Sanitation Compliance Rating (SCR) on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRAPASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, and FORM FDA 2359L-STATUS OF MILK PLANTS, and the ER from Parts I, II and III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date shall be the date of the first day of the rating of either the dairy farms (BTU), receiving station or transfer station, whichever is earliest in time. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, ultrapasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section H. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’s REPORT, 2., c.2) or 2., c.3). Both the receiving station or transfer station and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the IMS List.

2.) Attached Grade “A” Raw Milk Supply and Unattached Grade “A” Raw Milk Supplies:

A receiving station or transfer station with a source of Grade “A” raw milk under the jurisdiction of the same Regulatory Agency as the receiving station or transfer station and one (1) or more sources of Grade “A” raw milk from other IMS listed sources.

The raw milk SCR and earliest rating date shall be reported in the following manner:

The SCR of the attached supply of Grade “A” raw milk shall be reported as the raw milk SCR for the shared IMS listing. The earliest rating date shall be the date of the first day of the rating of either the dairy farm(s) (BTU), receiving station or transfer station, whichever is earliest in time. Both the receiving station or transfer station and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the IMS List. All unattached Grade “A” raw milk
supplies shall have an IMS listing. If Grade “A” raw milk milk is received from a source that is not IMS listed, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified and the receiving station or transfer station and the attached supply of Grade “A” raw milk included in the shared IMS listing shall be withdrawn from the IMS List.

Following the computation of the SCR on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, and FORM FDA 2359L-STATUS OF MILK PLANTS, and the ER from Parts I, II and III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. In addition, the name of each unattached IMS listed raw milk shipper, during the thirty (30) days preceding the rating, along with the SCR and the Expiration Rating Date of each IMS listed raw milk shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT.

3.) Unattached Grade “A” Raw Milk Supplies Only

A receiving station or transfer station with one (1) or more sources of Grade “A” raw milk received from other IMS listed sources.

When receiving and/or transfer station wish a separate IMS listing and receive Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and/or retort processed after packaging from one (1) or more IMS listed sources for trans-shipment, the procedures to be followed shall be that of Section H., 2., c.3.).

NOTE: For all of the ratings identified under this Item, if the ER for the IMS listed milk shipper is less than ninety percent (<90%), then the IMS listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

c. Milk Plant

1.) Attached Grade “A” Raw Milk Supply Only:

A milk plant with a single source of Grade “A” raw milk, both under the jurisdiction of the same Regulatory Agency.

Following the computation of the Sanitation Compliance Rating SCR on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, and FORM FDA 2359L-STATUS OF MILK PLANTS, and the ER from Parts I, II and III of on FORM FDA 2359j-MILK
SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date shall be the date of the first day of the rating of either the dairy farms (BTU) or milk plant, whichever is earliest in time. Both the milk plant and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the IMS List.

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

2.) Attached Grade “A” Raw Milk Supply and Unattached Grade “A” Raw Milk Supplies:

A milk plant with a source of Grade “A” raw milk under the jurisdiction of the same Regulatory Agency as the milk plant and one (1) or more sources of Grade “A” raw milk from other separate rated and IMS listed sources.

The raw milk SCR and earliest rating date shall be reported in the following manner:

The SCR of the attached supply of Grade “A” raw milk shall be reported as the raw milk SCR for the shared IMS listing. The earliest rating date shall be the date of the first day of the rating of either the dairy farm(s) (BTU) or milk plant, whichever is earliest in time. Both the milk plant and the attached supply of Grade “A” raw milk shall have attained an acceptable SCR and ER necessary for inclusion on the IMS List. All unattached Grade “A” raw milk supplies shall have an IMS listing. If Grade “A” raw milk is received from a source that is not IMS listed, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified and the milk plant and the attached supply of Grade “A” raw milk included in the shared IMS listing shall be withdrawn from the IMS List.

Following the computation of the Sanitation Compliance Rating SCR on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRAPASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING; and FORM FDA 2359L-STATUS OF MILK PLANTS, and the ER from Parts I, II and III of on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date and the Raw Milk Sanitation Compliance Rating SCR shall be computed by the following method: The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. In addition, the name of each unattached IMS listed raw milk shipper, during the thirty (30) days preceding the rating, along with the SCR and the Expiration Rating Date of each IMS listed raw milk shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s
All unattached supplies shall have a Sanitation Compliance Rating of ninety percent (90%) or greater. The Sanitation Compliance Rating of the attached supply shall be reported as the Raw Milk Sanitation Compliance Rating for the milk plant. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. In addition, the name of each unattached shipper, during the thirty (30) days preceding the rating, along with the Sanitation Compliance Rating and Date of Rating of each shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. If milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%), the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be notified and the milk plant shall be immediately withdrawn from the IMS List.

**NOTE:** If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

3.) Unattached Grade “A” Raw Milk Supplies Only:

A milk plant with one (1) or more sources of Grade “A” raw milk received from other rated and IMS listed sources.

The milk plant’s SCR and earliest rating date shall be reported in the following manner:

The calculated SCR of the milk plant shall be reported as the milk plant’s SCR for the IMS listing. The earliest rating date shall be the date of the first day of the rating. The milk plant shall have attained an acceptable SCR and ER necessary for inclusion on the IMS List. All unattached Grade “A” raw milk supplies shall have an IMS listing. If Grade “A” raw milk is received from a source that is not IMS listed, the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified and the milk plant shall be withdrawn from the IMS List.

Following the computation of the Sanitation Compliance Rating milk plant’s SCR on FORM FDA 2359L-STATUS OF MILK PLANTS and the milk plant’s ER from Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data SCR and ER shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The earliest rating date and the Sanitation Compliance Rating shall be computed by one (1) of in the following two (2) options manner:
NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

A.) Option 1: If all raw milk sources have a published, or submitted for publication, Sanitation Compliance Rating of ninety percent (90%) or greater and the milk plant desires to be listed with the milk plant rating date, then the raw milk SCR shall be reported as ninety percent (90%), or ninety percent (90%)-Outside Sources or listed with an asterisk (*), which denotes all Grade “A” raw milk supplies are ninety percent (90%) or greater IMS listed on. This shall eliminate the need for frequent updating of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT by the Rating Agency. Certain precautions shall be taken to ensure that the raw supply remains at or above the required listed ninety percent (90%) Sanitation Compliance Rating. The In addition, the name of each unattached IMS listed raw milk shipper, of raw milk for during the thirty (30) days preceding the rating shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT, along with their the Sanitation Compliance Rating SCR and the Expiration Rating Date of each unattached IMS listed raw milk shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT. The milk plant shall be immediately withdrawn from the IMS List when milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%). The appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified shall either of the above events occur.

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B.) Option 2: If the milk plant desires to be listed with the actual Sanitation Compliance Rating of the raw milk, a weighted average of all raw milk sources, the requirements of the preceding Option shall also apply except that:

(i) The earliest rating date of any of the raw milk sources or the milk plant, whichever is earliest in time, shall be shown as the earliest rating date on FORM FDA 2359i-INTERSTATE MILK SHIPPER’s REPORT.
(ii) The Raw Milk Sanitation Compliance Rating shall be prorated on a weighted basis as follows:

Supply Sanitation Compliance Rating X Percent of Supply =

Unattached Supply #1: 95 X .20 = 19
Unattached Supply #2: 90 X .35 = 31.5
Unattached Supply #3: 92 X .45 = 41.4

Total = 91.9
Raw Milk Sanitation Compliance Rating = 92%
The SRO shall re-compute the Raw Milk Sanitation Compliance Rating whenever any of the raw milk sources is re-rated and a new FORM FDA 2359- INTERSTATE MILK SHIPPER’s REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

NOTE: For all of the ratings identified under this Item, if the ER for the IMS listed milk shipper is less than ninety percent (<90%), then the IMS listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

NOTE: The acceptance of Grade “A” milk, which has a Sanitation Compliance Rating of less than ninety percent (90%), or is from an unlisted source that is not IMS listed, is considered a violation of the agreed upon provisions of Options 1 and 2 Section 11. of the Grade “A” PMO and shall initiate an immediate withdrawal of the milk shipper the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified and the milk shipper shall be withdrawn from the IMS List.

The utilization of Grade “A” milk from a separately rated an IMS listed source which has an Enforcement Rating ER of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating ER of less than ninety percent (90%), following a rating with an Enforcement Rating ER of less than ninety percent (90%), is considered a violation of Section 11. of the Grade “A” PMO and shall initiate an immediate withdrawal of the milk shipper the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified and the milk shipper shall be withdrawn from the IMS List.

MAKE THE FOLLOWING CHANGES TO FORM FDA 2359L-STATUS OF MILK PLANT (10/2015)

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

Bacterial Count and/or Drug Residue Analysis*
Coliform Count and/or Phosphatase Analysis*

FDA requests the Chair to assign to the NCIMS MMSR Committee and HACCP Implemental Committee to work with FDA the task of conducting a comprehensive and thorough review of the MMSR and to submit a Proposal to the 2019 Conference that will provide a proposed solution that will provide clarity, consistency and uniformity to text contained throughout the MMSR.

Grant FDA editorial license to work with the NCIMS Documents Review Committee to add “IMS” before listing, “Grade “A”” before milk and/or milk products, Sanitation Compliance Rating (SCR), Enforcement Rating (ER) and other editorial corrections that are identified in this Proposals, which may have been missed, wherever appropriate throughout the MMSRt to produce a more consistent and uniformly worded MMSR.
Note: This Proposal shall take immediate effect upon the issuance of the IMS-a Actions from the 2017 National Conference on Interstate Milk Shipments following FDA’s concurrence with the NCIMS Executive Board.

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

Modify and make the definition of “Officially Designated Laboratories the same in the PMO and EML.

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

Definitions were placed into NCIMS documents at the 2015 Conference. This proposal modifies and makes the definition uniform in the PMO and EML.

This change has no public health significance.
## C. Proposed Solution

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

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**SECTION 1. DEFINITIONS ...**

*Page 10:*

**NN. OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency or Milk Laboratory Control Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues and bacterial limits. This may include biological, chemical and/or physical testing as regulated under the PMO and related documents.

**MAKE THE FOLLOWING CHANGES TO THE 2015 EML**

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

**SECTION 1: DEFINITIONS ...**

*Page 4:*

10. **OFFICIALLY DESIGNATED LABORATORY:** A commercial laboratory authorized to do official work by the Regulatory Agency or Milk Laboratory Control Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues. This may include biological, chemical and/or physical testing as regulated under the PMO and related documents.
Name: Frank Barcellos
Agency/Organization: NCIMS Laboratory Committee
Address: ________________________________
City/State/Zip: __________________________
Telephone No.: 503-986-4724      E-mail Address: fbarcellos@oda.state.or.us
A. Summary of Proposal

To add the 3M™ Petrifilm™ Rapid Aerobic Count Plate to the EML as a method for the enumeration of total aerobic count from raw cow and goat milk, as well as pasteurized milk and milk products.

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

The 3M Petrifilm Rapid Aerobic Count Plate method is a new method. This method has been evaluated in a variety of matrices, including milk and milk products, in the AOAC Performance Tested Method (PTM) Program and was awarded PTM status (certificate #121403). This method was also evaluated in the AOAC Official Methods® of Analysis (OMA) Program and was assigned AOAC Official Methods number 2015.13. This method was recently evaluated in an FDA/NCIMS protocol, and a 2400 form will be presented for this method.
### C. Proposed Solution

Changes to be made on page(s):  Pages13-15, and page v in the Acronyms/Abbrevs of the (X - one of the following):

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To add the 3M™ Petrifilm™ Rapid Aerobic Count Plate to the EML as a method for the enumeration of total aerobic count from raw cow and goat milk, as well as pasteurized milk and milk products.

Name: Robert Jechorek

Agency/Organization: 3M Food Safety

Address: 3M Center, Bldg. 260-06-B-01

City/State/Zip: St. Paul, MN 55144

Telephone No.: 651-733-9764 E-mail Address: rpjechorek@mmm.com
A. Summary of Proposal

Change the way milk laboratory analyst split sample performance is determined from the current limits system to the systems based on commonly accepted international standards and guidelines. Evaluation criteria of split sample results vary on the type of data such as qualitative (Found or Not Found) or quantitative data.

The quantitative results of each certified analyst shall meet acceptance criteria determined by protocols based on ISO 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories. Generally, various international standards and guidelines do not address comparison of qualitative proficiency testing studies.

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

No direct public health significance. This change will bring the NCIMS Milk Laboratory Split Sample Program in line with how other programs determine performance of analysts.

Proficiency testing (PT) studies can be used to evaluate laboratories as a whole, teams within a whole laboratory, and/or individual analysts. Studies can be designed to evaluate the proficiency of the various types of participants described, but PT studies in the milk program are typically designed to evaluate performance of individual analysts. Evaluation of analysts is a requirement of regulatory programs and allows program managers to identify problem areas and determine if they are systematic, related to training, program-wide, or method related. Performance of individual analysts within a laboratory is indication of overall quality assurance system of the laboratory. These proposed procedures for the analysis of PT data are designed based on international data standards, review of the literature, and regulatory
guidelines. Well-defined procedures based on the current and up to date scientific methods for the analysis of qualitative PT data will enable PT providers to objectively evaluate participant performance.

Definitions


b. Qualitative data- descriptive and reported on a categorical or ordinal scale, e.g. identity of micro-organisms, or by identification of the presence of a specific measurand (such as a drug or a grading of a characteristic). Assessment of performance by statistical analysis may not be appropriate for qualitative examinations.

c. Quantitative data- numerical and are reported on an interval or a ratio scale. Tests for quantitative measurement may vary in their precision, trueness, analytical sensitivity, and specificity. In quantitative proficiency testing studies, numerical results are usually analyzed statistically.

d. Qualitative Method- results are typically yes or no, detected or not detected (ISO 22117:2010 8.4.1).

e. Limit of Detection- the lowest concentration level that can be determined statistically different from a blank at a specified level of confidence (ORA 5.4.5 2014).

f. Fractional Recovery- Set of samples which yield a partial number of positive determinations and a partial number of negative determinations within a replicate set of samples (FDA OFVM 2015).

g. Assigned Value- value attributed to a particular property of a proficiency test sample (ISO 17043:2010 3.1).

The purpose of proficiency testing is to assess how proficient participants are in achieving the “correct” result. However, in many proficiency testing studies, it is not possible to know the “correct” result, as numerous participants may all examine the same test material and all return a slightly different result. Instead, an estimate of the “correct” or “true” result should be made and this is referred to as the “assigned value”. The assigned value may be determined in a number of ways, as described in ISO/IEC 17043:2010, B.2 and ISO 13528.”- ISO 22117:2010 8.3.3.

h. Consensus Value- based on collaborative experimental work under the auspices of a scientific or technical group (ISO 3534.2: 20063.2.7).

i. z-score- standardized measure of laboratory bias, calculated using the assigned value and the standard deviation for proficiency assessment.

j. Consensus agreement- at least 80% agreement across all test results.

k. Expert Laboratory- experts that have demonstrable competence in the determination of the measurand(s) under test, using validated methods known to be highly accurate and comparable to methods in general use (ISO 17043:2010 B.2.1).

l. Proficiency Testing Round- single complete sequence of distribution of
proficiency test samples, and the evaluation and reporting of results to the participants (ISO 17043:2010 3.10).

m. Combined Performance Score- Performance may be evaluated on the basis of more than one result in a single proficiency testing round. This occurs when there is more than one proficiency test sample for a particular measurand, or a family of related measurands. In PT studies with multiple measurands and/or PT samples, the combined performance score is calculated for one measurand across multiple samples for the single PT round. This would be done to provide a more comprehensive evaluation of performance (ISO 13528: 2015 9.9, ISO 17043:2010 B.3.3).

Materials Required

a. Microsoft Excel
b. Statistical program/package capable of robust mean and standard deviation calculations.

Procedure

a. Type of Proficiency Testing Study
1. PTs fall into two broad categories: method specific and method independent. In method specific PT studies, participant results are evaluated separately based on method or class of method used. Classes of methods are evaluated together because they employ the same technologies or use similar procedures. In method independent PT studies, all results are analyzed together irrespective of method. The PT provider may decide to analyze methods separately in method independent PT studies based on obvious differences in detection from method to method or expert judgement.

2. PT studies administered in the FDA milk program consist of both method dependent/independent. Depending on the distribution of results (unimodal, bi-modal or multi-modal) results analyzed together with or without consideration for method. Instances in which results may be analyzed according to method/method class are those in which differences in limits of detection are known or methods are not well classified.

b. Determination of Assigned Value and Standard Deviation for Quantitative Data
1. The robust mean ($x_{pt}$) and standard deviation of the PT ($\sigma_{pt}$) are calculated according to Algorithm A and $x_{pt}$ is used as the assigned value for quantitative data. At least 80% of participant must submit quantitative results in order for the statistical calculations for $x_{pt}$ and $\sigma_{pt}$ to be executed. If this criterion is not met, those quantitative results will not be scored.

2. Algorithm A according to ISO 13528:2015 is used to calculate $x_{pt}$ ($x^*=$ robust average) and $\sigma_{pt}$ ($s^*=$ robust standard deviation). Other options for calculating mean and standard deviation are outlined in ISO 13528:2015, Algorithm A is used by FDA/LPET as it is a statistical method used by many PT providers domestically and internationally.
Calculations for microbiological testing are typically carried out on data that have been log transformed. Calculations for chemical testing are typically carried out on data that have undergone no transformation. Along with $x_{pt}$ and $\sigma_{pt}$, values for standard uncertainty ($u(x_{pt})$) divided by $\sigma_{pt}$ are calculated to ensure use of z-scores is appropriate. When $u(x_{pt})/\sigma_{pt} \leq 0.3$, the uncertainty of the assigned value may be considered to be negligible. If $u(x_{pt})/\sigma_{pt} > 0.3$, either $z$’ scores will be calculated ($z_i' = (x_i - x_{pt}) / (\sqrt{\sigma_{pt}^2 + u^2(x_{pt})})$) to take into account uncertainty of the assigned value or participants will be informed that uncertainty of the assigned value is not negligible and impact on scoring will be addressed.

c. Performance Evaluation for Quantitative Data

1. The z-score value summarizes how many standard deviations from the mean the reported value is located. This is known as standardizing, thus, analysts receive standard z-scores. The formula for z-score calculation is as follows: $z_i = (x_i - x_{pt})/\sigma_{pt}$ (where $x_i$ is the reported value, $x_{pt}$ is the PT mean/assigned value, and $\sigma_{pt}$ is the standard deviation for the PT, also referred to as target s.d.) (ISO 13528:2015). Data with a normal distribution have 95% of values within 2 $\sigma$ of the mean and 99.7% of values within 3 $\sigma$ (ISO 22117). According to ISO guidelines, results with a z-score greater than $|2|$ are considered questionable because only 5% of correct measurements are expected to be that different from the assigned value. Results with a z-score greater than $|3|$ are considered unsatisfactory because only 0.3% of correct measurements are expected to be that different from the assigned value (see ISO/IEC 17043:2010, B.4).

2. The interpretation of z-scores is as follows:
   - A z-score where $|z| \leq 2$ is acceptable and indicates that the performance of the analyst or laboratory is satisfactory.
   - Yellow= analysts/labs with z-scores $2 < |z| < 3$ are given a “warning signal” (ISO 13528)
   - Red= analysts/labs with z-scores $|z| \geq 3$ are given an “action signal” (ISO 13528)
   - * = Excluded from scoring because <80% of participants have submitted quantitative results for a single sample. The interlaboratory agreement is not sufficient to assign scores/performance indicators to participants (42 CFR §493.911(c).1).

d. Determination of Assigned Value for Qualitative Data

1. Assigned values are determined by one of the following (ISO 13528:2015 11.3.1):
   - participant consensus
   - expert laboratory results
• performance criterion based on expert judgement

a. Participant Consensus: The consensus value for qualitative PT studies conducted by the FDA Moffett Campus PT Laboratory is defined as 80% agreement of responses (per sample) (ISO 17043:2010 B.2.4). Consensus for a particular sample must be at least 80% for accurate scoring of results (42 CFR §493.911(c).1). The assigned value is determined using the consensus results of participants and the results of expert lab(s).

*In those PT samples where consensus among participant results is less than 80%, participant performance will not be evaluated. These guidelines accommodate for situations in which an analyte was spiked, but recovery is fractional among participants possibly due to differences in methodology, inhomogeneity, instability, etc.

b. Expert Laboratory Results: The results from PT provider laboratory may be considered in absence of equivalent to those of an expert, or reference, laboratory. Results from three separate sets of analyses will be considered during the determination of assigned values for qualitative PTs:

- Bulk scale trials
- Pre-shipment analytical tests
- Post-shipment analytical tests

c. Performance Criterion based on Expert Judgement: It is preferred that expert judgement comes from a panel or advisory group of qualified experts. In some cases, a single expert may be designated to determine the assigned value. Significant disagreement among a group of qualified experts for a PT sample must be noted, and if agreement cannot be reached, the PT sample will not be used to evaluate participant performance.

2. The evaluation of participant performance in qualitative PT studies is often dependent on the nature of the PT study report and the objective of the study. Therefore, the objective of the PT study and method for determining assigned value will be documented in the PT Planning prior to final shipment of PT samples. Proper planning will ensure the evaluation criteria for the PT scheme meets the objectives of the PT scheme. The origin or source of the final PT samples will also be documented in the PT Planning for traceability.

e. Performance Evaluation for Qualitative Data

1. The technique used by the FDA/LPET Moffett Campus PT Laboratory to analyze qualitative data is to compare participant results with assigned values (ISO/IEC 17043:2010 B.3.2.1).
2. Most reports for PT rounds involving qualitative data will employ the following performance indicators with color coding (deviation from this scoring scheme is at the discretion of the PT provider and must be documented in the PT Planning Record with technical justification):

- **Red** = Action Signal, reported result does not agree with assigned value and is unsatisfactory. Warrants corrective action at the discretion of technical advisory groups, program managers, or laboratory directors.
- **Yellow** = Warning Signal, reported result is in partial agreement with assigned value. Under most circumstances, the warning signal is not counted as unsatisfactory performance and not counted against the participant in the generation of combined performance scores. Participants are advised to check their procedures following warning signals to avoid future problems (ISO 13528: 2015 9.4.2).
- *** = Excluded from scoring, reported results from all participants on a single sample have <80% consensus. The interlaboratory agreement is not sufficient to assign scores/performance indicators to participants (42 CFR §493.911(c).1).**

f. Combined Performance Scores

1. Combined performance scores will be assigned to each participant for a single PT round.

- **Purpose:** Evaluation of performance can be made based on more than one result in a single PT round or study. This evaluation may occur when there is more than one PT item for a particular measurand, or a family of related measurands (ISO/IEC 17043:2010 B.3.3). The combined performance scores will be assigned to give a comprehensive evaluation of performance for each participant in a PT round or study. Combined performance scores will be assigned based on number of acceptable results out of total results reported per analyst. Limits of acceptability (i.e. allowable number of unacceptable or incorrect results) will be based on regulatory guidelines and PT objectives.

Use of combined performance scores also allows the PT provider to distribute some challenging samples with analyte levels near the limit of detection without penalizing analysts when testing samples that may have fractional recoveries.

- **Responses:** Acceptable are those results that are in agreement with the assigned value for a particular sample (ISO/IEC 17043:2010 B.3.2.1). Typically, those results with no color or a yellow warning signal will be counted as acceptable.

   **Assignment:** Combined performance scores are assigned when
multiple replicates for each PT sample are reported or when multiple PT samples are provided. Combined performance scores may be calculated by summarizing the proportion of correct results, calculating the sum of performance scores across all PT samples, or providing the count of each level of performance allocated (ISO 13528:2015 11.4.4, ISO/IEC 17043:2010 B.3.3). The combined performance score for most PT rounds will be evaluated as total number of unacceptable results allowed across all samples in a single PT round (ISO/IEC 17043:2010 B.3.3). The combined performance score criteria for satisfactory analyst performance for common Moffett Center PT studies are described below.

• For satisfactory analyst performance in the Milk Vitamins PTs:
  • analysts can have 1 result with an action signal/unsatisfactory result when 5 - 10 samples are analyzed
  • analysts can have 2 results with action signals/unsatisfactory results when 11 - 20 samples are analyzed
  • analysts can have 3 results with action signals/unsatisfactory results when 21 - 30 samples are analyzed, and so on and so forth

  g. Examples
  1. Example 1: 8 samples that are positive for Coliforms are sent out for a PT round. A participant submits results that indicate positive detection in 7 out of 8 samples. This participant is given a combined performance score of satisfactory because 7 out of 8 submitted results were acceptable, or in agreement with the assigned value and the analyst can receive action signals for up to 7 out of 8 samples for satisfactory performance.
  2. Example 2: A PT designed to evaluate performance of Coliforms detection in milk for 5 samples is sent out. A total of 10 analysts in three different laboratories participate. The table below lists the analysts as “laboratory ID number (LIN)- analyst ID number (AIN)”, assigned values for the 5 samples (+ = detected, - = not detected), the reported results for each analyst, yellow warning signals, red action signals, method used by each analyst, and combined performance scores.

<table>
<thead>
<tr>
<th>LIN-AIN</th>
<th>S1 AV (consensus)= +</th>
<th>S2 AV (consensus)= +</th>
<th>*S3 AV (consensus)= No consensus</th>
<th>S4 AV (consensus)= +</th>
<th>S5 AV (consensus)= -</th>
<th>Method Used by Analyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-1</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>12-2</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>13-1</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>13-2</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>1</td>
</tr>
<tr>
<td>15-1</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>3</td>
</tr>
</tbody>
</table>
Example 2 illustrates some key points related to combined performance scoring. First, analysts are not assigned scores for Sample 3 because agreement among analyst results is < 80%. When participant consensus is used to determine assigned values, Moffett PT requires that ≥80% of analyst results must be in agreement to reach consensus (MC-QA-PT-SOP-4.8-Statistical Analysis and Reporting). Therefore, combined performance scores are evaluated on a total of 4 samples rather than 5. This means analysts must have 1 or fewer action signals to receive a combined performance score of satisfactory (S). Advisory groups, program managers, and laboratory directors may want to assess problem areas/trends in unsatisfactory results. In this example, all analysts from labs 12, 15, and 20 received satisfactory combined performance scores, indicating proficiency in the detection of Coliforms in milk. Both analysts in lab 13 received unsatisfactory combined performance scores which may warrant further investigation by the laboratory director. In sample 3 where only 60% of analysts detected Coliforms, all results of - were reported from analysts using method 1. The advisory group, program manager, or laboratory director may want to gather information on how well method 1 is characterized for Coliform detection in milk.

3. Example 3: A PT was shipped with 6 milk samples to 10 laboratories with a total of 17 analysts for quantitative analysis of vitamin A. The table below lists the summary statistics for the PT.
The following table lists the participant results along with their z-scores. In this table, analysts are listed as “laboratory ID number (LIN)- analyst ID number (AIN)”.

<table>
<thead>
<tr>
<th>LIN/AIN</th>
<th>S1 Results</th>
<th>Z score</th>
<th>S2 Results</th>
<th>Z score</th>
<th>S3 Results</th>
<th>Z score</th>
<th>S4 Results</th>
<th>Z score</th>
<th>S5 Results</th>
<th>Z score</th>
<th>S6 Results</th>
<th>Z score</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-5</td>
<td>950.00</td>
<td>0.06</td>
<td>1200.00</td>
<td>0.44</td>
<td>2500.00</td>
<td>0.26</td>
<td>2600.00</td>
<td>0.23</td>
<td>1000.00</td>
<td>0.37</td>
<td>1200.00</td>
<td>0.38</td>
</tr>
<tr>
<td>11-7</td>
<td>1046.00</td>
<td>0.52</td>
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<td>2543.00</td>
<td>0.33</td>
<td>2588.00</td>
<td>0.21</td>
<td>978.00</td>
<td>0.25</td>
<td>1197.00</td>
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</tr>
<tr>
<td>11-8</td>
<td>1061.00</td>
<td>0.59</td>
<td>1192.00</td>
<td>0.41</td>
<td>2655.00</td>
<td>0.52</td>
<td>2720.00</td>
<td>0.46</td>
<td>1012.00</td>
<td>0.43</td>
<td>1164.00</td>
<td>0.24</td>
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<td>16-1</td>
<td>897.00</td>
<td>-0.19</td>
<td>1078.00</td>
<td>-0.04</td>
<td>2134.00</td>
<td>-0.36</td>
<td>2294.00</td>
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<td>-0.20</td>
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<tr>
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<td>0.98</td>
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<td>1.13</td>
<td>1983.00</td>
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</tr>
<tr>
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<td>0.41</td>
<td>1132.00</td>
<td>0.17</td>
<td>2416.00</td>
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<td>2448.00</td>
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<td>1016.00</td>
<td>0.45</td>
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<tr>
<td>31-1</td>
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<td>1124.00</td>
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<td>2297.00</td>
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<td>1169.00</td>
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<td>2522.00</td>
<td>0.30</td>
<td>2673.00</td>
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<td>0.91</td>
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<td>-1.21</td>
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<tr>
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<td>1942.00</td>
<td>3.35</td>
<td>3932.00</td>
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<td>1942.00</td>
<td>3.27</td>
</tr>
<tr>
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<td>975.70</td>
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<td>1192.90</td>
<td>0.41</td>
<td>2958.30</td>
<td>1.03</td>
<td>3198.20</td>
<td>1.35</td>
<td>1051.90</td>
<td>0.64</td>
<td>1184.40</td>
<td>0.32</td>
</tr>
<tr>
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<td>-0.95</td>
<td>671.00</td>
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<td>1731.00</td>
<td>-1.03</td>
<td>1865.00</td>
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<td>-1.07</td>
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<td>683.00</td>
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<td>783.00</td>
<td>-1.24</td>
</tr>
<tr>
<td>996-1</td>
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<td>3.75</td>
<td>1593.60</td>
<td>1.98</td>
<td>3238.43</td>
<td>1.50</td>
<td>3174.80</td>
<td>1.31</td>
<td>970.27</td>
<td>0.21</td>
<td>1251.77</td>
<td>0.59</td>
</tr>
</tbody>
</table>

C. Proposed Solution

Changes to be made on page(s): iv, v, 7, 13-15, 18, 31 and 32 of the (X - one of the following):

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

**MAKE THE FOLLOWING CHANGES TO THE 2015 EML**

Strike through text to be deleted and underlined text to be added.
ABBREVIATION AND ACRONYMS …

IS (Industry Supervisor)
ISO (International Standards Organization) …

Procedures (Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments)
PT (Proficiency Testing)
QA (Quality Assurance) …

5. Analysts meet the performance levels of the proficiency testing (PT) program (SECTION 3). The LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved. …

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SPLIT SAMPLE ANALYSIS
(Proficiency Testing Studies)

Evaluation criteria of split sample results vary on the type of data such as qualitative (Found or Not Found) or quantitative data. The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Peel Plate AC (PPAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), TEMPO AC (TAC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), and Electronic Phosphatase Count, and Vitamins A and D3 results are quantitatively reported. Each certified analyst shall fall within the limits shown in Table 2, page 32. The vitamin A and D3 results of each analyst shall be calculated by z-scores, which are based on ISO Standards, and are calculated for individual set of split samples. The quantitative results of each certified analyst shall meet acceptance criteria determined by protocols based on International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories. Generally, various international standards and guidelines do not address comparison of qualitative proficiency testing studies.

Determination of Assigned Value and Standard Deviation and Evaluation of Analysts Reporting Quantitative Data:

1. The robust mean \( (x_{pt}) \) and standard deviation of the PT \( (\sigma_{pt}) \) are calculated according to Algorithm A and \( x_{pt} \) is used as the assigned value for quantitative data. At least 80% of participant must submit quantitative results in order for the statistical calculations for \( x_{pt} \)
and $\sigma_{pt}$ to be executed. If this criterion is not met, those quantitative results will not be scored.

2. Algorithm A according to ISO 13528:2015 is used to calculate $x_{pt}$ ($x^* =$ robust average) and $\sigma_{pt}$ ($\sigma^* =$ robust standard deviation). Other options for calculating mean and standard deviation are outlined in ISO 13528:2015. Calculations for microbiological testing are typically carried out on data that have been log transformed. Calculations for chemical testing are typically carried out on data that have undergone no transformation. Along with $x_{pt}$ and $\sigma_{pt}$, values for standard uncertainty ($u(x_{pt})$) divided by $\sigma_{pt}$ are calculated to ensure use of z-scores is appropriate. When $u(x_{pt})/\sigma_{pt} \leq 0.3$, the uncertainty of the assigned value may be considered to be negligible. If $u(x_{pt})/\sigma_{pt} > 0.3$, either $z'$ scores will be calculated ($z'_i = (x_i - x_{pt}) / \sqrt{\sigma_{pt}^2 + u^2(x_{pt})}$) to take into account uncertainty of the assigned value or participants will be informed that uncertainty of the assigned value is not negligible and impact on scoring will be addressed.

3. Performance Evaluation for Quantitative Data

   a. The z-score value summarizes how many standard deviations from the mean the reported value is located. This is known as standardizing, thus, analysts receive standard z-scores. The formula for z-score calculation is as follows: $z_i = (x_i - x_{pt})/\sigma_{pt}$ (where $x_i$ is the reported value, $x_{pt}$ is the PT mean/assigned value, and $\sigma_{pt}$ is the standard deviation for the PT, also referred to as target s.d.) (ISO 13528:2015). Data with a normal distribution have 95% of values within 2 $\sigma$ of the mean and 99.7% of values within 3 $\sigma$ (ISO 22117). According to ISO guidelines, results with a z-score greater than $|2|$ are considered questionable because only 5% of correct measurements are expected to be that different from the assigned value. Results with a z-score greater than $|3|$ are considered unsatisfactory because only 0.3% of correct measurements are expected to be that different from the assigned value (see ISO/IEC 17043:2010, B.4).

Determination of Assigned Value and Evaluation of Analysts reporting Qualitative Data:

1. Assigned values are determined by one of the following (ISO 13528:2015 11.3.1); participant consensus, expert laboratory results and performance criterion based on expert judgement

   a. Participant Consensus: The consensus value for qualitative PT studies conducted by the FDA Moffett Campus PT Laboratory is defined as 80% agreement of responses (per sample) (ISO 17043:2010 B.2.4). Consensus for a particular sample must be at least 80% for accurate scoring of results (42 CFR §493.911(c).1). The assigned value is determined using the consensus results of participants and the results of expert lab(s). In those PT samples where consensus among participant results is less than 80%, participant performance will not be evaluated. These guidelines accommodate for situations in which an analyte was spiked, but recovery is fractional among participants possibly due to differences in methodology, inhomogeneity, instability, etc.

   b. Expert Laboratory Results: The results from PT provider laboratory may be
considered in absence of equivalent to those of an expert, or reference, laboratory. Results from three separate sets of analyses will be considered during the determination of assigned values for qualitative PTs: Bulk scale trials, Pre-shipment analytical tests and Post-shipment analytical tests.

c. Performance Criterion based on Expert Judgement: It is preferred that expert judgement comes from a panel or advisory group of qualified experts. In some cases, a single expert may be designated to determine the assigned value. Significant disagreement among a group of qualified experts for a PT sample must be noted, and if agreement cannot be reached, the PT sample will not be used to evaluate participant performance.

Evaluation of Analysts:

The evaluation of participant performance in qualitative PT studies is often dependent on the nature of the PT study report and the objective of the study. Therefore, the objective of the PT study and method for determining assigned value will be documented in the PT Planning prior to final shipment of PT samples. Proper planning will ensure the evaluation criteria for the PT scheme meets the objectives of the PT scheme. The origin or source of the final PT samples will also be documented in the PT Planning for traceability.

The interpretation of analyst results is as follows:

a. No color = Analysts/labs with z-score where $|z| \leq 2$ is acceptable and indicates that the performance of the analyst or laboratory is satisfactory.

b. Yellow = Analysts/labs with z-scores $2 < |z| < 3$ are given a “warning signal” (ISO 13528)

c. Red = Analysts/labs with z-scores $|z| \geq 3$ are given an “action signal” (ISO 13528)

Page 14:

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis is recommended.

2. Determine the logarithm of each test sample for the SPC, PAC, PPAC, PLC, BSC, TAC, SPLC, DMSCC, ESCC and Electronic Phosphatase Count using a table of common logarithms and list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for each sample.

3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L1). Rejection results are identified by applying to each analyst's result the limit (sample mean ± L1). Results falling outside the limit are classified as outliers and are unacceptable. Note, by sample and test, the analysts who have results
4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean ± L2). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.

5. Using Table 3, page 32, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L1 or L2 or both limits.

6. Analysts certified for vitamin analysis shall meet the acceptance criteria using z-scores.

72. An acceptable annual proficiency testing program for the BSC (all NCIMS approved models), shall meet the following applicable criteria.

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

(b) Split samples (minimum of fourteen (14)) shall be made up using BactoScan FC Blank solution and BSC Bacteria Control Samples.

(c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1 page 31.

8. The annual proficiency testing (PT) program for vitamins A and D3 shall be based on z-scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.

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ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the Grade “A” PMO shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the SPC, PAC, PPAC, PLC, BSC, TAC, SPLC, DMSCC, and ESCC and Electronic Phosphatase Count analysis, and BIOS approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3 Table 2, page 32.
2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using drug other than beta-lactam, samples shall be spiked in duplicate. See Table 32, page 32.

3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) within the specified limits in Table 2, page 32.

4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table 32, page 32.

5. CISs certified to perform Grade “A” PMO, Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 32, page 32.

6. Analysts certified to perform vitamins A and D₃ tests shall detect samples that contain vitamins A and D₃ and shall meet the acceptance limits and performance levels shown in Table 2, page 32, for the calculated z-scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations.

WATER MICROBIOLOGY …

Page 18:

SPLIT SAMPLE ANALYSIS

The multiple tube fermentation (Lauryl Tryptose Broth or Chromogenic substrate), membrane filtration and heterotrophic plate count result of each laboratory shall meet the criteria specified for microbiological split samples on pages 13 - xx fall within the limits shown in Table 2, page 32.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.

2. Determine the logarithm for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.

3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L₁). Rejection results are identified by applying to each laboratory's result the limit (sample mean ± L₁). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have
results outside of the limits.)

4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean ± L2). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.

52. Using Table 3, page 32, list indicate all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L1 or L2 or both limits.

63. Laboratories accredited for dairy water analysis shall meet the acceptance limits (L1 and L2) and performance levels shown in Tables 2 and 3 Table 2, page 32.

LABORATORY PERFORMANCE LEVEL

Laboratories accredited to perform the examinations of dairy water for coliforms required by the PMO shall meet the following performance levels on an annual basis.

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 32. …

---

Page 31:

**TABLE 1: RECOMMENDED SPLIT SAMPLE COMPOSITION**

<table>
<thead>
<tr>
<th>PRODUCTS</th>
<th>RECOMMENDED MINIMUM NUMBER OF SAMPLES</th>
<th>DUPLICATES</th>
<th>ANALYSIS</th>
<th>RECOMMENDED MINIMUM NUMBER OF PRODUCT SAMPLES ANALYZED</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVD, or 2%, or Skim</td>
<td>3</td>
<td>1</td>
<td>Plate Count /Coliforms</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Phosphatase</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamins</td>
<td>1-8</td>
</tr>
</tbody>
</table>

---

Page 32:
**TABLE 2: STATISTICAL LIMITS**

<table>
<thead>
<tr>
<th>TEST</th>
<th>REJECTION LIMIT 1 <em>(L₁)</em></th>
<th>REJECTION LIMIT 2 <em>(L₂)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Plate Counts</td>
<td>0.268</td>
<td>0.179</td>
</tr>
<tr>
<td>Direct Somatic Cell Count</td>
<td>0.300</td>
<td>0.200</td>
</tr>
<tr>
<td>Electronic Somatic Cell Count</td>
<td>0.212</td>
<td>0.143</td>
</tr>
<tr>
<td>Vitamins</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Electronic-Phosphatase Count</td>
<td>0.300</td>
<td>0.200</td>
</tr>
<tr>
<td>Dairy water MPN</td>
<td>0.949</td>
<td>0.632</td>
</tr>
<tr>
<td>Heterotrophic Plate Count</td>
<td>0.300</td>
<td>0.200</td>
</tr>
</tbody>
</table>

* To be used with logarithmic mean.
** Limits for vitamin test results shall be based on z-scores. Acceptable results shall be within plus or minus two (2) standard deviations.

**TABLE 32: MAXIMUM NUMBER OF UNACCEPTABLE RESULTS**

<table>
<thead>
<tr>
<th>NUMBER OF RESULTS PER TEST (N)</th>
<th>MAXIMUM NUMBER OF UNACCEPTABLE RESULTS PER TEST FOR APPROVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 – 10</td>
<td>1</td>
</tr>
<tr>
<td>11 – 20</td>
<td>2</td>
</tr>
<tr>
<td>21 – 30</td>
<td>3</td>
</tr>
</tbody>
</table>

Name: Dr. Thomas Graham

Agency/Organization: FDA/CFSAN/DFPST/LPET

Address: 6502 South Archer Rd.

City/State/Zip: Bedford Park, IL 60501

Telephone No.: (708) 924-0614 E-mail Address: Thomas.Graham@fda.hhs.gov
A. Summary of Proposal

To revise the EML (2015 Revision) to include the BactoCount IBC (BCC) and BactoCount IBCm (BCMC).

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

The BactoCount IBC and the BactoCount IBCm can produce bacterial counts with an accuracy, repeatability and reproducibility that is equal to or greater than traditional agar based methods and at the same time eliminate the need for serial dilutions, cut the time-to-result from 48 hours to 10 minutes, and minimize the effect of human error.
C. Proposed Solution

Changes to be made on page(s): p.3, p.11, p.13-16 of the (X - one of the following):

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

p.3
1. BACTOCOUNT INDUSTRY OPERATOR (BCIO): A person who operates a BactoCount IBC/IBCm under the supervision of a certified BactoCount analyst and analyzes samples for regulatory compliance.

p.11

APPROVAL OF BACTOCOUNT INDUSTRY OPERATORS

Approval of BactoCount Industry Operators (BCIO) shall be based on meeting the following requirements:

1. The industry operator shall complete the BCIO operating protocols, training and oversight specified in the training procedure document.

2. The laboratory shall maintain one (1) certified BactoCount analyst (see current FDA/NCIMS 2400 Form) for training and ongoing oversight of the BCIO(s).

3. Refer to the Bentley Instruments BactoCount IBC/IBCm BCIO Companion Protocol approved training procedures at the end of the BactoCount FDA/NCIMS 2400 Form.

4. The BCIO(s) meets the performance levels of the proficiency testing program (the examination of milk split samples)

5. Records are to be maintained for BCIO(s) oversight.

NOTE: A BCIO can analyze samples for regulatory compliance.

p.13
8. An acceptable annual proficiency testing program for the BactoCount IBC/IBCm (all NCIMS approved models), shall meet the following applicable criteria.

(a) The BactoCount IBC/IBCm (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BCIO using the procedures approved to operate the BactoCount IBC/IBCm and for which the analyst or BCIO has been certified/approved, respectively.

(b) Split samples (minimum of fourteen (14)) shall be made up using BactoCount Buffer Stock Solution or IBC Control Standard Buffer Solution and IBC Control Standard.
(c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1, page 31.

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Peel Plate AC (PPAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), BactoCount IBC Count (BCC), BactoCount IBCm Count (BCMC), TEMPO AC (TAC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), and Electronic Phosphatase Count result of each certified analyst shall fall within the limits shown in Table 2, page 32. The vitamin A and D3 results of each analyst shall be calculated by z-scores, which are based on ISO Standards, and are calculated for individual set of split samples.

p.14

2. Determine the logarithm of each test sample for the SPC, PAC, PPAC, PLC, BSC, BCC, BCMC, TAC, SPLC, DMSCC, ESCC and Electronic Phosphatase Count using a table of common logarithms and list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for each sample.

p.15

Analysts certified to perform the SPC, PAC, PPAC, PLC, BSC, BCC, BCMC, TAC, SPLC, DMSCC, ESCC and Electronic Phosphatase Count analysis, and BIOs approved to operate a BactoScan FC, and BCIOs approved to operate a BactoCount IBC/IBCm shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 32.

p.16

BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts.

BCIOs performance levels shall follow the performance procedures indicated above for fully certified analysts.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Dawn Terrell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency/Organization:</td>
<td>Bentley Instruments, Inc.</td>
</tr>
<tr>
<td>Address:</td>
<td>4004 Peavey Road</td>
</tr>
<tr>
<td>City/State/Zip:</td>
<td>Chaska, MN 55318</td>
</tr>
<tr>
<td>Telephone No.:</td>
<td>952-448-7600</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td><a href="mailto:dterrell@bentleyinstruments.com">dterrell@bentleyinstruments.com</a></td>
</tr>
</tbody>
</table>
A. Summary of Proposal

This proposal requests the formation of a Study Committee to update and make more complete the guidance for Dairy Farm Water Supply evaluation.

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

Actions have been proposed or taken against water supplies on routine dairy farm inspections and during Public Health Ratings that do not correspond to language in Item 8r “Water Supply” and Appendix D “Standards For Water Sources” of the 2015 PMO nor in the 2015 MMSR Appendix B “Table of Dairy Farm Water Supply Violations”. The proper placement of backflow preventers around plate heat exchangers is not clearly addressed nor is the regulation of pressure washers.

Outdated and incomplete resources are referenced in the PMO leading to misunderstanding of the regulations. The Drawings of Construction Details on pp.193-209 in Appendix D of the 2015 PMO are from an EPA resource published in 1973 and explanations are not provided for the drawings.

This has led to updated documents not referenced in the PMO and not accessible to all being
used regionally as enforcement guidance. Additionally, answers to questions in M-I’s are used for interpretation and enforcement, but have not been codified in the PMO.

Finally, the Major and Minor Debit Categories of the 2015 MMSR do not correspond to the language on the Dairy Farm Inspection Report. The inspection report only offers a 2 point debit for construction violations and the table specifies multiple 5 point debits.

C. Proposed Solution

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

____ 2015 PMO
____ 2015 EML
____ 2015 MMSR
____ 2400 Forms
____ 2015 Procedures
____ 2015 Constitution and Bylaws

NMPF requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The study committee is charged to update and make more complete guidances for Dairy Farm Water Supply evaluation, and may provide a report to the Conference at the biennial meeting in 2019 or a Conference proposal at NCIMS in 2019.

Name: NMPF NCIMS Committee
Agency/Organization: National Milk Producers Federation
Address: 2107 Wilson Blvd, Suite 600
City/State/Zip: Arlington, VA 22201
Telephone No.: 703-243-6111
E-mail Address: bbiczinski@nmpf.org
A. Summary of Proposal

This Proposal assigns to the NCIMS MMSR Committee the task of either developing a Milking Time Inspection Program or to eliminate Item 7-Milk time inspection program established on DAIRIES FARMS – PART I on FORM FDA 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (10/2013) and to redistribute the five (5) points between one (1) or more of the remaining Items under DAIRIES FARMS – PART I and to submit a Proposal addressing their decision proposed solution to the 2019 NCIMS Conference.

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

FDA’s Milk Safety Team (MST) has submitted Proposals over two previous NCIMS conferences to addressed this issue, either with the development of a Milk Time Inspection Program or to eliminate Item 7-Milk time inspection program established on DAIRIES FARMS – PART I on FORM FDA 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (10/2013) and to redistribute the five (5) points to one of the remaining Items under DAIRIES FARMS – PART I. Each time the MMSR has not been able to appropriately address the Proposal because of the lack of time to adequately review and recommend a milk time inspection program or to redistribute the five (5) points between one (1) or more of the remaining Items under DAIRIES FARMS – PART I. By assigning this to the MMSR Committee to work on during the time period between the 2017 Conference and the 2019 Conference this should provide them adequate time to make a decision to either develop a Milking Time Inspection Program or redistribute the five (5) points between one (1) or more of the remaining Items under DAIRIES FARMS – PART I.
C. Proposed Solution

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

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

FDA requests the Chair to assign to the NCIMS MMSR Committee the task of either developing a Milking Time Inspection Program or to eliminate Item 7-Milk time inspection program established on Dairies Farms – Part I on Form FDA 2359j-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (10/2013) and to redistribute the five (5) points between one (1) or more of the remaining Items under Dairies Farms – Part I and to submit a Proposal addressing their decision and proposed solution to the 2019 NCIMS Conference.

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

Approve a 2400 form for an automated, flow cytometry based individual bacteria count (IBC) method, BactoCount IBC (BCC), for raw commingled cow milk.

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

The BactoCount IBC (BCC) can produce bacterial counts with an accuracy, repeatability and reproducibility that is equal to or greater than traditional agar based methods and at the same time eliminate the need for serial dilutions, cut the time-to-result from 48 hours to 10 minutes, and minimize the effect of human error.
C. Proposed Solution

<table>
<thead>
<tr>
<th>Changes to be made on page(s):</th>
<th>New 2400 form</th>
<th>of the (X - one of the following):</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2015 EML</td>
<td></td>
</tr>
<tr>
<td>_______ 2015 MMSR</td>
<td>X 2400 Forms</td>
<td></td>
</tr>
<tr>
<td>_______ 2015 Procedures</td>
<td>2015 Constitution and Bylaws</td>
<td></td>
</tr>
</tbody>
</table>

BACTOCOUNT IBC
(Raw Commingled Cow Milk Only)

[Unless otherwise stated all tolerances are ±5%]

GENERAL REQUIREMENTS

1. Cultural Procedures, items 1-32, as appropriate
2. Sample Requirements, see CP items 33 & 34
   a. Raw milk tested only

PRE-REQUISITE

3. Comparative Test
   a. Test 25 samples in duplicate using the SPC (2400a) or PAC (2400a-4) and BactoCount IBC (BCC) methods
   b. Comparisons done by each analyst performing test
      1. Results must be shown to be acceptable before official tests may be performed by the analyst
   c. Copy of comparison and results in QC record (or easily accessible file in laboratory)
   d. Analysts certified for SPC or PAC methods
   e. Alternatively, a BactoCount Industry Operator (BCIO) can analyze samples for regulatory compliance
      1. Industry operator must complete the BCIO operating protocols, training and oversight. Records maintained
      2. Laboratory must maintain at least one certified BactoCount analyst
(item 3.a.b.c.d.) for training and ongoing oversight of the BCIO

3. Refer to BCIO approved training procedures at the end of this form

4. Records maintained for all BCIO oversight

4. Monitoring of Regulatory Cut-Off Level

a. Select 10 samples counting between 150,000 and 450,000 IBC/mL (50,000 and 150,000 CFU/mL) each month

b. Test each of these samples in duplicate (same dilution) using SPC or PAC and BCC

c. Report paired results (CFU/mL and IBC/mL) as specified by the FDA

APPARATUS

5. BactoCount IBC (BCC) Model

a. BCC 50 (speed 50 samples per hour)

b. BCC 100 (speed 100 samples per hour)

c. BCC 150 (speed 150 samples per hour)

REAGENTS

6. Purified Water, deionized (conductivity less than 2 μS/cm, see CP item 24.c.3)

7. BactoCount Reagents supplied by manufacturer

a. Nucleic Acid Marker

b. Enzyme

c. Solubilizer

d. Lysing Buffer Powder

e. Staining Buffer Part 1

f. Staining Buffer Part 2

g. RBS Cleaning Concentrate

h. Microspheres

i. Triton X-100
8. Bentley Disposable Filter Unit for Liquids, 0.2 μm

9. All Chemicals not Provided by Manufacturer, Analytical Grade

10. Stock Solutions

   a. Buffer Stock Solution

      1. Pour one bag of Lysing Buffer Powder (item 7d) into a container 10 L or larger

      2. Add 10 L purified water (item 6)

      3. Heat to 50°C and stir until completely dissolved

      4. Add one 10 mL vial of Solubilizer (item 7c)

      5. Mix until completely dissolved

      6. Store for up to 6 months at room temperature (< 25°C)

   Lab Prep. Date: __________ Exp. Date: __________

   b. Dye Stock Solution

      1. Pour Staining Buffer Part 1 (item 7e) and Staining Buffer Part 2 (item 7f) into a 1 L container

      2. Add 900 mL purified water (item 6)

      3. Mix until completely dissolved. Do not heat

      4. Add the Nucleic Acid Marker (item 7a), carefully rinsing all the contents of the vial into the solution with purified water (item 6)

      5. Add purified water (item 6) up to the 1000 mL mark

      6. Mix until completely dissolved. Do not heat

      7. Store in the dark for up to 6 months in the refrigerator (0-4.4°C)

   Lab Prep. Date: __________ Exp. Date: __________

   c. Microsphere Stock Solution

      1. Add one (1) drop of Microspheres (item 7h) to a 2 L container
2. Add 2 L purified water (item 6)

3. Add 20 mL Triton X-100 (item 7i)

4. Mix until completely dissolved. Do not heat

5. Store for up to 1 year in the refrigerator (0-4.4°C). Do not freeze

Lab Prep. Date: __________ Exp. Date: __________

11. Working Solutions

a. Incubation Reagent

1. Pour 1800 mL Buffer Stock Solution (item 10a), 100 mL Dye Stock Solution (item 10b) and 100 mL Enzyme (item 7b) into a 2 L container

2. Mix thoroughly

3. When not in use, store in refrigerator (0-4.4°C). Use within 7 days

Lab Prep. Date: __________ Exp. Date: __________

b. Carrier Fluid

1. Pour 400 mL RBS Cleaning Concentrate (item 7g) into a 20 L container

2. Add 19.6 L purified water (item 6)

3. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days

Lab Prep. Date: __________ Exp. Date: __________

c. Microsphere Working Solution

1. Pour 20 mL Microsphere Stock Solution (item 10c) and 180 mL purified water (item 6) into a 200 mL container

2. Mix thoroughly

3. Store for up to 6 months in refrigerator (0-4.4°C). Do not freeze

Lab Prep. Date: __________ Exp. Date: __________
4. Pour 60 mL Buffer Stock Solution (item 10a) into a container

2. Let the IBC Control Standard (item 7j) (V1) and the Buffer Stock Solution (item 10a) (V2) adjust to room temperature for 15 minutes

3. Using a disposable transfer pipette or pipet tip, transfer approximately 5 mL of fluid from V2 into V1. Let it dissolve for 2 minutes

4. Refill the pipette with clean fluid from V2

5. Pour the contents of V1 into V2. Use the contents of the pipette to rinse out V1 into V2. Mix gently

6. Let the mixture dissolve in V2 for 10 minutes ± 1 minute

7. Mix V2 gently

8. The rehydrated IBC Control Standard can be stored for up to 96 hours in the refrigerator (0-4.4°C)

Lab Prep. Date: __________ Exp. Date: __________

12. All Solution Containers Labeled with Solution Name, Date Prepared and Expiration Date (when relevant)

START-UP

13. Daily Instrument Start-up

a. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months

b. Check the filters (item 8) in positions F1, F2, F3 and CFP

   1. F1: changed within last 7 days and has no cracks
   2. F2: changed within last 14 days and has no cracks
   3. F3: changed within last 14 days and has no cracks
   4. CFP: changed within the last month and has no cracks

   c. Confirm that the incubation reagent (item 11a) is within expiration date. If not, discard and make a fresh mix
d. At the end of the incubation reagent intake line, replace the bottle containing purified water (item 6) with a bottle containing incubation reagent (item 11a)

e. Confirm that the carrier fluid (item 11b) is within expiration date. If not, discard and make a fresh mix

f. Check the syringes and seals for leaks

1. Confirm that no moisture has gathered under syringes in positions P9, P10, P11 and P12

g. Switch the system on

As the instrument warms up

h. Prime the incubation reagent minimum one (1) cycle

i. Check the instrument zero by running water samples

1. Fill a container (min. 200 mL) with purified water (item 6) and set it under the sample intake pipette

2. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is disabled

3. For the BCC 50 (item 5a) run 15 water samples, for the BCC 100 (item 5b) and BCC 150 (item 5c) run 33 water samples

4. Alternatively, fill 15 vials (for the BCC 50 (item 5a)) or 33 vials (for the BCC 100 (item 5b) and BCC 150 (item 5c)) with purified water (item 6) and place them in a rack

5. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is enabled

6. Run the batch

j. When the water samples have been tested, confirm that the average count is <5 K IBC

k. Prepare and analyze the Microsphere Working Solution (item 11c)

1. Confirm that the Microsphere Working Solution (item 11c) is within expiration date. If not, discard and make a fresh mix
2. Place a small container of the Microsphere Working Solution (item 11c) on the carousel deck

3. Pull the cytometer line out of its holder and place it directly into the Microsphere Working Solution (item 11c)

4. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples

5. Place the cytometer line back in its holder

I. When the Microsphere Working Solution (item 11c) has been analyzed, confirm that the instrument is stable and aligned

   1. STD < 0.015 (Log Unit)
   2. Each curve is bell shaped (Gaussian)
   3. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

m. Prepare the rehydrated IBC Control Standard (item 11d)

   1. See item 11d for rehydration procedure
   2. Store in refrigerator (0-4.4°C) until used

n. Prepare a 5-sample rack for the Startup (Carry-Over) test

   1. One (1) vial purified water (item 6)
   2. One (1) vial low control (low count routine milk sample)
   3. One (1) vial purified water (item 6)
   4. One (1) vial high control (IBC Control Standard (item 11d))
   5. One (1) vial purified water (item 6)

o. Run a Startup test (Carry-Over)

   1. Create a unique Batch ID
   2. Set the number of Samples to five (5)
   3. Choose Batch Type ‘Startup’
   4. Set the Number of Repeats to five (5)
5. Make sure that the ‘Autosampler Rack Advance’ is enabled

6. Run the batch

p. When the Startup batch has been analyzed, confirm that the Standard Deviations and Carry-over levels are acceptable

1. Low control (Sample 2) < 0.060 STD LOG (IBC)

2. High control (Sample 4) << 0.060 STD LOG (IBC)

3. Carryover to Sample 5 < 1%

q. If any of the above parameters fall outside of specifications and do not correct after re-measurement, seek technical assistance

r. Do not proceed with sample counting if any parameters fall outside of specifications

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

PROCEDURE

14. Handling Samples

a. Any tests for the presence of inhibitors must be completed prior to testing the samples on the BCC

b. Samples must be kept at 0-4.4°C until tested

15. Testing Samples

a. Before placing the samples in the racks, invert them 10 times to mix, or place samples in rack and invert rack with samples 10 times to mix

b. Place rack on conveyor and start the automatic testing procedure immediately

c. Samples run on the BCC may be immediately placed into a 37-42°C water bath to run for ESCC

d. Alternatively, refer to CP item 33.a.7.a.1

16. Results

a. The readout is in K IBC (Individual Bacteria Counts)/mL
b. Using the calibration entered into the instrument, K IBC/mL is converted into K CFU/mL and both outputs are listed in the report _________

c. Proper conversion factor has been entered for the regulatory range _________

17. Records

a. Maintain records of all results, controls and samples _________

18. End of Day Procedure

a. Replace the Incubation Reagent with purified water _________

b. Prime the incubation reagent minimum one (1) cycle _________

c. For BCC 50 (item 5a):

   1. Fill one (1) sample vial with carrier fluid (item 11b) and one (1) sample vial with purified water (item 6) _________

   2. Place the sample vials in the rack (carrier fluid vial first) _________

   3. Run a batch of 2 samples and 11 repeats using the routine automatic testing procedure _________

For BCC 100 (item 5b) and BCC 150 (item 5c):

   1. Fill three (3) sample vials with carrier fluid (item 11b) and three (3) sample vials with purified water (item 6) _________

   2. Place the sample vials in the rack (carrier fluid vials first) _________

   3. Run a batch of 6 samples and 11 repeats using the routine automatic testing procedure _________

d. Switch the system off _________

19. Reporting

a. Report the bacterial content of the milk as BCC CFU/mL (K CFU/mL × 1000 = CFU/mL) _________

   1. Instrument reports in K CFU/mL, laboratory analyst must convert to CFU/mL for official reporting _________

b. Report only first two left-hand digits _________

   1. If the third digit is 5, round the second digit using the following rules _________
a. When the second digit is odd, round up (odd up, 235 to 240) 

b. When the second digit is even, round down
   (even down, 225 to 220)

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BACTOCOUNT INDUSTRY OPERATOR (BCIO) APPROVAL PROCEDURES PROTOCOL

A. Training:

1. BactoCount Industry Operators (BCIO) are to receive one week of training conducted by a certified BactoCount analyst.

2. Follow the most current approved BactoCount 2400 Form requirements for training and testing.

3. Training Log signed by certified BactoCount analyst and BCIO.

4. Records maintained.

B. Daily Instrument Start Up Procedure:

BactoCount IBC (BCC) Procedure

1. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months.

2. Check the filters in positions F1, F2, F3 and CFP.
   a. F1: changed within last 7 days and has no cracks.
   b. F2: changed within last 14 days and has no cracks.
   c. F3: changed within last 14 days and has no cracks.
   d. CFP: changed within the last month and has no cracks.

3. Confirm that the incubation reagent is within expiration date. If not, discard and make a fresh mix:
   a. Pour 1800 mL Buffer Stock Solution, 100 mL Dye Stock Solution, and 100 mL Enzyme into a 2 L container. Mix thoroughly.
   b. When not in use, store in refrigerator (0-4.4°C). Use within 7 days.
   c. Label container with Date Prepared and Expiration Date.

4. At the end of the incubation reagent intake line, replace the bottle containing purified water with a bottle containing incubation reagent.
5. Confirm that the carrier fluid is within expiration date. If not, discard and make a fresh mix:
   a. Pour 400 mL RBS Cleaning Concentrate into a 20 L container.
   b. Add 19.6 L purified water.
   c. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days.
   d. Label container with Date Prepared and Expiration Date.

6. Check the syringes and seals for leaks.
   a. Confirm that no moisture has gathered under syringes in positions P9, P10, P11 and P12.

7. Switch the system on.

**BactoCount IBCm (BCMC) Procedure**

1. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months.

2. Check the Bentley filter on top of the carrier fluid pump (position P3).
   a. On top of P3: changed within the last month and has no cracks

3. Confirm that the carrier fluid is within expiration date. If not, discard and make a fresh mix:
   a. Pour 80 mL RBS Cleaning Concentrate into the Carrier Fluid Container. Add 3.92 L purified water.
   b. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days.
   c. Label container with Date Prepared and Expiration Date.

4. Check the syringes and seals for leaks.
   a. Confirm that no moisture has gathered under syringes and seals.

5. Switch the system on. Wait for the instrument to initialize.

6. Confirm that the incubator is on and heating.
   a. Indicator lights on the incubator will be blinking.
7. Start the software. Wait for the system to initialize.

8. Confirm that the incubator is connected.
   a. Indicator lights on the incubator will stop blinking and be on.

9. Place a small beaker with purified water under the sample intake pipette. Start running samples under the Microsphere setting to eliminate air pockets from the system.

10. Total warm-up time is 30 minutes.

C. As the instrument warms up:

   All Models

1. Confirm that the Microsphere Working Solution is within expiration date. If not, discard and make a fresh mix:
   a. Pour 20 mL Microsphere Stock Solution and 180 mL purified water into a 200 mL container. Mix thoroughly.
   b. Store for up to 6 months in refrigerator (0-4.4°C). Do not freeze.
   c. Label container with Date Prepared and Expiration Date.

2. Confirm that the rehydrated IBC Control Standard is within expiration date. If not, discard and make a fresh mix:
   a. Pour 60 mL Buffer Stock Solution into a container.
   b. Let the IBC Control Standard (V1) and the Buffer Stock Solution (V2) adjust to room temperature for 15 minutes.
   c. Using a disposable transfer pipette or pipet tip, transfer approximately 5 mL of fluid from V2 into V1. Let it dissolve for 2 minutes.
   d. Refill the pipette with clean fluid from V2.
   e. Pour the contents of V1 into V2. Use the contents of the pipette to rinse out V1 into V2. Mix gently.
   f. Let the mixture dissolve in V2 for 10 minutes ± 1 minute.
   g. Mix V2 gently.
h. The rehydrated IBC Control Standard can be stored for up to 96 hours in
the refrigerator (0-4.4°C).

i. Label container with Date Prepared and Expiration Date.

**BactoCount IBC (BCC) Procedure**

1. Prime the incubation reagent.

2. Check the instrument zero by running water samples:
   a. Fill a container (min. 200 mL) with purified water and set it under the sample intake pipette.
   b. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is disabled.
   c. For the BCC 50 run 15 water samples, for the BCC 100 and BCC 150 run 33 water samples.
   d. Alternatively, fill 15 vials (for the BCC 50) or 33 vials (for the BCC 100 and BCC 150) with purified water and place them in a rack.
   e. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is enabled.
   f. Run the batch.

3. When the water samples have been tested, confirm that the average count is <5 K IBC.

4. Analyze the Microsphere Working Solution
   a. Place a small container of the Microsphere Working Solution on the carousel deck.
   b. Pull the cytometer line out of its holder and place it directly into the Microsphere Working Solution.
   c. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples.
   d. Place the cytometer line back in its holder.

5. When the Microsphere Working Solution has been analyzed, confirm that the instrument is stable and aligned:
a. STD < 0.015 (Log Unit).

b. Each curve is bell shaped (Gaussian).

c. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

6. Prepare a 5-sample rack for the Startup (Carry-Over) test.
   a. One (1) vial purified water.
   b. One (1) vial low control (low count routine milk sample).
   c. One (1) vial purified water.
   d. One (1) vial high control (IBC Control Standard).
   e. One (1) vial purified water.

7. Run a Startup test (Carry-Over).
   a. Create a unique Batch ID.
   b. Set the number of Samples to five (5).
   c. Choose Batch Type ‘Startup’.
   d. Set the Number of Repeats to five (5).
   e. Make sure that the ‘Autosampler Rack Advance’ is enabled.
   f. Run the batch.

8. When the Startup batch has been analyzed, confirm that the Standard Deviations and Carry-over levels are acceptable:
   a. Low control (Sample 2) < 0.060 STD LOG (IBC).
   b. High control (Sample 4) << 0.060 STD LOG (IBC).
   c. Carryover to Sample 5 < 1%.

**BactoCount IBCm (BCMC) Procedure**

1. Fill a beaker with carrier fluid for vial cleaning.

2. Fill a beaker with purified water for vial rinsing.
3. Clean the stainless steel vials in the cleaning solution, then rinse in purified water, briefly place them bottom up on an absorbent material and then place them bottom down on the preheating area of the incubator.

4. Confirm that the incubation reagent is within expiration date. If not, discard and make a fresh mix.
   a. Pour 18 parts IBCm Bacto Kit Component 1, 1 part IBCm Bacto Kit Component 2, and 1 part IBCm Bacto Kit Component 3 into a suitable container. Mix thoroughly.
   b. When not in use, store in refrigerator (0-4.4°C). Use within 7 days.
   c. Label container with Date Prepared and Expiration Date.

5. Pour incubation reagent into amber glass media bottle and affix the bottle top dispenser. Pump 2-3 strokes to expel possible air pockets, apply fresh syringe filter, pump another 2-3 strokes to prime the filter.

6. Check the instrument zero by testing purified water samples.
   a. Test a total of five (5) purified water samples using the routine testing procedure.
   b. After testing is completed, confirm that the average count is <5 K IBC.

7. Analyze the Microsphere Working Solution.
   a. Place a small container of the Microsphere Working Solution under the sample intake pipette.
   b. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples.
   c. When the Microsphere Working Solution has been analyzed, confirm that the instrument is stable and aligned.
      1. STD < 0.015 (Log Unit).
      2. Each curve is bell shaped (Gaussian).
      3. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

9. Check instrument and chemical functionality by testing the rehydrated IBC Control Standard
a. Test a total of five (5) IBC Control Standard samples using the routine testing procedure.

b. After testing is completed, confirm that results are within specifications.
   1. Each curve is bell shaped (Gaussian).
   2. The average count is within ± 10% of the reference value found on the Certificate of Analysis.

All Models

1. If any of the above parameters fall outside of specifications and do not correct after re-measurement, seek technical assistance.

2. Do not proceed with sample counting if any parameters fall outside of specifications.

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

D. Handling Samples:

1. Any tests for the presence of inhibitors must be completed prior to testing the samples on the BCC.

2. Samples must be kept at 0-4.4°C until tested.

E. Testing Samples:

**BactoCount IBC (BCC) Procedure**

1. Before placing the samples in the racks, invert them 10 times to mix, or place samples in rack and invert rack with samples 10 times to mix.

2. Place rack on conveyor and start the automatic testing procedure immediately.

3. Samples run on the BCC may be immediately placed into a 37-42°C water bath to run for ESCC.

**BactoCount IBCm (BCMC) Procedure**

1. Before testing the samples, invert them 10 times to mix.

2. Add 2.0 mL incubation reagent to a preheated stainless steel vial, using the supplied bottle top dispenser.

3. Transfer 1.0 mL of the sample to the stainless steel vial using the supplied fixed volume pipette and pipette tips.
4. Place the filled stainless steel vial on one of the designated incubation slots on the incubator.

5. Choose the appropriate Product Type on the computer screen.

6. At preset times during incubation, the software will request a round of sonication. Place the sonicator on top of the stainless steel vial, push downwards and release promptly. The sonicator will be activated for the required time. When sonication is completed, place the sonicator back in the sonicator rest.

7. When incubation time is completed, move the vial to the area under the sample intake pipette.

8. Using the software, start the sample. The sample intake pipette will pull the sample automatically and the counting starts.

9. When the sample has been pulled, discard the remaining liquid.

10. Clean the stainless steel vial in the cleaning solution, then rinse in the purified water, briefly place the vial bottom up on an absorbent material and then place it bottom down on the preheating area of the incubator.

F. Results:

1. The readout is in K IBC (Individual Bacteria Counts)/mL. Using the calibration entered into the instrument, K IBC/mL is converted into K CFU/mL and both outputs are listed in the report.

G. Records:

1. Maintain records of all results, controls and samples.

2. All records signed by a certified BactoScan analyst.

H. End of Day Procedure:

BactoCount IBC (BCC) Procedure

1. Replace the Incubation Reagent with purified water.

2. Prime the incubation reagent minimum one (1) cycle

3. For BCC 50:

   a. Fill one (1) sample vial with carrier fluid and one (1) sample vial with purified water.
b. Place the sample vials in the rack (carrier fluid vial first).

c. Run a batch of 2 samples and 11 repeats using the routine automatic testing procedure.

For BCC 100 and BCC 150:

a. Fill three (3) sample vials with carrier fluid and three (3) sample vials with purified water.

b. Place the sample vials in the rack (carrier fluid vials first).

c. Run a batch of 6 samples and 11 repeats using the routine automatic testing procedure.

4. Switch the system off.

**BactoCount IBCm (BCMC) Procedure**

1. Place a container with carrier fluid under the sample intake pipette.

2. Run 10 samples under the 'Microsphere' setting.

3. Place a container with purified water under the sample intake pipette.

4. Run 10 samples under the 'Microsphere' setting.

5. Switch the system off.

I. **Proficiency (Initial Approval then Monthly):**

1. Have BCIO analyze one set of 10 split milk samples.

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

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

4. Records maintained.

J. **Evaluation (Monthly):**

1. Spot check BCIO performing different areas of the operation (e.g. start-up, making rehydrated IBC Control Standard, check prep dates, shut downs, records, etc.).

2. Records maintained.
A BCIO can run official samples for regulatory purposes without a certified BactoCount analyst on site or present, but available to the BCIO operator.
A. Summary of Proposal

Approve a 2400 form for a semi-automated, flow cytometry based individual bacteria count (IBC) method, BactoCount IBCm (BCMC), for raw commingled cow milk.

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

The BactoCount IBCm (BCMC) can produce bacterial counts with an accuracy, repeatability and reproducibility that is equal to or greater than traditional agar based methods and at the same time eliminate the need for serial dilutions, cut the time-to-result from 48 hours to 10 minutes, and minimize the effect of human error.
C. Proposed Solution

Changes to be made on page(s): New 2400 form of the (X - one of the following):

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

**BACTOCOUNT IBCM**
(Raw Commingled Cow Milk Only)
[Unless otherwise stated all tolerances are ±5%]

**GENERAL REQUIREMENTS**

1. **Cultural Procedures,** items 1-32, as appropriate

2. **Sample Requirements,** see CP items 33 & 34
   - a. Raw milk tested only

**PRE-REQUISITE**

3. **Comparative Test**
   - a. Test 25 samples in duplicate using the SPC (2400a) or PAC (2400a-4) and BactoCount IBCm (BMC) methods
   - b. Comparisons done by each analyst performing test
      - 1. Results must be shown to be acceptable before official tests may be performed by the analyst
   - c. Copy of comparison and results in QC record (or easily accessible file in laboratory)
   - d. Analysts certified for SPC or PAC methods
   - e. Alternatively, a BactoCount Industry Operator (BCIO) can analyze samples for regulatory compliance
      - 1. Industry operator must complete the BCIO operating protocols, training and oversight. Records maintained
      - 2. Laboratory must maintain at least one certified BactoCount analyst (item 3.a.b.c.d.) for training and ongoing oversight of the BCIO
3. Refer to BCIO approved training procedures at the end of this form

4. Records maintained for all BCIO oversight

4. Monitoring of Regulatory Cut-Off level
   a. Select 10 samples counting between 150,000 and 450,000 IBC/mL (50,000 and 150,000 CFU/mL) each month
   b. Test each of these samples in duplicate (same dilution) using SPC or PAC and BCMC
   c. Report paired results (CFU/mL and IBC/mL) as specified by the FDA

APPARATUS

5. BactoCount IBCm (BCMC) Model
   a. BCMC IBCm
   b. BCMC Incubator
   c. BCMC Sonicator
   d. BCMC Sonicator rest
   e. BCMC Stainless steel vials
   f. BCMC Carrier fluid container

REAGENTS

6. Purified Water, deionized (conductivity less than 2 µS/cm, see CP item 24.c.3)

7. BactoCount Reagents Supplied by Manufacturer
   a. IBCm Bacto Kit Component 1 Lot #:________ Exp. Date:________
   b. IBCm Bacto Kit Component 2 Lot #:________ Exp. Date:________
   c. IBCm Bacto Kit Component 3 Lot #:________ Exp. Date:________
   d. RBS Cleaning Concentrate Lot #:________ Exp. Date:________
   e. Microspheres Lot #:________ Exp. Date:________
   f. Triton X-100, bottle Lot #:________ Exp. Date:________
g. IBC Control Standard   Lot #:________ Exp. Date:_________ _________

h. IBC Control Standard Buffer Solution Lot #:________ Exp. Date:_________ _________

8. Other Consumables and Equipment Provided by Manufacturer

a. Bentley Disposable Filter Unit for Liquids, 0.2 µm

b. Syringe filter, 0.2 µm

c. Amber glass media bottle, 500 mL

d. Bottle top dispenser, 2 mL

e. Fixed volume pipette, 1 mL

f. Pipette tips, 100-1,000 µL

9. All Chemicals not Provided by Manufacturer, Analytical Grade

10. Stock Solutions

a. Microsphere Stock Solution

1. Add one (1) drop of Microspheres (item 7e) to a 2 L container

2. Add 2 L purified water (item 6)

3. Add 20 mL Triton X-100 (item 7f)

4. Mix until completely dissolved. Do not heat

5. Store for up to 1 year in the refrigerator (0-4.4°C). Do not freeze

Lab Prep. Date: _________ Exp. Date: _________

11. Working Solutions

a. Incubation Reagent

1. Pour 18 parts IBCm Bacto Kit Component 1 (item 7a), 1 part IBCm Bacto Kit Component 2 (item 7b), and 1 part IBCm Bacto Kit Component 3 (item 7c) into a suitable container

2. Mix thoroughly
3. When not in use, store in refrigerator (0-4.4°C). Use within 7 days

   Lab Prep. Date: __________ Exp. Date: __________

b. Carrier Fluid

   1. Pour 80 mL RBS Cleaning Concentrate (item 7d) into the Carrier Fluid Container (item 5f)

   2. Add 3.92 L purified water (item 6)

   3. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days

   Lab Prep. Date: __________ Exp. Date: __________

c. Microsphere Working Solution

   1. Pour 20 mL Microsphere Stock Solution (item 10a) and 180 mL purified water (item 6) into a 200 mL container

   2. Mix thoroughly

   3. Store for up to 6 months in refrigerator (0-4.4°C). Do not freeze

   Lab Prep. Date: __________ Exp. Date: __________

d. Rehydrated IBC Control Standard

   1. Pour 60 mL IBC Control Standard Buffer Solution (item 7h) into a container

   2. Let the IBC Control Standard (item 7g) (V1) and the IBC Control Standard Buffer Solution (item 7h) (V2) adjust to room temperature for 15 minutes

   3. Using a disposable transfer pipette or pipet tip, transfer approximately 5 mL of fluid from V2 into V1. Let it dissolve for 2 minutes

   4. Refill the pipette with clean fluid from V2

   5. Pour the contents of V1 into V2. Use the contents of the pipette to rinse out V1 into V2. Mix gently

   6. Let the mixture dissolve in V2 for 10 minutes ± 1 minute

   7. Mix V2 gently
8. The rehydrated IBC Control Standard can be stored for up to 96 hours in refrigerator (0-4.4°C) _________

   Lab Prep. Date: _________ Exp. Date: _________ _________

12. All Solution Containers Labeled with Solution Name, Date Prepared and Expiration Date (when relevant) _________

START-UP

13. Daily Instrument Start-up _________

   a. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months _________

   b. Check the Bentley filter (item 8a) on top of the carrier fluid pump (position P3) _________

      1. On top of P3: changed within the last month and has no cracks _________

   c. Confirm that the carrier fluid (item 11b) is within expiration date. If not, discard and make a fresh mix _________

   d. Check the syringes and seals for leaks _________

      1. Confirm that no moisture has gathered under syringes and seals _________

   e. Switch the system on. Wait for the instrument to initialize _________

   f. Confirm that the incubator (item 5b) is on and heating _________

      1. Indicator lights on the incubator (item 5b) will be blinking _________

   g. Start the software. Wait for the system to initialize _________

   h. Confirm that the incubator (item 5b) is connected _________

      1. Indicator lights on the incubator (item 5b) will stop blinking and be on _________

   i. Place a small beaker with purified water (item 6) under the sample intake pipette. Start running samples under the Microsphere setting to eliminate air pockets from the system _________

   j. Total warm-up time is 30 minutes _________

As the instrument warms up _________

k. Fill a beaker with carrier fluid (item 11b) for vial cleaning _________
I. Fill a beaker with purified water (item 6) for vial rinsing

m. Clean the stainless steel vials (item 5e) in the cleaning solution (item 13k), then rinse in purified water (item 13l), briefly place them bottom up on an absorbent material and then place them bottom down on the preheating area of the incubator (item 5b)

n. Confirm that the incubation reagent (item 11a) is within expiration date. If not, discard and make a fresh mix

o. Pour incubation reagent (item 11a) into amber glass media bottle (item 8c) and affix the bottle top dispenser (item 8d). Pump 2-3 strokes to expel possible air pockets, apply fresh syringe filter (item 8b), pump another 2-3 strokes to prime the filter

p. Confirm that the Microsphere Working Solution (item 11c) is within expiration date. If not, discard and make a fresh mix

q. Prepare the rehydrated IBC Control Standard (item 11d)
   1. See item 11d for rehydration procedure
   2. Store in refrigerator (0-4.4°C) until used

   When the instrument is warmed up

r. Check the instrument zero by testing purified water (item 6) samples
   1. Test a total of five (5) purified water (item 6) samples using the routine testing procedure (item 15)
   2. After testing is completed, confirm that the average count is <5 K IBC

s. Analyze the Microsphere Working Solution (item 11c)
   1. Place a small container of the Microsphere Working Solution (item 11c) under the sample intake pipette
   2. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples
   3. When the Microsphere Working Solution (item 11c) has been analyzed, confirm that the instrument is stable and aligned
      a. STD < 0.015 (Log Unit)
b. Each curve is bell shaped (Gaussian)

c. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

t. Check instrument and chemical functionality by testing the rehydrated IBC Control Standard (item 11d)

1. Test five (5) IBC Control Standard (item 11d) samples using the routine testing procedure (item 15)

2. After testing is completed, confirm that results are within specifications

   a. Each curve is bell shaped (Gaussian)

   b. The average count is within ± 10% of the reference value found on the Certificate of Analysis

u. If any of the above parameters fall outside of specifications and do not correct after re-measurement, seek technical assistance

v. Do not proceed with sample counting if any parameters fall outside of specifications.

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

PROCEDURE

14. Handling Samples

   a. Any tests for the presence of inhibitors must be completed prior to testing the samples on the BCMC

   b. Samples must be kept at 0-4.4°C until tested

15. Testing Samples

   a. Before testing the samples, invert them 10 times to mix

   b. Add 2.0 mL incubation reagent (item 11a) to a preheated stainless steel vial (item 5e), using the supplied bottle top dispenser (item 8d)

   b. Transfer 1.0 mL of the sample to the stainless steel vial (item 5e), using the supplied fixed volume pipette (item 8e) and pipette tips (item 8f)
c. Place the filled stainless steel vial (item 5e) on one of the designated incubation slots on the incubator (item 5b)

d. Choose the appropriate Product Type on the computer screen

e. At preset times during incubation, the software will request a round of sonication. Place the sonicator (item 5c) on top of the stainless steel vial (item 5e), push downwards and release promptly. The sonicator will be activated for the required time. When sonication is completed, place the sonicator back in the sonicator rest (item 5d)

f. When incubation time is completed, move the vial to the area under the sample intake pipette

g. Using the software, start the sample. The sample intake pipette will pull the sample automatically and the counting starts

h. When the sample has been pulled, discard the remaining liquid

i. Clean the stainless steel vial (item 5e) in the cleaning solution (item 13k), then rinse in the purified water (item 13l), briefly place the vial bottom up on an absorbent material and then place it bottom down on the preheating area of the incubator (item 5b)

16. Results

a. The readout is in K IBC (Individual Bacteria Counts)/mL

b. Using the calibration entered into the instrument, K IBC/mL is converted into K CFU/mL and both outputs are listed in the report

c. Proper conversion factor has been entered for the regulatory range

17. Records

a. Maintain records of all results, controls and samples

18. End of Day Procedure

a. Place a container with carrier fluid (item 11b) under the sample intake pipette

b. Run 10 samples under the 'Microsphere' setting

c. Place a container with purified water (item 6) under the sample intake pipette

d. Run 10 samples under the ‘Microsphere’ setting
19. Reporting

a. Report the bacterial content of the milk as BCMC CFU/mL
   \( (K \text{ CFU/mL} \times 1000 = \text{CFU/mL}) \)

   1. Instrument reports in K CFU/mL, laboratory analyst must convert to CFU/mL for official reporting

b. Report only first two left-hand digits

   1. If the third digit is 5, round the second digit using the following rules
      a. When the second digit is odd, round up (odd up, 235 to 240)
      b. When the second digit is even, round down (even down, 225 to 220)
BACTOCOUNT INDUSTRY OPERATOR (BCIO) APPROVAL PROCEDURES PROTOCOL

A. Training:

1. BactoCount Industry Operators (BCIO) are to receive one week of training conducted by a certified BactoCount analyst.

2. Follow the most current approved BactoCount 2400 Form requirements for training and testing.

3. Training Log signed by certified BactoCount analyst and BCIO.

4. Records maintained.

B. Daily Instrument Start Up Procedure:

BactoCount IBC (BCC) Procedure

1. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months.

2. Check the filters in positions F1, F2, F3 and CFP.
   a. F1: changed within last 7 days and has no cracks.
   b. F2: changed within last 14 days and has no cracks.
   c. F3: changed within last 14 days and has no cracks.
   d. CFP: changed within the last month and has no cracks.

3. Confirm that the incubation reagent is within expiration date. If not, discard and make a fresh mix:
   a. Pour 1800 mL Buffer Stock Solution, 100 mL Dye Stock Solution, and 100 mL Enzyme into a 2 L container. Mix thoroughly.
   b. When not in use, store in refrigerator (0-4.4°C). Use within 7 days.
   c. Label container with Date Prepared and Expiration Date.

4. At the end of the incubation reagent intake line, replace the bottle containing purified water with a bottle containing incubation reagent.

5. Confirm that the carrier fluid is within expiration date. If not, discard and make a fresh mix:
a. Pour 400 mL RBS Cleaning Concentrate into a 20 L container.

b. Add 19.6 L purified water.

c. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days.

d. Label container with Date Prepared and Expiration Date.

6. Check the syringes and seals for leaks.

a. Confirm that no moisture has gathered under syringes in positions P9, P10, P11 and P12.

7. Switch the system on.

**BactoCount IBCm (BCMC) Procedure**

1. Confirm that the Annual Preventive Maintenance check has been completed within the last 12 months.

2. Check the Bentley filter on top of the carrier fluid pump (position P3).

a. On top of P3: changed within the last month and has no cracks

3. Confirm that the carrier fluid is within expiration date. If not, discard and make a fresh mix:

a. Pour 80 mL RBS Cleaning Concentrate into the Carrier Fluid Container. Add 3.92 L purified water.

b. Store at room temperature (< 25°C) up to 7 days or at 25-35°C up to 2 days.

c. Label container with Date Prepared and Expiration Date.

4. Check the syringes and seals for leaks.

a. Confirm that no moisture has gathered under syringes and seals.

5. Switch the system on. Wait for the instrument to initialize.

6. Confirm that the incubator is on and heating.

a. Indicator lights on the incubator will be blinking.

7. Start the software. Wait for the system to initialize.
8. Confirm that the incubator is connected.
   a. Indicator lights on the incubator will stop blinking and be on.

9. Place a small beaker with purified water under the sample intake pipette. Start running samples under the Microsphere setting to eliminate air pockets from the system.

10. Total warm-up time is 30 minutes.

C. As the instrument warms up:

   All Models

1. Confirm that the Microsphere Working Solution is within expiration date. If not, discard and make a fresh mix:
   a. Pour 20 mL Microsphere Stock Solution and 180 mL purified water into a 200 mL container. Mix thoroughly.
   b. Store for up to 6 months in refrigerator (0-4.4°C). Do not freeze.
   c. Label container with Date Prepared and Expiration Date.

2. Confirm that the rehydrated IBC Control Standard is within expiration date. If not, discard and make a fresh mix:
   a. Pour 60 mL Buffer Stock Solution into a container.
   b. Let the IBC Control Standard (V1) and the Buffer Stock Solution (V2) adjust to room temperature for 15 minutes.
   c. Using a disposable transfer pipette or pipet tip, transfer approximately 5 mL of fluid from V2 into V1. Let it dissolve for 2 minutes.
   d. Refill the pipette with clean fluid from V2.
   e. Pour the contents of V1 into V2. Use the contents of the pipette to rinse out V1 into V2. Mix gently.
   f. Let the mixture dissolve in V2 for 10 minutes ± 1 minute.
   g. Mix V2 gently.
   h. The rehydrated IBC Control Standard can be stored for up to 96 hours in the refrigerator (0-4.4°C).
   i. Label container with Date Prepared and Expiration Date.
BactoCount IBC (BCC) Procedure

1. Prime the incubation reagent.

2. Check the instrument zero by running water samples:
   a. Fill a container (min. 200 mL) with purified water and set it under the sample intake pipette.
   b. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is disabled.
   c. For the BCC 50 run 15 water samples, for the BCC 100 and BCC 150 run 33 water samples.
   d. Alternatively, fill 15 vials (for the BCC 50) or 33 vials (for the BCC 100 and BCC 150) with purified water and place them in a rack.
   e. Create a batch by clicking the ‘Batch’ icon, giving the batch a unique ID and choosing the Batch Type ‘Normal’. Make sure that the ‘Autosampler Rack Advance’ is enabled.
   f. Run the batch.

3. When the water samples have been tested, confirm that the average count is <5 K IBC.

4. Analyze the Microsphere Working Solution
   a. Place a small container of the Microsphere Working Solution on the carousel deck.
   b. Pull the cytometer line out of its holder and place it directly into the Microsphere Working Solution.
   c. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples.
   d. Place the cytometer line back in its holder.

5. When the Microsphere Working Solution has been analyzed, confirm that the instrument is stable and aligned:
   a. STD < 0.015 (Log Unit).
   b. Each curve is bell shaped (Gaussian).
c. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

6. Prepare a 5-sample rack for the Startup (Carry-Over) test.
   a. One (1) vial purified water.
   b. One (1) vial low control (low count routine milk sample).
   c. One (1) vial purified water.
   d. One (1) vial high control (IBC Control Standard).
   e. One (1) vial purified water.

7. Run a Startup test (Carry-Over).
   a. Create a unique Batch ID.
   b. Set the number of Samples to five (5).
   c. Choose Batch Type ‘Startup’.
   d. Set the Number of Repeats to five (5).
   e. Make sure that the ‘Autosampler Rack Advance’ is enabled.
   f. Run the batch.

8. When the Startup batch has been analyzed, confirm that the Standard Deviations and Carry-over levels are acceptable:
   a. Low control (Sample 2) < 0.060 STD LOG (IBC).
   b. High control (Sample 4) << 0.060 STD LOG (IBC).
   c. Carryover to Sample 5 < 1%.

**BactoCount IBCm (BCMC) Procedure**

1. Fill a beaker with carrier fluid for vial cleaning.

2. Fill a beaker with purified water for vial rinsing.

3. Clean the stainless steel vials in the cleaning solution, then rinse in purified water, briefly place them bottom up on an absorbent material and then place them bottom down on the preheating area of the incubator.
4. Confirm that the incubation reagent is within expiration date. If not, discard and make a fresh mix.
   a. Pour 18 parts IBCm Bacto Kit Component 1, 1 part IBCm Bacto Kit Component 2, and 1 part IBCm Bacto Kit Component 3 into a suitable container. Mix thoroughly.
   b. When not in use, store in refrigerator (0-4.4°C). Use within 7 days.
   c. Label container with Date Prepared and Expiration Date.

5. Pour incubation reagent into amber glass media bottle and affix the bottle top dispenser. Pump 2-3 strokes to expel possible air pockets, apply fresh syringe filter, pump another 2-3 strokes to prime the filter.

6. Check the instrument zero by testing purified water samples.
   a. Test a total of five (5) purified water samples using the routine testing procedure.
   b. After testing is completed, confirm that the average count is <5 K IBC.

7. Analyze the Microsphere Working Solution.
   a. Place a small container of the Microsphere Working Solution under the sample intake pipette.
   b. Choose the ‘Microspheres’ Batch Type and run a ‘Microspheres’ batch with 10 samples.
   c. When the Microsphere Working Solution has been analyzed, confirm that the instrument is stable and aligned.
      1. STD < 0.015 (Log Unit).
      2. Each curve is bell shaped (Gaussian).
      3. Average Heights of each curve is centered on the Recommended Intensity Value (RIV) ± 0.1

9. Check instrument and chemical functionality by testing the rehydrated IBC Control Standard
   a. Test a total of five (5) IBC Control Standard samples using the routine testing procedure.
   b. After testing is completed, confirm that results are within specifications.
1. Each curve is bell shaped (Gaussian).

2. The average count is within ± 10% of the reference value found on the Certificate of Analysis.

**All Models**

1. If any of the above parameters fall outside of specifications and do not correct after re-measurement, seek technical assistance.

2. Do not proceed with sample counting if any parameters fall outside of specifications.

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

**D. Handling Samples:**

1. Any tests for the presence of inhibitors must be completed prior to testing the samples on the BCC.

2. Samples must be kept at 0-4.4°C until tested.

**E. Testing Samples:**

**BactoCount IBC (BCC) Procedure**

1. Before placing the samples in the racks, invert them 10 times to mix, or place samples in rack and invert rack with samples 10 times to mix.

2. Place rack on conveyor and start the automatic testing procedure immediately.

3. Samples run on the BCC may be immediately placed into a 37-42°C water bath to run for ESCC.

**BactoCount IBCm (BCMC) Procedure**

1. Before testing the samples, invert them 10 times to mix.

2. Add 2.0 mL incubation reagent to a preheated stainless steel vial, using the supplied bottle top dispenser.

3. Transfer 1.0 mL of the sample to the stainless steel vial using the supplied fixed volume pipette and pipette tips.

4. Place the filled stainless steel vial on one of the designated incubation slots on the incubator.

5. Choose the appropriate Product Type on the computer screen.
6. At preset times during incubation, the software will request a round of sonication. Place the sonicator on top of the stainless steel vial, push downwards and release promptly. The sonicator will be activated for the required time. When sonication is completed, place the sonicator back in the sonicator rest.

7. When incubation time is completed, move the vial to the area under the sample intake pipette.

8. Using the software, start the sample. The sample intake pipette will pull the sample automatically and the counting starts.

9. When the sample has been pulled, discard the remaining liquid.

10. Clean the stainless steel vial in the cleaning solution, then rinse in the purified water, briefly place the vial bottom up on an absorbent material and then place it bottom down on the preheating area of the incubator.

F. Results:

1. The readout is in K IBC (Individual Bacteria Counts)/mL. Using the calibration entered into the instrument, K IBC/mL is converted into K CFU/mL and both outputs are listed in the report.

G. Records:

1. Maintain records of all results, controls and samples.

2. All records signed by a certified BactoScan analyst.

H. End of Day Procedure:

**BactoCount IBC (BCC) Procedure**

1. Replace the Incubation Reagent with purified water.

2. Prime the incubation reagent minimum one (1) cycle

3. For BCC 50:
   a. Fill one (1) sample vial with carrier fluid and one (1) sample vial with purified water.
   b. Place the sample vials in the rack (carrier fluid vial first).
   c. Run a batch of 2 samples and 11 repeats using the routine automatic testing procedure.
For BCC 100 and BCC 150:

a. Fill three (3) sample vials with carrier fluid and three (3) sample vials with purified water.

b. Place the sample vials in the rack (carrier fluid vials first).

c. Run a batch of 6 samples and 11 repeats using the routine automatic testing procedure.

4. Switch the system off.

BactoCount IBCm (BCMC) Procedure

1. Place a container with carrier fluid under the sample intake pipette.

2. Run 10 samples under the ‘Microsphere’ setting.

3. Place a container with purified water under the sample intake pipette.

4. Run 10 samples under the ‘Microsphere’ setting.

5. Switch the system off.

I. Proficiency (Initial Approval then Monthly):

1. Have BCIO analyze one set of 10 split milk samples.

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

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

4. Records maintained.

J. Evaluation (Monthly):

1. Spot check BCIO performing different areas of the operation (e.g. start-up, making rehydrated IBC Control Standard, check prep dates, shut downs, records, etc.).

2. Records maintained.

A BCIO can run official samples for regulatory purposes without a certified BactoCount analyst on site or present, but available to the BCIO operator.
A. Summary of Proposal

To add the Bentley Somacount FC to those approved Electronic Somatic Cell Counting methods now accepted for official use in the IMS program.

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

The Somacount FC is based on the same methodology/technology as the previously approved Somacount models. The instrument is an updated version of the older approved SomaCount line of equipment utilizing the same chemistry, laser based flow cytometry and fluid handling methods. Data sets have been generated in accordance with previously established protocol and submitted to the FDA for evaluation. Proposed modifications to the 2400 form are attached for review by the laboratory committee.

C. Proposed Solution

Changes to be made on page(s): Pages 1,2,3 of the (X - one of the following):

- 2015 PMO
- 2015 MMSR
- 2015 Procedures
- 2015 EML
- X 2400 Forms
- 2015 Constitution and Bylaws
Modify the 2400 form, page 1, title section, Add FC to list of instruments

**ELECTRONIC SOMATIC CELL COUNT**

*Bentley Somacount™ 150/300/500/FCM/FC*
*(Raw Commingled Cow, Sheep, Goat, Water Buffalo and Camel Milk)*
*IMS #16*

Modify the 2400 form, page 2, Section 4, Add item 4e. Somacount FC to list of instruments

4. **Electronic Somatic Cell Counter**
   - a. Bentley Somacount 150
   - b. Bentley Somacount 300
   - c. Bentley Somacount 500
      Dual Channel Machine (DCM)
   - d. Bentley Somacount FCM
      Dual Channel Machine (DCM)
   - e. Bentley Somacount FC

Modify the 2400 form, page 2, Section 6 Stock Dye/Buffer Solution, Item 6a.

6. **Stock Dye/Buffer Solution**
   - a. Dissolve 80g of tripotassium citrate monohydrate, (K3C6H5O7,H2O), 3.0g of citric acid monohydrate (C6H8O7,H2O), and 0.25g (1 tablet or equivalent) of ethidium bromide (C21H20BrN3) in 750 mL of deionized (DI) or MS water. Heat to 40-60°C and stir until totally dissolved

Modify the 2400 form, page 2, Section 8 Rinse Solutions, item 8a.

8. **Rinse Solution**
   - a. Add 20 mL of alkaline detergent, RBS-35, per liter of DI or MS water and mix
   - b. Use within 7 days

Lab Prep Date: __________ Lab Exp. Date: ________________

Modify the 2400 form, page 3, Section 11 Cell Counter, Items 11d. and 11e.
11. **Cell Counter**

   a. Check that the volume of dye/buffer solution (item 7) and rinse solution (item 8) in the supply containers is of sufficient volume for the number of samples to be tested

   b. Solutions not to be used beyond expiration date(s)

   c. Turn on computer and instrument, wait 20 minutes before proceeding

   d. Laser power > 0.25 mW

   e. |PMT voltage| > 10 mV

   d. **For Somacount FC**

      1. Laser Power > 2.0 mW
      2. PMT Voltage > 0.005 Volts

   e. **For All other models (Somacount 150/300/500/FCM)**

      1. Laser power > 0.25 mW
      2. |PMT Voltage| > 10 mV

   f. Dye/Coil temperature between 67-73°C

   g. Test DI or MS water at least 3 times on each channel in use; (i.e. 6 times for dual channel instruments) reading must be zero (0) on every test

   h. **IF ANY ABOVE PARAMETERS ARE OUT OF TOLERANCE, CORRECT BEFORE PROCEEDING**

   i. Maintain records on all parameters each time instrument is used

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**Name:** Tod Schilling

**Agency/Organization:** Bentley Instruments Inc.

**Address:** 4004 Peavey Road

**City/State/Zip:** Chaska, MN 55318

**Telephone No.:** 952-448-7600  
**E-mail Address:** tschilling@bentleyinstruments.com
ELECTRONIC SOMATIC CELL COUNT

Bentley Somacount™ 150/300/500/FCM/FC
(Raw Commingled Cow, Sheep, Goat, Water Buffalo and Camel Milk)
IMS #16

(Unless otherwise stated all tolerances ±5%)

1. Laboratory Requirements (see Cultural Procedures (CP) items 33 & 34) ________
   a. Un-preserved samples may be run up to 72 hours after initial collection ________
   b. Samples may be tested up to 7 days after initial collection if preserved
      with 0.02% 2-bromo-2-nitropropane-1,3-diol (Bronopol™) or 0.05%
      potassium dichromate (K2Cr2O7) ________

2. Comparative Test with DMSCC
   [NOT required as a co-requisite for certification of analysts in laboratories
    purchasing standards from a CERTIFIED provider (item 12.b)] ________
   a. Analyst(s) certified for DMSCC ________
   b. Each analyst seeking certification for the ESCC test shall perform the
      comparative test ________
      1. Test 4 samples (100K-200K, 300K-500K, 600K-800K and
         900K-1.2M) in triplicate for both DMSCC (three separate
         smears each) and ESCC ________
      2. Results must be evaluated by the FDA/LPET LEO or LEO and
         shown to be acceptable prior to official use of test in laboratory ________
      3. Copy of comparison and results in QC record (or easily accessible
         on file in the laboratory); kept for as long as analyst is certified ________
   c. Required for laboratories preparing in house standards or using commercially
      prepared standards (items 12.a and c) and for those testing goat or camel
      milk ________

APPARATUS

3. See CP Items 1-4 ________

4. Electronic Somatic Cell Counter ________
   a. Bentley Somacount 150 ________
5. **Water Bath**

   a. Circulating and thermostatically controlled to 37-42°C

**REAGENTS**

6. **Stock Dye/Buffer Solution**

   a. Dissolve 80g of tripotassium citrate monohydrate, (K$_3$C$_6$H$_5$O$_7$.H$_2$O), 3.0g of citric acid monohydrate (C$_6$H$_8$O$_7$.H$_2$O), and 0.25g (1 tablet or equivalent) of ethidium bromide (C$_{21}$H$_{20}$BrN$_3$) in 750 mL of deionized (DI) or MS water. Heat to 40-60°C and stir until totally dissolved

   b. Add 10 mL of neutral detergent, Triton X-100, and stir until totally dissolved. Adjust volume to 1 Liter with DI or MS water

   c. Store refrigerated (0-4.5°C) in airtight, light-proof container for no longer than 90 days

   Lab Prep Date: __________ Lab Exp. Date: ________________

**WORKING SOLUTIONS**

7. **Dye/Buffer Solution**

   a. Dilute 1 part of Stock Dye/Buffer solution with 9 parts of DI or MS water

   b. Protect from light and use within 21 days

   Lab Prep Date: __________ Lab Exp. Date: ________________

8. **Rinse Solution**

   a. Add 20 mL of alkaline detergent, **RBS-35**, per liter of DI or MS water and mix
9. Optionally, Use Manufacturer's Reagent Kits and Instructions

10. All Solutions Labeled with Date Prepared and Expiration Date

START UP

11. Cell Counter

a. Check that the volume of dye/buffer solution (item 7) and rinse solution (item 8) in the supply containers is of sufficient volume for the number of samples to be tested

b. Solutions not to be used beyond expiration date(s)

c. Turn on computer and instrument, wait 20 minutes before proceeding

d. Laser power > 0.25 mW

e. |PMT voltage| > 10 mV

d. For Somacount FC
   1. Laser Power > 2.0 mW
   2. PMT Voltage > 0.005 Volts

e. For All other models (Somacount 150/300/500/FCM)
   1. Laser power > 0.25 mW
   2. |PMT Voltage| > 10 mV

f. Dye/Coil temperature between 67-73°C

g. Test DI or MS water at least 3 times on each channel in use; (i.e. 6 times for dual channel instruments) reading must be zero (0) on every test

h. IF ANY ABOVE PARAMETERS ARE OUT OF TOLERANCE, CORRECT BEFORE PROCEEDING

i. Maintain records on all parameters each time instrument is used
12. Milk Standards

a. Commercially prepared: ____________________
   
   Lot#: ________    Date Rcd.: ___________
   
   1. Four standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M
   
   2. Perform DMSCC in triplicate on each standard in set and average counts; maintain records
   
   3. Perform DMSCC check in rotation by all certified analysts
   
   4. Standards used within one week
   
   Lab Exp Date: ____________

b. Certified provider: _________________________________

   Lot#: ________    Exp. Date: ________    Date Rcd.: ________

   1. Four standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M
   
   2. Maintain copies of all provided DMSCC values
   
   3. Measure and maintain records of temperature (0.0-7.5°C) of standards as received
   
   4. Maintain copies of all correspondence regarding problems
   
   5. Standards used by manufacturer’s expiration date
   
   6. Failed standards shall be verified with DMSCC
   
   a. If no analysts certified for DMSCC then a new set of Standards is required
   
   b. Do not continue with official testing until the new standard(s) test(s) in range
   
   c. Laboratory prepared (weekly)
   
   1. Prepare from raw milk >18 hours old preserved with 0.05%
Appendix

potassium dichromate (K2Cr2O7) ________

2. Or, preserved with 0.02% 2-bromo-2-nitropropane-1,3-diol (Bronopol™) ________

3. Standards cannot be preserved with formalin ________

4. Prepare 4 standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M, use within one week ________

   Lab Prep Date: ________  Lab Exp. Date: ________________ ________

5. Perform DMSCC in triplicate on each standard prepared and average counts; maintain records ________

6. Perform DMSCC check in rotation by all certified analysts ________

d. Hourly Control Sample (instrument drift check) ________

1. Use one of the standards (items 12.a, b or c) in the 600-800K range; test in triplicate and determine average ________

2. Optionally, prepare sufficient control/sample 600-800K range, test in triplicate and determine average ________

PROCEDURE

13. Testing Standards (each time instrument used) ________

   a. Heat standards to 37-42°C (using a temperature control) and test within 30 min of reaching temperature, use once and discard; i.e., do not re-use ________

   b. Mix by inverting at least 2x, test standards within 3 min ________

   c. Test the standards in triplicate and average the counts for each level; maintain records ________

   d. Each standard's average must be within 10% of the DMSCC (item 12) for that level, except within 15% for 100-200K standard; maintain records ________

   e. Repeatability - a standard in the 300K to 800K range must have a coefficient of variation (CV) of 5% or less on 10 replicates (Refer to Operating Manual); maintain records ________

   f. For dual channel machines, the standards must be run in triplicate on each channel and coefficient of variation (Cv) must be determined
for each channel that is in use.

g. **THESE PARAMETERS MUST BE ACHIEVED BEFORE PROCEEDING**

h. Dual Channel Machines (DCM) can be run on single channel

1. Switch off channel that does not meet above parameters per operating instructions

2. Run machine on single channel

14. **Testing Samples**

a. Heat samples to 37-42°C (using a temperature control) and read within 30 min of reaching temperature

b. Test samples within 10 min after removal from water bath

c. Mix by inverting at least 2x, test samples within 3 min

d. Record number of cells counted for each sample

15. **With Continuous Operation:**

a. Run zero control (item 11.g) hourly

b. Test a standard or optionally a control/sample (item 11.d) in the 600K to 800K range hourly in triplicate and determine the average, must be within 5% of the original established instrument average value (optionally, within 10% of original DMSCC average)

c. For dual channel machines, the hourly control in triplicate and the zero control must be tested and found acceptable for each channel that is in use

e. Maintain records

16. **Routine Maintenance**

a. Maintain records

**REPORTING**

17. **Computing and Reporting of Counts**

a. Count obtained x 1000 is the cell count/mL milk
b. In reporting electronic somatic cell counts (ESCC/mL), record only first two left hand digits, raising second digit to next higher number when third digit is 6 or more

c. Report the two left hand digits (rounded)

1. If the third digit is 5, the second digit is rounded by the following rule

   a. When second digit is odd round up, raising the second digit by 1 (odd up, 235 to 240)

   b. When second digit is even round down, delete the 5 and report the second digit as is (even down, 225 to 220)

d. If count on instrument is < 100, report count as < 100,000 ESCC/mL

e. If goat or camel milk is over the regulatory limit, follow confirmation procedure in PMO
A. Summary of Proposal

To update the 2400 Cultural Procedures General Testing requirements to include a new method for the enumeration of aerobic bacteria.

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

Anytime a new method is approved for inclusion in the 2400 form, the 2400 Cultural Procedures-General Requirements also needs to be updated. The 3M™ Petrifilm™ Rapid Aerobic Count Plate has been submitted to the 2017 Laboratory Committee for approval. This proposal cites the necessary changes to the 2400 Cultural Procedures-General Requirements form.
C. Proposed Solution

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<thead>
<tr>
<th>Changes to be made on page(s):</th>
<th>______________________</th>
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<td>2015 EML</td>
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<tr>
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<td>X</td>
<td>2400 Forms</td>
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<tr>
<td>2015 Procedures</td>
<td>2015 Constitution and Bylaws</td>
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</tbody>
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Page 11

24. Microbiologically Suitable (MS) Water
Standard plate count and Petrifilm Aerobic Count films or 3M™ Petrifilm™ Rapid Aerobic Count Plate or Charm Peel Plate Aerobic Count
< 1,000 colonies/mL(< 10,000 colonies/mL if stored)

Page 14

27. Media
3M Petrifilm Rapid Aerobic Count Plate ________
1. Lot No. _________ Exp. Date __________

Pages 18, 19

29. Prepared Media Storage
h. 3M Petrifilm Rapid Aerobic Count Plate storage
1. Store unopened 3M Petrifilm RAC Plate pouches refrigerated or frozen (-20 to 8°C / -4 to 46°F).
2. Just prior to use, allow unopened pouches to come to room temperature before opening (20-25°C / <60% RH).
3. Return unused 3M Petrifilm RAC Plates to pouch. Seal by folding the end of the pouch over and applying adhesive tape.
4. To prevent exposure to moisture, do not refrigerate opened pouches.
5. Store resealed pouches in a cool dry place for no longer than one month.
6. It is recommended that resealed pouches of 3M Petrifilm RAC Plates be stored in a freezer if the laboratory temperature exceeds 25°C (77°F) and/or the laboratory is located in a region where the relative humidity exceeds 50% (with the exception of air conditioned premises).
7. To store opened pouches in a freezer, place 3M Petrifilm RAC Plates in a sealable container.
8. The freezer that is used for open pouch storage must not have an automatic defrost cycle as this would repeatedly expose the plates to moisture which can damage the plates.
9. 3M Petrifilm RAC Plates should not be used past their expiration date.
10. Do not use 3M Petrifilm RAC Plates that show discoloration.
11. Expiration date and lot number are noted on each package of 3M Petrifilm RAC Plates.
    The lot number is also noted on individual 3M Petrifilm RAC Plates.
Robert Jechorek

Agency/Organization: 3M Food Safety

Address: 3M Center, Bldg. 260-06-B-01

City/State/Zip: St. Paul, MN 55144

Telephone No.: 651-733-9764  E-mail Address: rpjechorek@mmm.com
A. Summary of Proposal

This proposal is written for the 3M™ Petrifilm™ Rapid Aerobic Count Plate method as a new method for the enumeration of aerobic bacteria in milk products. Also included is an update to M-a-98-10 Table 3 with the matrices validated with the new method.

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

Purpose:
The purpose of this study was to conduct a method comparison evaluation of the 3M™ Petrifilm™ Rapid Aerobic Count (RAC) Plate to the US FDA Form 2400a Standard Plate Count (SPC) Method [1]. The 2400a SPC reference method is applicable to the enumeration of aerobic microorganisms in raw and pasteurized milk and dairy products and is recognized as the official reference method for dairy product analysis by the Interstate Milk Shipments (IMS). The design of this study was based on the FDA Laboratory Proficiency and Evaluation Team (FDA/LPET) guidance document “New Method/Equipment Evaluation Criteria” (rev 04-25-2007) [2]. The goal of the study was to gain approval for the 3M Petrifilm RAC Plate for use in the NCIMS Grade A Milk Laboratory Program. The data collected during this study have been shared with the FDA-LPET and the NCIMS Laboratory Committee. In addition, a new 2400 form needs to be approved and the M-a-98-10 Table 3 needs to be updated with the new test and the matrices that may be tested with the new test.
Scope:
The test methods outlined here are described in the Food and Drug Administration (FDA), FDA/NCIMS 2400 Forms. The 3M Petrifilm RAC Plate was compared to the FDA 2400a SPC method and the 3M™ Petrifilm™ Aerobic Count (AC) Plate, an equivalent method recognized by NCIMS. For the evaluation, 18 matrices, including two raw milk products, were evaluated. Table 1 provides a summary of the matrices evaluated in the study and their current testing status.

Table 1: Study Summary of the 3M Petrifilm RAC Plate NCIMS Evaluation

<table>
<thead>
<tr>
<th>Matrix</th>
<th>Matrix</th>
<th>Matrix</th>
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<tr>
<td>Raw Cow Milk</td>
<td>Pasteurized Flavored Milk Whole</td>
<td>Ultra-Pasteurized White Milk</td>
</tr>
<tr>
<td>Raw Goat Milk</td>
<td>Pasteurized Flavored Milk Low-Fat</td>
<td>Pasteurized Lactose Free/Low Sodium Milk</td>
</tr>
<tr>
<td>Pasteurized White Milk Whole</td>
<td>Pasteurized Strawberry Milk Whole</td>
<td>Pasteurized Goat Milk</td>
</tr>
<tr>
<td>Pasteurized White Milk, Skim</td>
<td>Pasteurized Strawberry Milk Low-Fat</td>
<td>Ultra-Pasteurized Goat Milk</td>
</tr>
<tr>
<td>Pasteurized Chocolate Milk Whole</td>
<td>Half and Half</td>
<td>Ultra-Pasteurized Flavored Milk</td>
</tr>
<tr>
<td>Pasteurized Chocolate Milk Skim</td>
<td>Ultra-Pasteurized Cream</td>
<td>Dry Milk Powder</td>
</tr>
</tbody>
</table>

For each matrix evaluated, 25 samples were analyzed in duplicate by all three methods. Samples were sent to four NCIMS accredited laboratories for testing by accredited analysts. A total of 150 data points (25 samples evaluated in duplicate for each method: the 3M Petrifilm RAC, 3M Petrifilm AC and 2400a SPC) were generated by each laboratory for a total of 400 data points for each product. Data from each method, along with the final report, will be submitted to the FDA/LPET for repeatability statistical analysis. The goal of the study was to generate data that from three contamination levels that would cover the range of aerobic bacteria that would normally be found in the products with one level being evaluated at the regulatory level for each matrix. Table 2 presents the number of test replicates to be analyze by each method.

Table 2: Summary of Test Samples

<table>
<thead>
<tr>
<th>Data Points Per Matrix¹</th>
<th>SPC 2400a</th>
<th>3M Petrifilm RAC Plate</th>
<th>3M Petrifilm AC Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25 samples in duplicate =</td>
<td>25 samples in duplicate =</td>
<td>25 samples in duplicate =</td>
</tr>
<tr>
<td></td>
<td>Total of 50</td>
<td>Total of 50</td>
<td>Total of 50</td>
</tr>
<tr>
<td>Data Points for 18 Matrices</td>
<td>900</td>
<td>900</td>
<td>900</td>
</tr>
</tbody>
</table>

¹Each sample was plated in duplicate replicates
2. **Test Portion Preparation:**

Samples from various lots of pasteurized milk and milk products were obtained from local retailers by the coordinating laboratory. Each lot was pre-screened for total aerobic count using the 3M Petrifilm Aerobic Count (AC) plate method. The objective was to obtain a range of counts that would be expected to be found within that matrix, with one level being near the regulatory limit. The targeted range was designed to include data points from a low level (100/mL) all the way to the regulatory limit (20,000/mL) for pasteurized milk products. For raw milk products, the range was expanded to cover the higher regulatory limit [100,000/mL for raw goat milk or 300,000/mL (for co-mingled raw cow milk)].

For each matrix and each contamination level, 30 mL or gram of matrix was transferred into a sterile container and shipped to four IMS approved laboratories. Each participating laboratory received a set of twenty-five (25) different samples covering the targeted ranges. All samples were sent with a randomized, blind-coded 3-digit number affixed to the sample container. Test portions were shipped on cold packs via overnight delivery and held by the collaborating laboratory at refrigeration temperature (0-4.4 °C) until analyzed. Samples were analyzed on the day of receipt. In addition to the test portions, collaborators received a sample container labeled as ‘temperature control’ with each shipment. Participants were instructed to obtain the temperature of this portion immediately upon receipt of the package, document the result on the Sample Receipt Confirmation (SRC) form provided and fax or email to the designated study director. Sample receipt criteria was required to be in compliance with current NCIMS program dictates.

3. **Standard Plate Count**

Participants were instructed to prepare each sample for analysis by preparing 1:10 dilutions in Butterfield’s Phosphate Buffered Diluent (BPD), by adding 11 mL of sample to 99 mL of BPD. Sample bottles were shaken vigorously 25 times within 7 seconds in a 30 cm arc. For solid products, 11 g of product were weighed into 99 mL of BPD. Ten-fold serial dilutions were prepared by transferring 11 mL from the previous dilution into 99 mL of BPD. Each sample dilution was analyzed by all three test methods. A flow chart of the study design is presented in Appendix 1.

**3M Petrifilm Rapid Aerobic Count Plate/ 3M Petrifilm Aerobic Count Plate:**

For each matrix, duplicate 3M Petrifilm RAC Plates and 3M Petrifilm AC Plates [2400a-4 Petrifilm Plating (10/13)] were placed on a flat, level surface for each dilution to be tested. The top film of the Petrifilm was lifted, and with the pipette perpendicular to the plate, a 1 mL aliquot of each dilution was dispensed onto the center of the bottom film. The film was rolled down onto the sample on the 3M Petrifilm RAC Plate and dropped onto the sample on the 3M Petrifilm AC Plate. The 3M Petrifilm Flat Spreader (#6425) was placed onto the center of the 3M Petrifilm RAC Plate and gently pressed to distribute the sample evenly. For the 3M Petrifilm AC Plate, the 3M Petrifilm Spreader was applied with the recessed side down on the center to distribute the sample evenly. The spreaders were removed and the plates were left undisturbed for at least one minute to permit the gel to form.

All plates were incubated at 32 ± 1°C in a horizontal position with the clear side up in stacks of no more than 20. The 3M Petrifilm RAC plates were enumerated after 24 ± 2 hours of incubation (or 48 ± 3 hours in the case of low moisture dairy powders). The 3M
Petrifilm AC plates were enumerated after 48 ± 3 hours of incubation for all matrices. Laboratories had the option to use a standard colony counter with the use of a back light or an illuminated magnifier to assist with the estimated enumeration. Plates containing less than 300 colonies were enumerated for the 3M Petrifilm RAC plate and for the 3M Petrifilm AC plates, SPC 2400a plates containing 25-250 colonies were enumerated. Laboratories were instructed to enumerate all colonies, regardless of size, color, or intensity. When counting spreader colonies, laboratories were instructed to follow the guidance provided in the FDA 2400 forms. If plates exceeded the countable range, laboratories were instructed to estimate counts as per 3M manufacturer instructions. If plates were below the countable range, the actual number was recorded. If all plates showed no colonies, a count of 0 was reported.

2400a Standard Plate Count

Using the sample dilutions prepared above, 1 mL aliquots of each dilution were plated in duplicate. A 15- 20 mL aliquot of tempered (44-47°C) Standard Methods Agar (SMA) was added, swirled and allowed to solidify. For dry milk powder a 3 - 5 mL overlay of SMA was added onto the dried plates to help prevent spreader colonies. Plates were incubated inverted at 32 ± 1°C for 48 ± 3 hours for all dairy products except dry milk powder. For dry milk powder, plates were incubated at 32 ± 1°C for 72 ± 3 hrs.

After incubation, typical colonies were enumerated. The countable range for the method was 25-250. For plates containing greater than 250 colonies, results were reported as Too Numerous To Count (TNTC). For plates containing less than 25 colonies, the actual number of colonies in the lowest dilution were reported. All colonies were enumerated, regardless of size, color, or intensity. When counting spreader colonies, laboratories were instructed to follow the guidance provided in the FDA 2400 forms. If there were no plates yielding colonies in the countable range, the laboratories were instructed to enumerate the plate with numbers that are closest to the countable range. If plates from all dilutions exceed the countable range, laboratories were instructed to enumerate the plate nearest 250 and multiply by the dilution. If colonies were below the countable range, the actual number was recorded. If all plates showed no colonies, a count of 0 was reported.

Study Flow Diagram
C. Proposed Solution

Changes to be made on page(s):

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

This is a new 2400 Form submission of the (X - one of the following):

- 2015 PMO
- 2015 EML
- 2015 MMSR
- 2015 Procedures
- 2015 Constitution and Bylaws
3M™ PETRIFILM™ RAPID AEROBIC COUNT PLATE METHOD

[Unless otherwise stated all tolerances are ±5%]

SAMPLES
1. Laboratory Sample Requirements (see Cultural Procedures [CP] items 33 & 34) [For inhibitor testing requirements, refer to Section 6 of the PMO]

MATERIALS AND APPARATUS
2. 3M Petrifilm Rapid Aerobic Count (3M Petrifilm RAC)
3. Plastic Spreaders (Manufacturer supplied Catalog 6425 #)

PROCEDURE
4. Work Area
   a. Level plating bench not in direct sunlight
   b. Sanitize immediately before start of plating

5. Selecting Dilutions
   a. 3M Petrifilm RAC
      1. Plate two decimal dilutions per sample
   b. Select dilutions that would be expected to yield one plate with <300 colonies
      a. Raw milk is normally diluted to 1:100 and 1:1000
      b. Finished products are normally diluted to 1:10 and 1:100
   c. 3M Petrifilm RAC not performed on cultured or acidified products
   1. For pasteurized fluid milk samples, 1 mL direct and/or decimal dilutions, as appropriate
   2. A 1:10 minimum dilution required for: sour cream, yogurt, and sour cream based dips (flavored milk optional)
   3. Test 5 mL of 1:5 dilution (5 mL on 1 plate) or test 10 mL of 1:10 dilution (5 mL on 2 plates); generally high fat and viscous products
   d. For acidified products, add 1.0 N NaOH drop wise (approx. 0.1 mL per gram of product) to sample dilution blank until small portion tested (pH paper or pH meter/probe) falls within the following: ________
   3. Refer to manufacturer’s instructions for list of low pH products that may require adjustment before plating

6. Identifying Petrifilm Plates
   a. Select number of samples in any series so that all will be plated within 20 min (pref. ≤ 10) after diluting first sample
   b. Label each plate with sample or control identification and dilution
   c. Arrange plates in order before preparation of dilutions

CONTROLS
7. Controls (AM and PM)
   a. Check sterility of dilution blanks, 3M Petrifilm RAC plates, and pipets/tips used for each group of samples
   b. Expose a rehydrated 3M Petrifilm RAC plate to air during plating for 15 min
   1. The air control plate must be the first plate set up immediately before samples are shaken and must be located such that it is in the area of the plating activity (not off to the side)
a. Inoculate the center of the 3M Petrifilm RAC plate with 1 mL dilution buffer
d. Roll top film back and completely expose both rehydrated surfaces for 15 min; timer used
e. After 15 min, roll top film back down and incubate as described in item 14
2. After incubation, air plate(s) shall contain ≤10 colonies
c. Maintain records
d. Include information on bench sheet, work sheet or report sheet(s)

DILUTING SAMPLES
8. Sample Agitation
a. When appropriate, wipe top of unopened containers with sterile, ethyl alcohol-saturated cloth
b. Before removal of any portion or sub-samples, thoroughly mix contents of each container
1. Mix raw sample(s) by shaking 25 times in 7 sec with a 1 ft movement (containers approx. ¾ full)
2. Mix retail milk samples by inverting containers top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times
c. Remove test portion within 3 min of sample agitation

9. Dilution Agitation
a. Before removal of any portion, shake each dilution bottle 25 times in 7 sec with a 1 ft movement
b. Remove test portion within 3 min of dilution agitation
c. Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria

PLATING
10. Sample & Dilution Measurements, pipets
a. Use separate sterile pipets for the initial transfers from each container, adjusting pipets in pipet container without touching the pipets
b. Do not drag pipet tip over exposed exterior of pipets in pipet container
c. Do not drag pipet across lip or neck of sample container or dilution blank
d. Insert pipet not more than 2.5 cm (1") below sample surface or dilution surface (avoid foam and bubbles)
e. Using pipet aid, draw test portion above pipet graduation mark and remove pipet from liquid (mouth pipetting not permitted)
f. Adjust test volume to mark with lower side of pipet
1. In contact with inside of sample container (above the sample surface)
2. Or, in contact with inside of dilution blank neck or area above buffer on straight-walled container
3. Ensure excess liquid does not adhere when pipet is removed from the sample container or dilution blank
g. For dilutions, dispense test portion to dilution blank (with lower side of pipet in contact with neck of dilution blank, or area above buffer on straight-walled containers) with column drain of 2-4 sec ________
1. Release sample or dilution portion onto the center of the 3M Petrifilm RAC of the plate base film with tip slightly above but not in contact with plate base film with a column drain of 2-4 sec ________
a. Using pipet aid, blow out last drop of undiluted sample, away from main part of sample on plate ________
b. Gently touch off pipet to dry area ________
2. 3M Petrifilm RAC – Carefully drop the top film onto the inoculum ________
i. Place the plastic spreader on the top film over the inoculums ________
j. Gently press down on the center of the spreader to distribute inoculum ________
k. Leave plates undisturbed for gel solidification 1 min: ________
l. Discard pipets into disinfectant OR dispose into biohazard bags or containers to be sterilized, (using this method of disposal does not require placing into disinfectant first) ________

a. Each day before use, vigorously depress plunger 10x to redistribute lubrication and assure smooth operation (mechanical pipettors) ________
b. Before each use examine pipettor to assure that no liquid is expelled from the pipettor nose-cone (contaminated), if fouling is detected do not use until cleaned as per manufacturer recommendation ________
c. Use separate sterile tip for the initial transfers from each container ________
d. Depress plunger to first stop (mechanical pipettors) ________
e. Do not drag tip/barrel across lip or neck of sample container or dilution blank, and do not allow pipettor barrel within sample container ________
f. Insert tip approximately 0.5-1.0 cm below sample or dilution surface (avoid foam and bubbles) ________
g. With pipettor vertical, slowly and completely release plunger on mechanical pipettor; do not lay pipettor down once sample is drawn up, use vertical rack or charging stand if necessary ________
h. Touch off lower side of tip:
1. To inside of sample container above the sample surface, excess liquid not adhering to tip ________
2. Or to the inside of dilution blank neck or area above buffer on straight-walled containers, excess liquid not adhering to tip ________
a. For dilutions, hold pipettor nearly vertical with lower side of tip touching neck of dilution blank (or area above buffer on straight-walled containers), dispense test portion to blank by slowly depressing plunger to stop (mechanical pipettor) ________
3. For two (2) stop pipettors, depress plunger to second stop with tip remaining in contact with dilution blank ________
i. Lift the top film and deposit 1 mL of sample or dilution keeping pipettor nearly vertical ________
1. Release sample or dilution portion onto the center of the 3M Petrifilm RAC a. If pipettor has two (2) stops, depress plunger to second stop ________
b. Do not touch off pipettor tip(s) on plates ________
c. Optionally, deposit samples with pipettor capable of making a
1:10 dilution in the tip

2. Carefully drop the top film onto the inoculum

1. Gently press down on the center of the spreader
to distribute inoculum

k. Leave plate undisturbed for gel solidification for 1 min

l. Discard tips into disinfectant OR dispose into biohazard bags or containers to be sterilized, (using this method of disposal does not require placing into disinfectant first)

12. Samples Other than Milk

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45ºC

13. Dry Milk Product Samples

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45ºC

b. Wet sample completely with gentle inversions

c. Let soak a minimum of 2 min; shake 25 times in 7 sec with a 1 foot movement; use within 3 min of agitation

INCUBATION

14. Incubating 3M Petrifilm RAC Plates

a. Stack plates in horizontal position, clear side up no more than 10 high

b. Incubate within 10 min

1. Incubate 24±2 hours at 32±1°C

2. For low moisture dairy powders incubate 48±3 hours at 32±1°C

COUNTING COLONIES

15. Counting Aids (see CP item 17)

a. Count colonies with aid of magnification under uniform and properly controlled artificial illumination

b. Hand tally (see CP item 17)

16. Counting, Recording and Computing PAC

a. After incubation count all colonies on selected plates

b. Where impossible to count at once, store plates at 0.0-4.5ºC for not longer than 24 hours (avoid as a routine practice)

c. Record results of sterility and control tests

d. Record dilutions used and number of colonies on each plate counted

e. When possible, select spreader colony free plates with <300 colonies and count all colonies regardless of size, color or intensity

1. Use higher magnification if necessary to distinguish colonies from foreign matter

2. Examine edge of plates for colonies

f. If consecutive plates yield <300 colonies, count all colonies on plates from both dilutions

g. Spreader colonies or plates with gel liquefaction

1. Count colonies on representative portion only when colonies are well distributed and area covered, repressed or liquefied colonies do not exceed 25% of plate

2. Do not count if repressed growth area or gel liquefaction > 25% of plate area

3. When spreader colonies must be counted, count each as a single colony
4. Count chains/spreader colonies from separate sources as separate colonies ________
5. If 5% of plates are more than 25% liquefied or covered by spreader colonies, take immediate steps to eliminate and resolve problem ________
h. If there is no plate yielding <300 colonies, use plate having nearest to 300 colonies ________
i. If plates from all dilutions exceed 300 colonies, estimate (as per 3M manufacturer instructions) ________
j. If plates from all dilutions yield < 25 colonies each, record actual number in lowest dilution ________
k. If all plates from a sample show no colonies, record count as 0 ________
l. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution ________
1. If consecutive dilutions yield <300 colonies, compute count using formula below ________
   \[ N = \frac{\Sigma C}{(1 \times n1) + (0.1 \times n2)} \times d \]
   Where, \( N \) = number of colonies per milliliter or gram
   \( \Sigma C \) = sum of all colonies on all plates counted
   \( n1 \) = number of plates in lower dilution counted
   \( n2 \) = number of plates in next highest dilution counted
   \( d \) = dilution from which the first counts were obtained
   Example: 1:100 = 244 colonies 1:1,000 = 28 colonies
   \[ N = \frac{244 + 28}{(1 \times 1) + (0.1 \times 1)} \]
   = \[ 272/[1.1] \]
   = 24,727 [25,000 (reported)]
   Note: In the NCIMS Program the denominator will always be 0.11 for 1:10 dilutions and 0.011 for 1:100 dilutions

18. Identifying Counting Errors ________
a. Perform monthly counting for 3M Petrifilm RAC ________
   1. With 3 or more analysts, use the RpSm method (see current SMEDP); maintain records ________
   2. With two analysts, comparative counts agree within ≤ 10%; maintain records ________
   3. If only one analyst, replicate counts agree within 8% of one another; maintain records ________

REPORTING
19. Reporting ________
   [When samples are demonstrated to contain inhibitors, no bacteria counts are reported; report as positive for inhibitors or growth inhibitors (GI)]
a. 3M Petrifilm RAC ________
   1. Report computed count as 3M Petrifilm Rapid Aerobic Count Plate/mL or /g when taken from plate(s) in the 25-250 range ________
   2. Report 3M Petrifilm RAC counts of 0 to 24 as < 25 times the reciprocal of the dilution and report as Estimated 3M Petrifilm RAC (ERAC) ________
   3. When colonies on 3M Petrifilm RAC plates exceed 100/sq. cm, compute count by multiplying 100 x dilution factor x 30 sq. cm and report as > computed
4. If computed counts from 3M Petrifilm RAC plates >300, report as Estimated 3M Petrifilm RAC (ERAC) __________
5. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (ERAC) __________

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### A. Summary of Proposal

This is an update of the 2400 Pasteurized Milk Containers, Closures and Packaging in support of a new bacterial method for the enumeration of aerobic count bacteria.

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

When new bacterial methods are accepted into the 2400 forms, those methods must also show that they meet the 2400 Pasteurized Milk Containers, Closures and Packaging requirements found in Appendix J. The 3M™ Petrifilm™ Rapid Aerobic Count Plate is the new method being introduced. It was evaluated using a nutrient broth rinse of gallon containers. This method was found to be equivalent to 2400 reference method and it is submitted for inclusion as an alternative method for testing dairy containers. A copy of the full report was sent to the FDA/LPET and to each member of the NCIMS Technical Committee.

**Purpose:**

The purpose of this study was to evaluate the 3M™ Petrifilm™ Rapid Aerobic Count (RAC) Plate as an acceptable method for analyzing dairy product containers as outlined in the US FDA Form 2400i Pasteurized Milk Containers, Closures and Packaging [1]. The 2400i SPC reference method is applicable to the enumeration of aerobic microorganisms in milk and dairy product containers and is recognized as the official reference method for dairy product
container analysis by the National Conference on Interstate Milk Shipments (NCIMS). The design of this study was based on an FDA/Laboratory Proficiency and Evaluation Team (LPET) guidance document “New Method/Equipment Evaluation Criteria” (rev 04-25-2007) [2]. The goal of the study was to gain approval for the 3M Petrifilm RAC Plate for use in the NCIMS Grade A Milk Laboratory Program as an alternative method for dairy container testing.

Scope:

The test methods outlined here are described in the Food and Drug Administration (FDA), FDA/NCIMS 2400 Forms. The 3M Petrifilm RAC Plate was compared to the FDA 2400a SPC method [3] and the 3M™ Petrifilm™ Aerobic Count (AC) Plate, an equivalent method recognized by NCIMS. Fifty (50) samples were evaluated at a high and low level by three IMS approved laboratories by approved analysts. Table 1 provides a brief overview of the study.

Table 1: Study Summary of the 3M Petrifilm RAC Plate NCIMS Dairy Container Evaluation

<table>
<thead>
<tr>
<th>Inoculating Organisms</th>
<th>Inoculation Level</th>
<th>Target Inoculum Level</th>
<th># of Replicates For SPC 2400a</th>
<th># of Replicates 3M Petrifilm RAC</th>
<th># of Replicates For 3M Petrifilm AC</th>
<th>Reference Method</th>
<th>3M™ Petrifilm™ AC Method</th>
<th>3M™ Petrifilm™ RAC Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 35032</td>
<td>Low</td>
<td>Total</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>SMEDP 48 ± 3 hours</td>
<td>48 ± 3 hours</td>
<td>24 ± 2 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total in Duplicate</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>32 ± 1°C</td>
<td>32 ± 1°C</td>
<td></td>
</tr>
<tr>
<td><em>E. coli</em> ATCC 51813</td>
<td>High</td>
<td>Total</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total in Duplicate</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lactococcus cremoris</em> ATCC 19257</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For each contamination level evaluated, 50 samples were analyzed in duplicate by all three methods. Samples were sent to three NCIMS accredited laboratories for testing by accredited analysts. A total of 300 data points (50 samples in duplicate for each method: the 3M Petrifilm RAC, 3M Petrifilm AC and 2400a SPC) were generated for each inoculation level. Data from each method will be submitted to the FDA/LPET for repeatability statistical analysis.

2. Test Portion Preparation:

Each laboratory was provided all materials, including inoculation cultures, required to conduct
the testing. Each culture was prepared by breaking the vial at the top of the Quick-Stik and allowing the liquid to flow down the container. Once moistened with liquid, the pellet at the bottom of the Quick-Stik was homogenized by hand. The Quick-Stiks were placed upright in a 32°C incubator for 30 minutes to allow for reconstitution of the entire pellet. After 30 minutes, all the liquid from the Quick-Stik was removed and transferred into 13 x 100 mm test tubes. For each culture, 5 separate test tubes of Tryptic Soy Broth (TSB) were inoculated with 10 µL of the culture suspension and incubated at 32°C for 24 ± 2 hours.

After incubation, cultures were diluted as shown in Figure 1 and described below. Using 99 mL

Butterfield’s Phosphate Diluent (BPD) two separate culture suspensions were prepared. From 1 TSB tube containing *P. aeruginosa*, a 1:100 dilution of the culture was performed by transferring 1 mL into 99 mL of BPD. A subsequent 1:10 dilution (1:1000 from the initial suspension) was performed by transferring 11 mL into 99 mL of BPD. The process was repeated for both *E. coli* and *L. cremoris*. Using the 1:1000 dilution, a stock spiking suspension was prepared by transferring 0.5 mL (for *P. aeruginosa* and *L. cremoris*) or 0.25 mL (for *E. coli*) into a single 99 mL BPD bottle. The entire culture dilution process was repeated using a second TSB tube of each culture to prepare a total of two 99 mL BPD stock
spiking suspensions.

**Total Aerobic Count Plate Count**

Participants were instructed to prepare the high inoculum samples by transferring an 11 mL aliquot of the stock spiking solution into 99 mL of Nutrient Broth (NB). The low inoculum samples were prepared by transferring 11 mL of the high inoculum samples into 99 mL of NB. From each high and low inoculum sample 1.0 mL aliquots were plated onto 2 separate 3M Petrifilm RAC plates, onto 2 separate 3M Petrifilm AC plates, and onto 2 separate Petri dishes for analysis by the FDA 2400a method.

**3M Petrifilm Rapid Aerobic Count Plate/ 3M Petrifilm Aerobic Count Plate:**

Duplicate 3M Petrifilm RAC Plates and 3M Petrifilm AC Plates [2400a-4 Petrifilm Plating (10/13)] were placed on a flat, level surface for each dilution to be tested. The top film of the Petrifilm was lifted, and with the pipette perpendicular to the plate, a 1 mL aliquot of each dilution was dispensed onto the center of the bottom film. The film was rolled down onto the sample on the 3M Petrifilm RAC Plate and dropped onto the sample on the 3M Petrifilm AC Plate. The 3M Petrifilm Flat Spreader (#6425) was placed onto the center of the 3M Petrifilm RAC Plate and gently pressed to distribute the sample evenly. For the 3M Petrifilm AC Plate, the 3M Petrifilm Spreader was applied with the recessed side down on the center to distribute the sample evenly. The spreaders were removed and the plates were left undisturbed for at least one minute to permit the gel to form.

All plates were incubated at 32 ± 1°C in a horizontal position with the clear side up in stacks of no more than 20. The 3M Petrifilm RAC plates were enumerated after 24 ± 2 hours of incubation. The 3M Petrifilm AC plates were enumerated after 48 ± 3 hours of incubation for all matrices. Laboratories had the option to use a standard colony counter with the use of a back light or an illuminated magnifier to assist with the estimated enumeration. Plates containing less than 300 colonies were enumerated for the 3M Petrifilm RAC plate and for the 3M Petrifilm AC plates, SPC 2400a plates containing 25-250 colonies were enumerated. Laboratories were instructed to enumerate all colonies, regardless of size, color, or intensity. When counting spreader colonies, laboratories were instructed to follow the guidance provided in the FDA 2400 forms. If plates exceeded the countable range, laboratories were instructed to estimate counts as per 3M manufacturer instructions. If plates were below the countable range, the actual number was recorded. If all plates showed no colonies, a count of 0 was reported.

**2400a Standard Plate Count**

Using the sample dilutions prepared above, 1 mL aliquots of each dilution were plated in duplicate. A 15- 20 mL aliquot of tempered (44-47°C) Standard Methods Agar (SMA) was added, swirled and allowed to solidify. Plates were incubated inverted at 32 ± 1°C for 48 ± 3 hours.

After incubation, typical colonies were enumerated. The countable range for the method was
25-250. For plates containing greater than 250 colonies, results were reported as Too Numerous To Count (TNTC). For plates containing less than 25 colonies, the actual number of colonies in the lowest dilution were reported. All colonies were enumerated, regardless of size, color, or intensity. When counting spreader colonies, laboratories were instructed to follow the guidance provided in the FDA 2400 forms. If there were no plates yielding colonies in the countable range, the laboratories were instructed to enumerate the plate with numbers that are closest to the countable range. If plates from all dilutions exceed the countable range, laboratories were instructed to enumerate the plate nearest 250 and multiply by the dilution. If colonies were below the countable range, the actual number was recorded. If all plates showed no colonies, a count of 0 was reported.

**Statistical Analysis**

Data from each lab was submitted to the coordinating laboratory for statistical analysis. Results from the high inoculum level produced counts that were TNTC. Results for the low inoculum level were logarithmically transformed and averaged. The difference between the Log10 mean of the 2400a SPC method and the Log10 mean of 3M Petrifilm RAC Plate was calculated. The difference between the Log10 mean of the 3M Petrifilm AC Plate and the Log10 mean of 3M Petrifilm RAC Plate was also calculated. Table 2 presents a summary of the statistical Analysis.

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<th>Matrix</th>
<th>Contamination Level</th>
<th>3M Petrifilm RAC Mean Log10 CFU</th>
<th>2400a Form Mean Log10 CFU</th>
<th>3M Petrifilm AC Mean Log10 CFU</th>
<th>p-Value 3M Petrifilm RAC vs. 2400a Form</th>
<th>p-Value 3M Petrifilm AC vs. 3M Petrifilm AC</th>
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</tr>
</tbody>
</table>

*1 A p value of < 0.05 indicates a statistical difference between the two methods; 2TNTC – Too Numerous To Count; N/A – Not Applicable

**References**

1. FDA Form 2400i: *Pasteurized Milk Containers, Closure and Packaging*. 1/13
3. FDA Form 2400a: Standard Plate Count, Coliform and Simplified Count Methods. 10/13
C. Proposed Solution

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

_____ 2015 PMO       _____ 2015 EML

_____ 2015 MMSR       X 2400 Forms

_____ 2015 Procedures  _____ 2015 Constitution and Bylaws

PASTEURIZED MILK CONTAINERS, CLOSURES AND PACKAGING
IMS #22

[Unless otherwise stated all tolerances are ±5%]

1. Laboratory Requirements ________
   a. Record time and date when samples received ________
   b. Record time and date when samples examined ________

RINSE METHOD APPARATUS
2. See Cultural Procedures (CP) items 1-23 ________
3. To Add Rinse Solution to Containers ________
   a. Sterile hypodermic syringes (capacity 20 or 100 mL) and needles ________
   b. Or, sterile pipets ________
   c. Or, sterile automatic syringe ________
   d. Or, sterile graduated cylinder ________
   e. Or, pre-dispensed dilution bottles or tubes with rinse solution (see CP item 29.f); volumes checked ________

MATERIALS
4. See CP items 24-32 ________
5. Rinse Solutions ________
   a. Buffered Rinse Solution or Nutrient broth (see CP items 27.i-j) for Standard Plate Count (SPC) and Coliform Plate Count (CPC) agar based media ________
   b. Nutrient broth (see CP item 27.m) for 3M™ Petrifilm™ Aerobic Count (PAC), Coliform Count (PCC) and High Sensitivity Coliform Count (HSCC) plates, Charm® Peel Plate™ Aerobic Count (PPAC), Coliform Count (PPEC) and High Volume Sensitivity Coliform Count (PPECHVS) 3M™ Petrifilm™ Rapid Aerobic Count Plate ________
   6. Ethyl Alcohol, 70% ________
   7. Plastic Tape ________

PROCEDURE
8. Identify Plates (See SPC item 5, Petrifilm item 5 or Peel Plate item 5) ________

9. Controls (See SPC item 6, Petrifilm item 5 or Peel Plate item 6), in addition;
a. Transfer 1 mL of rinse solution to SPC, PAC or PPAC, or 3M Petrifilm RAC plate for sterility control ________

10. Rinse Solution Volumes for Collection of Surface Rinse Samples ________
  a. 100 mL (±2 mL) for gallons (3784 mL) or larger ________
  b. 50 mL (±1 mL) for ½ gallons (1892 mL) ________
  c. 20 mL (±0.4 mL) for 100 mL to ½ pints (236 mL), pints (473 mL), and quarts (946 mL) ________
  d. For containers <100 mL and closures use swab method, see items 18-32 ________
  e. Irregular shaped containers of <100 mL, use rinse method in item 10.c.
     Equally distribute the 20 mL among multiple units with the amount per unit no more than 20% of the volume ________

11. Collection of Surface Rinse Samples ________
  a. Firm walled paper containers, sealed on line ________
     1. Swab top of containers with 70% alcohol at the site of injection ________
     2. Add required amount of rinse solution to each container by injection and seal puncture with plastic tape ________
     3. Vigorously shake container length-wise on flat sides (or quadrants of round containers) 10 times, holding container horizontally ________
     4. Each shake a complete back and forth movement of approximately 20 cm ________
     5. Turn container 90° and repeat horizontal shaking treatment ________
     6. Turn container 90° twice more and repeat horizontal shaking ________
     7. Grasp container and swirl 20 times in a small flat circle while upright (top up) ________
     8. Invert (top down) and repeat swirling of container 20 times ________
     9. Stand upright and allow to drain for 1-3 min ________
  b. Plastic capped containers (submitted with caps) ________
     1. Swab top of container with 70% alcohol when appropriate ________
     2. Add required amount of rinse solution by aseptically removing cap, pouring in solution without touching the top and replace cap ________
  c. Flexible-walled containers/bags ________
     1. Add 100 mL aseptically by swabbing an area of tube adjacent to liner with 70% alcohol; introduce rinse by syringe and seal puncture with plastic tape ________
     2. Place container/bag on smooth, clean, firm horizontal surface as flat as its construction permits ________
     3. With hands or roller, move rinse solution back and forth 10 times, contacting all surfaces completely ________
     4. Lift liner and hang with “fill tube” down to permit rinse solution to collect for 1-3 min ________
     5. Transfer rinse solution to sterile container by cutting “fill tube” with sterile scissors ________
  d. Irregular shaped containers of <100 mL ________
     1. Swab top of container with 70% alcohol when appropriate e.g. at injection site ________
2. Aseptically add required amount of rinse solution to each container, seal with cap or appropriate sterile closure

3. Complete rinse procedure as described in 11.a.3-9 above

4. Transfer rinse solutions of the multiple containers in sequence by aseptically removing cap or sterile closure, pouring solution into a common sterile container without touching the tops and replacing cap or sterile closure on the sterile container

12. Sample Measurements
a. As described in SPC items 9 & 10, Petrifilm items 10 & 11 or Peel Plate items 9 & 10, or 3M Petrifilm RAC Plate 10 & 11 except:
   1. For Residual Bacterial Count (RBC), pipet 2 mL portion in a single SPC plate or pipet two 1 mL portions on 2 PAC or 2 PPAC plates or 2 3M Petrifilm RAC Plates

   2. For Residual Coliform Count (RCC), pipet 10 mL of remaining rinse solution among 3 CPC plates, or pipet ten 1 mL portions of remaining rinse solution on 10 PCC or PPEC plates or two 5 mL portions on 2 HSCC or PPECHVS plates

13. Pouring Agar (See SPC item 13)

14. Incubating Plates (See SPC item 14, Petrifilm item or 3M Petrifilm RAC Plate item 13 or Peel Plate item 13)

15. Confirmation Test for CPC (See SPC item 17.c)

16. Counting and Recording Colonies (See SPC items 15-17, Petrifilm items 14-16 or Peel Plate items 14-16)
   a. Count obtained from RBC plate(s) recorded as colonies counted
   b. If no colonies on RBC plate(s), record as 0
   c. Count obtained from RCC plates recorded as colonies counted
   d. If no colonies on RCC plates, record as 0
   e. Values are recorded as number of colonies per container

REPORTS
17. Reporting Counts
   a. Report computed bacterial count as RBC/container
      1. Containers rinsed with 20 mL
         a. 2 mL plated for RBC, multiply colony count by 10
         2. Containers rinsed with 50 mL
         a. 2 mL plated for RBC, multiply colony count by 25
         3. Containers rinsed with 100 mL
         a. 2 mL plated for RBC, multiply colony count by 50
      b. Report computed coliform count as RCC/container
         1. Containers rinsed with 20 mL
         a. 10 mL plated for RCC, multiply colony count by 2
         2. Containers rinsed with 50 mL
         a. 10 mL plated for RCC, multiply colony count by 5
         3. Containers rinsed with 100 mL
         a. 10 mL plated for RCC, multiply colony count by 10
c. If no colonies appear on plate(s), report as less than n/container, substituting for n the number that would be reported if 1 colony had been counted from the volume of rinse solution plated and multiplied by appropriate factor ________

SWAB METHOD

APPARATUS

18. See CP items 1-23 ________

19. Screw-capped Containers ________
   a. 7 to 10 cm long to contain: ________
      1. 5 mL rinse solution for non-soluble swabs (see item 5) ________
      2. 4.5 mL rinse solution for alginate swabs (see item 5, SPC & CPC only) ________
   b. Sterile ________

20. Swabs ________
   a. Cotton, non-absorbent (firmly twisted to about 5 mm diameter by 2 cm long over one end of applicator stick 12-15 cm long) ________
   b. Or, calcium alginate fibers (SPC & CPC only) ________
   c. Or, polyester or rayon fibers ________
   d. Commercial source, sterile, non-toxic in protected containers ________
      1. Supporting documentation from manufacturer ________
      2. Maintain records ________

MATERIALS

21. See Items 4 & 5 ________

22. Sodium Hexa-metaphosphate Solution, 10% (if calcium alginate swabs used, SPC & CPC only), sterile ________

23. Shaking Machine, optional (See SPC item 8.c, PAC item 9.c or PPAC item 8.c) ________

PROCEDURE

24. Identify Plates (See SPC item 5, Petrifilm item 6 or Peel Plate item 5) ________

25. Controls (See SPC item 6, or Petrifilm item 7 or Peel Plate item 6), in addition;
   a. Pipet 1 mL of rinse solution to SPC, PAC 3M Petrifilm RAC or PPAC plate for sterility control ________
   b. For calcium alginate swab, break off swab head in container with 4.5 mL rinse solution plus 0.5 mL Na Hexa-metaphosphate solution and continue as described in 27.a.1, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle ________
   c. For all other fibers, break off swab head in container with 5 mL rinse solution and continue as described in item 27.a.2 & 27.b, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle ________

26. Collection of Swab Samples from Product Contact Surfaces ________
   a. 250 sq. cm of product contact surface must be swabbed or five 50 sq. cm for a total of 250 sq. cm (calculate or use template – must be sterile if swab will be in contact with template) ________
b. Aseptically remove sterile swab from container ________
c. Open vial of solution, wet swab and press out excess solution ________
d. Holding swab at 30° angle to surface, rub over 50 sq. cm area three times, reversing direction between successive strokes ________
1. For snap or screw cap closures, calculate number of closures required for product contact surface area of 50 sq. cm ________
2. For cup shaped containers, determine 50 sq. cm for the product contact surface ________
e. Rinse swab in solution and press out excess ________
f. Swab four additional 50 sq. cm areas ________
g. After fifth area has been swabbed, position swab head in vial and break stick, leaving swab head in vial ________

27. Sample Measurement ________
a. As described in SPC items 9 & 10; ________
    1. For calcium alginate, add 0.5 mL of sterile Na Hexa-metaphosphate solution (see item 22) to 4.5 mL rinse solution in vial and shake until dissolved [Not acceptable for use with 3M Petrifilm or Charm Peel Plate] ________
2. For all other fibers: ________
    a. Shake swab container 50 times ________
    b. Each shake a complete back and forth movement of approximately 15 cm ________
    c. Strike palm of hand at end of each cycle ________
    d. Complete shaking in approximately 10 sec ________
    b. As described in Petrifilm items 10 & 11 or Peel Plate items 9 & 10; ________
    1. Shake swab container 50 times ________
    2. Each shake a complete back and forth movement of approximately 15 cm ________
    3. Strike palm of hand at end of each cycle ________
    4. Complete shaking in approximately 10 sec ________
    c. For RBC, pipet 1 mL portion to a single SPC, PAC or PPAC plate ________
    d. For RCC, pipet 3 mL to a single CPC plate or three 1 mL portions on three PCC or PPEC plates ________

28. Pouring Agar (See SPC item 13) ________

29. Incubation (See SPC item 14, Petrifilm item 13 or Peel Plate item 12) ________

30. Confirmation for CPC test (See SPC item 17.c) ________

31. Counting and Recording Colonies
(See SPC items 15-17, Petrifilm items 14-16 or Peel Plate items 14-16) ________
a. Count obtained from RBC plates, record as colonies counted ________
b. If no colonies on RBC plates, record as 0 ________
c. Count obtained from RCC plate(s) record as colonies counted ________
d. If no colonies on RCC plate(s), record as 0 ________

REPORTS
32. Reporting Counts ________
a. Report the count in 31.a as the RBC/50 sq. cm ________
b. If no colonies on RBC plate, report as < 1/50 sq. cm __________
c. Report the count in 31.c as the RCC __________
d. If no colonies on RCC plate(s), report as < 1 __________

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A. Summary of Proposal

This proposal seeks clarification in FDA/NCIMS 2400 Cultural Procedures – General Requirements regarding the storage of Petrifilm™

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

The wording in 29e1 FDA/NCIMS 2400 Cultural Procedures – General Requirements (CP) should include the word “freeze” since the temperature range given (at or below 8°C) includes both refrigeration and freezer temperatures. The wording in 29e1 and 29e5 of CP should be consistent when referring to allowing the Petrifilm™ that has been frozen to acclimate to room temperature. When the same procedure is described in different ways in the same document it can lead to confusion for the analyst. The wording in section 29e4 & 5 of CP displays a contradiction where 29e4 states to store opened (re-sealed) packages at ≤ 25°C indicating that refrigeration temperature would be acceptable, while 29e5 states in bold print Do not refrigerate opened packages.

C. Proposed Solution

Changes to be made on page(s): 18, 19 of the (X - one of the following):

_____ 2015 PMO 2015 EML
_____ 2015 MMSR 2400 Forms Cultural Procedures General
_____ 2015 Procedures X Requirements rev. 02/16
2015 Constitution and Bylaws
MAKE THE FOLLOWING CHANGES TO THE 2400 Cultural Procedures-General Requirements

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

Pg. 18 29e1

e. Petrifilm™ plate storage
   1. Refrigerate or freeze unopened packages of Petrifilm plates at or below 8°C; if frozen, allow 30 min unopened packages to acclimate to room temperature before opening packages

Pg. 19 29e4

4. Store opened (re-sealed) packages in a cool, dry place at room temperature not to exceed ≤ 25°C.

5. Do not refrigerate opened packages. If laboratory temperature exceeds 25°C, store resealed pouches of Petrifilm plates in freezer. Allow plates to acclimate to room temperature before using

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Telephone No.: 231-357-3514 E-mail Address: Dankertp@michigan.gov
A. Summary of Proposal

This proposal would add bulk milk tanker sampling requirement information into the FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13. The additional information would include:

1) Acceptable temperature requirements for receiving raw milk in bulk milk tanker trucks
2) Acceptable volume limits in a sample container
3) Proper identification of bulk milk tanker truck samples

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

Since many Appendix N Industry Supervisors, Certified Industry Supervisors and Industry Analysts do not act as Industry Plant Samplers and, since all Appendix N Industry Supervisors, Certified Industry Supervisors and Industry Analysts are trained using the FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13 then the FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13 should contain relevant information pertaining to the collection of Appendix N bulk tanker samples including temperature, volume and identification requirements thereof. The current information provided in section 9 of FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13 does not contain this information. Adding the information empowers Appendix N Industry Supervisors, Certified Industry Supervisors and Industry Analysts to reject loads for out-of-range temperatures, to reject samples for being over full and to reject samples that do not properly identify which tanker they represent. This information is found in Appendix B of the Grade “A” Pasteurized Milk Ordinance 2015 revision (PMO) and may not readily available in the documents used for training and/or evaluating Appendix N Industry Supervisors, Certified Industry Supervisors and Industry Analysts.
C. Proposed Solution

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

- 2015 PMO
- 2015 EML
- 2015 MMSR
- 2400 Forms General Requirements rev. 10/13
- 2015 Procedures
- 2015 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13

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

Page 5 of FORM FDA/NCIMS 2400n Appendix N – General Requirements rev. 10/13

…

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; maintain records

   a. Acceptable tanker temperature range is 0.0-7.0°C (32-45°F)

3. Secure a representative sample for testing. 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.

   a. Sample container shall not be more than ¾ full

   b. Sample container shall be identified with the tanker identification (and compartment identification if more than one compartment in the tanker)

4. Tanker sample(s) tested promptly upon arrival at the testing location (date and time recorded)

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Telephone No.: 231-357-3514 E-mail Address: Dankertp@michigan.gov
A. Summary of Proposal

To allow estimated DMSCC counts / ml for goat, sheep and other Apocrine (caprine) secretory systems ovine to be reported out as the final result. When acceptable by the state regulatory agency. (example: >1,500,000 estimated DMSCC/ml for goats and >750,000 estimated DMSCC/ml for sheep, camel, and other Apocrine (caprine) secretory systems ovine)

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

To improve laboratory efficacy when confirming the number of SCC by the DMSCC test method for goat, sheep, camel, and other Apocrine (caprine) secretory systems ovine. Goat milk SCC for example can become highly elevated due to the natural cycle of seasonal milk production.

C. Proposed Solution

Changes to be made on page(s):

| Form 2400d DMSCC Rev 2/16 pg 8 |
| of the (X - one of the following): |
| 2015 PMO | 2015 EML |
| 2015 MMSR | x 2400 Forms |
| 2015 Procedures | 2015 Constitution and Bylaws |
Modify Form FDA/NCIMS 2400d Direct Microscopic Somatic Cell Count Rev. 2/16 by adding the following:

Item:
25…

g. Identifying and counting somatic cells
1. Cells possess a nucleus that stains dark blue for cow, water buffalo and other Merocrine (bovine) secretory systems
2. Cells possess a nucleus that stains blue or blue-green for goats, sheep and other Apocrine (caprine) secretory systems

a Optionally, when counting Apocrine (caprine) secretory system smears, count enough cells where the number of cells counted x SSF(item10.c.2.b) is > 1,600,000 for goats or where the number of cell counted x SSF(item10.c.2.b) is > 850,000 for sheep, camel and other Apocrine (ovine) secretory systems

3. Count those cells (nuclear masses) within the strip and also those cells that are touching one edge of the strip, but not the other edge
4. Fragments are counted only if more than 50% of the nuclear material is visible
5. Count clusters of cells as one unless nuclear unit(s) is clearly separated: focus up and down to ensure there are no bridges connecting nuclear masses
6. If in doubt, do not count

h. After examination of each smear record strip count
i. Conduct monthly comparative counting between analysts (see plate count procedure FDA/NCIMS 2400 forms, Identifying Counting Errors)

REPORTS

26. Records and Reporting
a. Record of strip count for each smear examined
b. Compute DMSCC/mL, multiply number of cells counted (strip count) by the SSF (item 10.c.2.b)
c. Report somatic cell counts as DMSCC/mL, record only first two left hand digits, round as necessary
   1. If the third digit is 5 round the second number using the following rules
      a. When the second digit is odd round up (odd up, 235 to 240)
      b. When the second digit is even round down (even down, 225 to 220)

2. Optionally, when allowed by the state regulatory agency, analysts report > 1,500,000 estimated DMSCC/mL for goat smears (item 25.g.2.a) or >750,000 estimated DMSCC/mL for sheep and camel smears and other Apocrine (caprine) secretory systems ovine (item 25.g.2.a)

d. Maintain records
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34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 246
(#231-2013/#246/2015)
Committee: 2400-Lab/
Scientific Advisory

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A. Summary of Proposal

Extend the allowable time for the transportation of water samples from 30 hours to 48 hours for water samples tested in IMS listed laboratories.

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

Background and Current Standards

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 36 hour time for milk samples to be in transit first to 48 hours and then to 60 hours at the 2009 NCIMS conference.

The Environmental Protection Agency (EPA) test procedures require that tests be started within 30 hours of sample collection. The EPA drinking water program has no mandatory cooling requirement but encourages water samples in transit to be stored at 10° C or less. Safe sample standards are established as <1 coliform per 100 ml is satisfactory for drinking water purposes, ≥1 coliform per 100 ml is unsatisfactory for drinking water purposes. In the Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register the standard for water sample storage during transportation was not changed.

The FDA Pasteurized Milk Ordinance (PMO) requirements are a little more stringent.
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 when going to a Grade “A” certified laboratory. When going to an EPA certified laboratory samples are not required to be refrigerated but are recommended to be refrigerated at 10°C. Sample testing must still begin within 30 hours. Results standards are the same <1 coliform per 100 ml is satisfactory, ≥1 coliform per 100 ml is unsatisfactory.

Discussion

Five (5) independent studies cited in this proposal. These studies were directed mainly to justify the need to refrigerate samples to preserve the sample in a truly representative state. Data extracted from the studies also shows that not only does refrigeration preserve the sample but that preserved sample will be truly representative for a longer period of time than is currently accepted. The standard for drinking water accepted during the time period of the studies was a more lenient standard than used currently.

An in house study was also conducted to specifically examine the effects of time on refrigerated samples. This study used both seeded prepared samples and raw natural samples collected from various dairy water sources. The samples were held at 4.4°C and tests were conducted at 0, 30, 48, 54, and 72 hour hold times. The in house study also indicated that the temperature preserved sample will be truly representative at 72 hours as well as at 0 hours or 30 hours. There was some variation in microbial counts over the testing period and some between laboratories. However, the variations were not statistically significant from 30 hours to 72 hours after sample collection. At no time did counts decrease to a point that would produce a false negative under current standards.

Data

Several scientific studies were reviewed to obtain data that relates to the effect of hold time on water samples. Generally the studies were done to show either the relationship of ambient temperatures and sample storage or to justify the refrigeration to preserve a sample. The data does support the hypothesis that hold time can be extended without adversely affecting the sample. All of the studies used MF and MPN analysis techniques except the in-house study which used several types of analysis.

Data found in 2 studies indicate that hold time of unrefrigerated samples up to 48 hours does not significantly change number of positive results.

In a study conducted by S.C. Hsu and T.J. Williams in 1981 over 4658 samples of municipal and private water were analyzed. Hold times were measured in days rather than hours at ambient temperatures. Study findings suggest that cyclical die-off and regrowth patterns may occur over periods of days for some members of the coliform group. The percentage of positive coliform test results did not exhibit regular increases.
or decreases with increasing sample hold times.

Another study conducted by Jon H. Standridge and Joseph J. Delfino in 1983. In this study 3154 samples of private and municipal water were analyzed after 24 hours and 48 hours hold time at ambient temperatures (20 ± 2°C). Study findings indicate the total number of coliform-positive samples was unchanged by increasing storage time to 48 hours.

In 3 studies reviewed samples were held at two temperatures ambient temperature and 5°C. All of the studies had similar results.

A 1983 study conducted by A.E. McDaniel and R.H. Bordner collecting 50L samples were collected weekly or bi-weekly for 15 weeks. Each sample was broken down into 7 subsamples, one subsample for chemical analysis and 6 for bacteriological analysis. Samples were held at 22°C and at 5°C and analyzed at 12 hours, 24 hours, and 48 hours. The results as seen in Fig. 4 of this study indicated that the unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

Another study conducted by A.E. McDaniel, et. al. had similar results. Over 512 samples were collected from a municipal water supply plus a 50-60 liter samples. Samples were inoculated with E. cloacae and C. freundii. Samples were stored at 5°C and at 22°C at 24 hours, 30 hours, and 48 hours. The results as seen in Fig. 4 of this study were similar to the 1983 study. The unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

A third 1955 study by E. E. Geldreich was reviewed. Samples were taken in winter and summer, 3 each, from six sources farm wells, rivers and a lake for a total of 36 samples. Samples were held at 5°C, at room temperature (13°C-32°C) and at 35°C. Samples were analyzed at 24 hours, 48 hours, and 72 hours. Results varied in this study but comparing mean ratios as in Table 4 all samples showed significant loss in the first 24 hours, however, the refrigerated samples showed significantly less loss in 48 hours and 72 hours than did the unrefrigerated samples. The ratios still indicate that the loss still would not have produced a negative result under current standards.

The In house study was conducted in 2011. Samples were tested at 4 laboratories the MRC Laboratory, Oklahoma State Department of Agriculture Laboratory, Kansas State Board of Agriculture Laboratory, and the Arkansas Department of Health Laboratory.
A combination of prepared samples and natural samples were used in this study. Well water, chill water from a dairy plant and glycol from a dairy plant was collected to prepare samples to be shipped to the various laboratories. Samples were seeded with *E. coli*, and *K. pneumonia* to achieve a target count of approximately 30 CFU’s/100ml. *Pseudomonas aeruginosa* was added to see if it had any effect on coliform survival. All samples were stored and shipped at temperatures between 0-4°C. Samples were analyzed at 0 hours, 24 hours, 30 hours, 48 hours, 60 hours, 72 hours, and 96 hours.

Different analysis methods were used to compare results. Membrane filtration was used at 2 of the laboratories, Colilert was used at two laboratories, Colisure was used at one laboratory, and MPN was used in three laboratories.

The results over all showed that the microbial loss over the analysis period was statistically insignificant. There were a few instances that numbers dropped slightly but not enough to produce a negative result. There was also some instances that a drop in numbers occurred at one analysis time but the count rebounded by the next analysis.

Data extracted from the various studies along with the in-house study would indicate that allowing and extended hold time of up to 60 hours would not have an adverse effect on the number of positive samples. Given current standards and current testing technology none of the data reviewed would indicate an adverse effect on positive samples if the samples were transported and/or held up to at least 48 hours. Some of the data actually indicates a 60 hour hold time is feasible without adverse effects since there appears to be some cyclical loss and growth even under refrigeration during the hold period. Protecting the public health is still served very well. If coliform is present in a sample it will still likely be present at some level above the standard.

**Conclusion**

It is clear that the milk program will continue to use EPA certified laboratories and they will be allowed to accept samples up to 30 hours without refrigeration. As presented in the various papers samples that are refrigerate show less die off at 48 plus hours, possibly out to 72 hours, than those that are held 30 hours without refrigeration. This extended time, necessary for travel from point of collection to laboratory in many cases, would have little if any effect on the sample on samples currently tested under the dairy water program and these samples will continue to be more representative of the when they were collected verse the 30 hour unrefrigerated samples that we accept the results on that are tested in an EPA certified laboratory.

**Literature Cited**


### C. Proposed Solution

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

<table>
<thead>
<tr>
<th>2011 PMO</th>
<th>2011 EML</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 MMSR</td>
<td>X</td>
</tr>
<tr>
<td>2011 Procedures</td>
<td>2011 Constitution and Bylaws</td>
</tr>
</tbody>
</table>

Edit 2400m Dairy Waters as follows

1. Laboratory Requirements

e. Transit time does not exceed 30 48 hours
f. Samples examined within 30 48 hours of collection or within 2 hours of receipt (item 1d)

<table>
<thead>
<tr>
<th>Name: R. Lynn Young</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency/Organization: Milk Regulatory Consultants, LLC</td>
</tr>
<tr>
<td>Address: 56820 HWY A</td>
</tr>
<tr>
<td>City/State/Zip: Russellville, MO 65074</td>
</tr>
<tr>
<td>Telephone No.: 573-338-1785</td>
</tr>
</tbody>
</table>