

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	212
Committee:	Appendix N

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

**A. Summary of Proposal**

Require testing of all raw milk for sulfonamides, especially sulfamethazine.

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

A recent widespread dairy recall due to sulfamethazine in contamination of raw milk points to a gap in this aspect of raw milk adulteration and contamination testing. Existing antibiotic test equipment is capable of testing for sulfamethazine. As a potential human carcinogen, sulfamethazine is particularly of concern to the pregnant women, nursing mothers, and mothers raising small children who represent the American dairy industry's largest and arguably most important demographic.

**C. Proposed Solution**

Changes to be made on page(s): 30, 363, and 374 of the (X - one of the following):

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

Modify the 2013 PMO, page 30, SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS, Item 5.

5. ~~Beta lactam~~ Drug Residue methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam and Sulfonamide drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam and Sulfonamide drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam or Sulfonamide drug test kits available. (Refer to M-a-85, latest revision, for the approved drug tests and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved drug tests available.) Regulatory action shall be taken on all confirmed positive Beta lactam and Sulfonamide results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam or Sulfonamide if it has been obtained by using a 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.

Modify the 2013 PMO, page 363, 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 Sulfonamide drug residues.

Modify the 2013 PMO, page 374, APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE, V. Approved Methods.

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk pickup tankers for Beta lactam and Sulfonamide residues, following the testing procedures specified in Section III of this Appendix.

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

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal: 213  
Committee: Appendix N/Lab

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

**A. Summary of Proposal**

This Proposal addresses Proposal 220 from the 2013 NCIMS Conference that was assigned to the Appendix N Modification Committee addressing the procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is a drug testing method **AVAILABLE** that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11).

It further addresses a request from FDA to the Appendix N Modification Committee and accepted by the Appendix N Modification Committee to develop a procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is **NOT** a drug testing method that has been evaluated and accepted by FDA and the NCIMS available.

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

Proposal 220 at the 2013 NCIMS Conference was assigned to the Appendix N Modification Committee. The Committee was assigned to address the procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is a drug testing method **AVAILABLE** that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11). This Appendix N violation has been occurring for a period of time and was brought to the attention of all parties four (4) years ago. NMPF submitted Proposal 220 to the 2013 NCIMS Conference that proposed a study committee to address this Appendix N violation. The authors and other dairy industry sponsors of Proposal 220 stated to FDA at the 2013 NCIMS Conference that the Committee would come back to the 2015 NCIMS Conference, if not before by going through the M-a



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

**V. APPROVED TEST METHODS**

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

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

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Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, aseptic processing and packaging, or retort processed after packaging. In addition, drug tests for Beta lactams on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests for Beta lactams, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) ...

Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using a test method which has not been evaluated and accepted by FDA and the NCIMS, without additional confirmation required, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N of this Ordinance. ...

**ADMINISTRATIVE PROCEDURES ...**

**LABORATORY TECHNIQUES: ...**

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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 safe 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 ~~drug test kits~~ methods available. (Refer to M-a-85, latest revision, for the approved Beta lactam drug tests test methods and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved Beta lactam drug tests test methods available.) Regulatory Enforcement action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N of this Ordinance.) A result shall be considered confirmed positive for

Beta ~~lactam~~ 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.

Once a drug test method(s) for a particular drug or drug family, other than Beta lactams, has been independently evaluated, or evaluated by FDA, and has been found acceptable by FDA and the NCIMS, only those accepted drug or drug family test methods shall be used for detecting the particular drug or drug family residues in raw milk. (Refer to M-a-85, latest revision, and M-I-92-11 for the approved test methods.) Enforcement action shall be taken on all confirmed positive results. (Refer to Appendix N of this Ordinance.) A result shall be considered confirmed positive 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.

One (1) year after a test method(s) has been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated test methods for that particular non-Beta lactam drug or drug family are not acceptable for determining a Screening Test Positive (Confirmation) of a milk tank truck load of milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers. The acceptance of evaluated 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 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.

Provided, that until an additional test method is 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. tolerance levels. (Refer to Section VI of Appendix N of this Ordinance.) Non-Beta lactam test methods which have been evaluated by FDA and have been found acceptable by FDA and the NCIMS as cited in M-a-85, latest revision, and M-I-92-11 for detecting non-Beta lactam drug residues in raw milk shall be used during the confirmation step. (Refer to M-I-96-10, latest revision, and M-a-98, latest revision, for the specific raw milk for which there are approved non-Beta lactam test methods available.) Enforcement action shall be taken on all confirmed positive non-Beta lactam results. (Refer to Section II of Appendix N of this Ordinance.) A result shall be considered confirmed positive for non-Beta lactam drug residue if it has been obtained by using a test method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS established in memoranda transmitted periodically by FDA.

Provided further, that until a test method is found acceptable by FDA and the NCIMS for detecting a particular drug or drug family other than Beta lactams 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 and verified screening positive steps, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. tolerance levels. Enforcement action as cited in Appendix N of this Ordinance shall be taken on all verified screening positive non-Beta lactam results. (Refer to Section VI of Appendix N of this Ordinance.) ...

## 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-lactams drug residues. Additionally, other drug residues shall be ~~screened~~ tested for by employing a random sampling and testing 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*.) 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.

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

**NOTE:** On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted by the Regulatory Agency where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency in which the dairy farm is located as specified in Appendix B of this Ordinance and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues using approved test methods or verified

screening positive test results using test methods not evaluated by FDA and accepted by the NCIMS from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, or farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be retained or disposed of as determined by the Regulatory Agency.

All presumptive positive test results for drug residues on finished milk and/or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

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#### **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 (~~confirmed~~) 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.

Further pickups or 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.

#### **RECORD REQUIREMENTS:**

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information: ...

8. Prior test documentation shall be provided for a presumptive positive load using approved test methods or a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS. ...

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Records of all sample test results shall be maintained for a minimum of six (6) months by the industry at the location where the ~~tests~~ test methods were run, and/or another location as directed by the Regulatory Agency.

## II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another Regulatory Agency's jurisdiction, 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, it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from which the milk originated.

### MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The test method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the test method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the ~~industry analyst~~ Industry Analyst (IA) test the samples. Receiving locations that choose to certify all receiving ~~analysts~~ IAs, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving ~~Industry Analysts~~ IAs and Industry Supervisors (ISs) successfully participate in a biennial on-site evaluation and annual split sample comparisons by LEOs are also exempt from the sample collection requirements of this Section. ...

To satisfy these requirements:

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- a. There should be ~~an~~ a documented agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be "timely" for example by telephone or fax, and supported in writing.
- b. The ultimate disposition should either be prearranged in ~~an~~ a documented agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted ~~Beta-lactam~~ specified drug residue milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CSI). Positive producers shall be handled in accordance with this Appendix.

d. All verified screening test positive loads using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

~~de.~~ 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 (confirmed) for drug residues using approved test methods, 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. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS. Positive producers shall be handled in accordance with this Appendix.

f. 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 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. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

eg. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry, under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records ~~should~~ shall be maintained by industry and/or the Regulatory Agency that:

- (1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and
- (2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. ENFORCEMENT of this Appendix, as applicable, based on the test method utilized, and has cleared the milk for pick up and/or use.

Sufficient records ~~should~~ shall be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues

determined to be necessary as outlined in Section 6 of this *Ordinance*.

**ENFORCEMENT:**

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

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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.

**Prevention of the Sale of Milk:** Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, the Regulatory Agency shall immediately take effective measures to prevent the sale of milk containing drug residues.

**Penalties:** Future pickups and/or use of the violative individual producer’s milk are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer’s milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

**Reinstatement:** When the permit has been suspended as required, ~~The~~ the Grade “A” producer’s permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue.

**Follow-Up:** Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including: ...

**Permit Revocation:** After a third violation for a drug residue using approved test methods in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer’s Grade “A” permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

**REGULATORY AGENCY RECORDS:**

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency’s records shall indicate the following: ...

4. What screening and/or confirmatory ~~test(s)~~ test method(s) were used and who were the analyst(s)? ...

### III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED

#### DEFINITIONS:

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For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85, (latest revision), or M-I-92-11 approved test method, which has been promptly repeated 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.

2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive (confirmation) result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method as that used for the presumptive positive, with a positive (+) and negative (-) control that give the proper results, and either or both of the duplicates are positive. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ (CIS) using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Suspension Action:** A producer trace back/permit suspension action test is performed after a screening test positive load (confirmation) is identified by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS using the same or an equivalent (M-I-96-10, latest revision) test method as was used to obtain the screening test positive (load (confirmation)). A confirmed producer test positive result is obtained in the same manner as a ~~confirmation~~—(screening test positive (confirmation)) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the producer presumptive positive result. This testing is performed with a positive (+) and negative (-) control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

**NOTE:** 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 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 (~~confirmed~~) for drug residues using approved test methods, 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. ...

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6. **Industry Analyst (IA):** A person under the supervision of a Certified Industry Supervisor (CIS) or Industry Supervisor (IS) who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N drug residue requirements.

7. **Industry Supervisor/Certified Industry Supervisor (IS/CIS):** An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts (IAs) who test milk tank trucks and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N drug residue requirements.

8. **Certified Industry Supervisor (CIS):** An Industry Supervisor (IS) who is evaluated and listed by a LEO as certified to conduct drug residue screening tests using approved test methods at industry drug residue screening sites for *Grade "A" PMO*, Appendix N regulatory enforcement actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit actions).

9. **Verified Screening Positive:** A verified screening positive test is a positive result from an initial testing using test methods not evaluated by FDA and accepted by the NCIMS of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers, which has been promptly repeated 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.

10. **Producer Trace Back With Permit Suspension Action Not Required:** A producer trace back test is performed after a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, is identified by an industry laboratory using the same test method as was used to obtain the verified screening positive load. A verified screening positive producer test result is obtained in the same manner as a verified screening positive for a bulk milk pickup tanker. After an initial positive result is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the initial producer positive result. This testing is performed with a positive (+) and negative (-) control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is verified as screening positive. (Refer to Section VI of this Appendix.)

**NOTE:** 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 used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be verified screening positive for drug residues using only 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.

## **CERTIFIED INDUSTRY SUPERVISORS (CISs); EVALUATION AND RECORDS:**

Reference: *EML*

1. **Certified Industry Supervisors (CISs)/Industry Supervisors (ISs)/Industry Analysts (IAs):** Regulatory Agencies may choose to allow ~~Industry Supervisors ISs~~ to be certified. Under this program, these ~~Certified Industry Supervisors CISs~~ may officially confirm using

approved test methods presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO shall use the appropriate Appendix N. FDA/NCIMS 2400 Form when evaluating Official Laboratories, Officially Designated Laboratories or ~~Certified Industry Supervisors~~ CISs, ~~Industry Supervisors~~ ISs and ~~Industry Analysts~~ IAs.

The ~~Certified Industry Supervisor/Industry Supervisor~~ CIS/IS shall report to the LEO the results of all competency evaluations performed on ~~Industry Analysts~~ IAs. The names of all ~~Certified Industry Supervisors~~ CISs, ~~Industry Supervisors~~ ISs and ~~Industry Analysts~~ IAs, as well as their training and evaluation status, shall be maintained by the LEO and updated as replacement, additions and/or removals occur. The LEO shall verify (document) that each ~~Certified Industry Supervisor~~ CIS and/or ~~Industry Supervisor~~ IS has established a program that ensures the proficiency of the ~~Industry Analysts~~ IAs they supervise. The LEO shall also verify that each ~~Industry Supervisor~~ IS and ~~Industry Analysts~~ IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the ~~Industry Supervisor~~ IS or ~~Industry Analysts~~ IA to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of ~~Industry Supervisors~~ ISs and/or ~~Industry Analysts~~ IAs. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for ~~Certified Industry Supervisors~~ CISs and the training requirements for ~~Industry Supervisors~~ ISs and ~~Industry Analysts~~ IAs.) ...

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**4. Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

**5. Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results:** If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw

milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the Regulatory Agency.

**BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST: ...**

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. ~~Industry analysts IAs~~ may screen tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the ~~Industry Supervisor IS~~ Certification Program.

a. Industry Presumptive Positive Options Using Approved Test Methods: There are two (2) industry options for the milk represented by a presumptive positive sample using approved test methods:

(1) 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 in an Official Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor CIS~~ at a location acceptable to the Regulatory Agency. Documentation of 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 tankers 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 the same or equivalent test method (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. 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 correct reactions, the sample is deemed a Screening Test Positive (~~Confirmed~~ Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers 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. ...

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**NOTE:** 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 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 (~~confirmed~~) for drug residues using an approved test method, 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.

3. **Re-Sampling:**

a. Presumptive Results Using Approved Test Methods: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained using approved test methods. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results Using Approved Test Methods: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP*, FDA/NCIMS 2400 Forms, Appendix N and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency shall be based on objective evidence. A Regulatory Agency allowing re-sampling shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is are necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

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4. **Producer Trace Back:**

a. All screening test confirmed positive (~~confirmed~~) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor~~ CIS. Positive producers shall be handled in accordance with this Appendix.

**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 (~~confirmed~~) for drug residues using an approved test method, 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.

b. All verified screening positive loads using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be broken down (producer trace back) using the same test method. Verification producer trace back tests shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be

handled in accordance with this Appendix.

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 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. ...

**Record Requirements:** Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information: ...

4. Identity of the test method performed/lot #/any and all controls (+/-);
8. Prior test documentation shall be provided for a presumptive positive load when using an approved test method or a verified screening positive load when using test methods not evaluated by FDA and accepted by the NCIMS. ...

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**SCREENING TESTS TEST METHODS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:**

1. **Performance Tests/Controls (+/-):**
  - a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
  - b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
  - c. All NCIMS Approved Confirmation Test Methods for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Tests Include the Following Format:  
All presumptive positive test results shall be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with ~~single~~ positive (+) and negative (-) controls by a certified analyst (Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control results, the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency in which the testing was conducted, as a screening test positive (confirmed).
  - d. All Test Methods Used by Industry, which have Not been Evaluated by FDA and Accepted by the NCIMS for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Include the Following Format:  
One (1) of the options provided for in Section VI of this Appendix shall be followed.
  - e. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug. ...

6. Screening Test Method Sampling Requirements: ...
7. Screening Test Method Volumetric Measuring Devices: ...

## V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use ~~tests~~ test methods from ~~the most recent revision of 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~~ Ordinance. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory Enforcement action based on each test ~~kit~~ 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~~ Ordinance.

One (1) year after a drug test(s) test method(s) have has been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated drug tests test methods for that particular non-Beta lactam drug or drug family are not acceptable for ~~screening milk~~ 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 tests 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.

## 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):

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 tankers 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 Tankers 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.

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 tankers 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 Tankers 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.

**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 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. 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. Enforcement action involves the penalty of the removal of the adulterated milk 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 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 shall be made to determine the cause. The farm inspection is 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)/silo(s), 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.

*Note: This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

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



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 214  
Committee: Appendix N/Lab

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

**A. Summary of Proposal**

This proposal will establish a pilot program to be developed through the Appendix N Modification Committee to review the effectiveness of a **voluntary program for the rapid screening of raw milk for drugs other than beta-lactams (where an evaluated and accepted methodology exists in M-a-85 or M-I-92-11)**; allowing time to work through issues that may arise; and to fully develop language that would be recommended to the 2017 NCIMS Conference.

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

This pilot is needed for consistent framework of voluntary testing for drugs other than beta - lactams to meet other product specification requirements. The NCIMS Appendix N Modification Committee shall be responsible for the oversight of this pilot in consultation with FDA, **including the further refinement of language**, resolution of issues of test methodology and the availability of tests to the program, and for the committee to provide for a report and completion of the pilot at the 2017 NCIMS Conference. This is a proposed solution for proposal 2013 - 220 for **a voluntary testing program using a rapid screening method that has not been evaluated by FDA and accepted by the NCIMS where an evaluated and accepted methodology exists in M-a-85 or M-I-92-11.**

**C. Proposed Solution**

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

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

The Appendix N Modification Committee 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.

**For the purpose of the Pilot the following criteria will be considered**

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

**ADMINISTRATIVE PROCEDURES ...**

**LABORATORY TECHNIQUES: ...**

Page 30:

5. Beta-lactam 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 safe 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 drug test kits available. (Refer to M-a-85, latest revision, for the approved drug tests and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved drug tests available.) Regulatory action shall be taken on all confirmed positive Beta-lactam results. (Refer to Appendix N.) A result shall be considered positive for Beta-lactam if it has been obtained by using a 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.

When testing for non-Beta-lactams, non-Beta-lactam screening methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for initial screening, provided that test kit manufacturer's data indicates that testing sensitivity is at or below current U.S. safe or tolerance levels. Non-Beta-lactam methods which have been evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting non-Beta-lactam drug residues in raw cow's milk shall be used during the confirmation step. This does not apply to raw milk from other hooved mammals for which there are not any approved non-Beta-lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved non-Beta-lactam drug tests and M-a-98, latest revision, for the specific raw milk for which there are approved

non-Beta-lactam drug tests available.) Enforcement action shall be taken on all confirmed positive non-Beta-lactam results. (Refer to Section II of Appendix N.) A result shall be considered confirmed positive for non-Beta-lactam drug residue if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS established in memoranda transmitted periodically by FDA.

6. Screening and Confirmatory Methods for the detection of Abnormal Milk: ....

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

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### **V. APPROVED METHODS**

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 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 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. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit 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 test(s) have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta-lactam drug or drug family, other unevaluated tests are not acceptable for determining a Screening Test Positive on a load and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of non-Beta-lactam evaluated tests does not mandate any additional screening by industry with the evaluated method.

### **APPENDIX N PART B. VOLUNTARY DRUG RESIDUE TESTING AND FARM SURVEILLANCE FOR DRUGS OTHER THAN BETA-LACTAMS**

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

#### **II. METHODS FOR WHEN AN NCIMS TEST KIT LISTING EXISTS IN M-a-85 or M-I-92-11 AND WHERE M-I-96-10 (LATEST REVISION) METHOD(S) SHALL BE USED FOR CONFIRMATION.**

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 kit, a prior documented agreement shall be obtained among the user of the test kit, 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 method evaluated by FDA and accepted by the NCIMS as cited in the most recent revision of M-a-85 or M-I-92-11. An M-I-96-10 (latest revision) 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 kit 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, on the same sample. The initial test result is verified as a positive when one (1) or both of these duplicate retests give a positive result. The Regulatory Agency(ies) involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the verified positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that verified positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test from the most recent revision of M-a-85 or M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor 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 tankers confirmation. The verified 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. 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 Tankers 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 Sections I and II of this Appendix shall occur.

2. If the initial test result from a drug test kit 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 from the most recent revision of M-a-85 or M-I-92-11. The initial positive M-a-85 or 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, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency(ies) 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 Certified Industry Supervisor 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 tankers 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. 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 Tankers 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 Sections I Industry Responsibilities and II Regulatory Agency Responsibilities of this Appendix shall occur.

The Appendix N Modification Committee stands ready to begin work on the framework for this pilot program immediately and requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

Name:	Appendix N Modification Committee (Roger Hooi – Chair)		
Agency/Organization:	NCIMS		
Address:	2711 North Haskell Avenue		
City/State/Zip:	Dallas, Texas 75204		
Telephone No.:	214-721-1101	E-mail Address:	hooir@yahoo.com



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 215  
Committee: Appendix N/Lab

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

**A. Summary of Proposal**

This proposal requests a pilot program be developed with the oversight of the Appendix N Modification Committee in consultation with FDA to create and further refine the regulatory framework to **voluntarily test raw milk for the presence of drugs other than beta-lactams using unreviewed tests when approved (M-a-85) tests do not exist.**

The ultimate goal of such a program once developed and implemented would be to prevent potentially adulterated milk from entering the human food chain.

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

This pilot is needed for consistent framework of **voluntary testing for drugs other than beta-lactams using unreviewed tests when approved (M-a-85) tests do not exist.** The NCIMS Appendix N Modification Committee shall be responsible for the oversight of this pilot program in consultation with FDA, including the further refinement of language, resolution of issues of test methodology and the availability of tests to the program, and for the committee to implement the pilot and provide a report and/or proposal(s) at the 2017 NCIMS Conference.

### C. Proposed Solution

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

\_\_\_\_\_ 2013 PMO                      \_\_\_\_\_ 2011 EML  
\_\_\_\_\_ 2013 MMSR                  \_\_\_\_\_ 2400 Forms  
\_\_\_\_\_ 2013 Procedures          \_\_\_\_\_ 2013 Constitution and Bylaws

The Appendix N Modification Committee 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.

For the purposes of this pilot program the following criteria will be considered:

In advance of using an unreviewed test kit, a written agreement shall be obtained among the user of the test kit, the milk supplier, and the relevant Regulatory Agency(ies). This would delineate the responsibilities of each participant when the presence of a non-Beta-lactam drug residue is detected with an unreviewed test when an approved (M-a-85) test does not exist.

#### **Notes for this Proposal:**

1. This option is not permitted for beta-lactam residue testing (i.e., testing that is currently required for regulatory purposes under Appendix N).
2. “Unreviewed” tests kits: those test kits that have not been validated by FDA nor accepted by NCIMS.
3. “Approved” test kits: those test kits that have been validated by FDA and accepted by NCIMS.
4. “Human Food Chain”: food for humans as well as animals.

#### **Overview**

1. This option is dependent upon a collaborative agreement among the user of the “unreviewed” test kit, the milk supplier, and the State Regulatory Agency(ies).
2. The basis for this Option is that an approved/certified confirmation lab of the animal drug residue (with the approved drug residue test kit) is **not** employed and the “unreviewed” test kit is known to test below the U.S.-recognized safe/tolerance level (therefore, a positive result from use of this test does not necessarily indicate a violation of U.S.-recognized safe/tolerance levels).
3. In advance of using the “unreviewed” test, the user, the milk supplier, and the State Regulatory Agency(ies) shall determine the appropriate response to positive results from the “unreviewed” test kit.
4. The State Regulatory Agency(ies) will determine with the user of the test and the milk supplier if the presumptive “unreviewed” testing (using the “unreviewed” test kit to determine a presumptive “unreviewed” positive) is performed in a lab with oversight.

**Outline of the Program:**

*The basic concept of this option, an alternative method to use an “unreviewed” test kit, is that the “unreviewed” test kit is used both for initial screening and presumptive “unreviewed” screening. With this option, the ultimate goal is to remove the potentially adulterated milk (milk that may contain a drug residue, as determined by the “unreviewed” test kit) from the human food chain.*

- a. Initial positive result is returned with an “unreviewed” test kit.
- b. (Optional) Based on an agreement with the State Regulatory Agency(ies), the positive result may be reported by the test kit user to the State.
- c. The same sample that tested positive with an “unreviewed” test kit shall be tested in duplicate with positive and negative controls (as is currently required in Appendix N). If one (or both) of the test results is positive from the duplicate tests, the sample shall be considered a presumptive “unreviewed” screening positive test.
- d. The relevant State Regulatory Agency(ies) shall be notified.
- e. Product is properly disposed of such that it is ultimately removed from the human food chain.
- f. Producer traceback with the same “unreviewed” test kit will be performed by industry, at the direction of the State Regulatory Agency(ies).
- g. Using the same “unreviewed” or equivalent (testing at the same level, or more sensitive) test kit, once a milk sample from the producer(s) is negative for the drug residue, the State Regulatory Agency(ies) is notified and the producer shall resume shipping and sale of milk into the human food chain.
- h. The State Regulatory Agency(ies) may oversee an investigation to determine the cause of the drug residue and what procedures may be put in place to prevent recurrence of residues in the future.
- i. Because the test kit(s) is/are “unreviewed”, no official regulatory action is taken against the producer (permit suspension, fines, etc.).
  - i. Penalty of the removal of the food from the human food chain is managed between the user of the test, the milk supplier, and the producer.
  - ii. Potentially adulterated milk is removed from the human food chain. The ultimate disposition of the milk shall be reported to the appropriate State Regulatory Agency(ies)

The Appendix N Modification Committee stands ready to begin work on the framework for this pilot program immediately and requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

Name: Appendix N Committee Modification Committee (Roger Hooi – Chair)

Agency/Organization: NCIMS

Address: 2711 North Haskell Avenue

City/State/Zip: Dallas, Texas 75204

Telephone No.: 214-721-1101

E-mail Address: [hooir@yahoo.com](mailto:hooir@yahoo.com)

# 35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	216
Committee:	Appendix N/Lab

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

## A. Summary of Proposal

This Proposal seeks to modify the minimum sensitivity requirement, the 50% detection level of the safe/tolerance level rule, for the acceptance of test methods for drug residue analysis by making safe levels of drugs not applicable with the exception of penicillin G. The proposal would delete the word “safe” from the 50% rule and from the text of the PMO, where appropriate.

For test methods for tetracycline drugs, modify the minimum sensitivity requirement. Test methods that meet or exceed the 90/95 detection levels for oxytetracycline and tetracycline of the currently accepted test kit may be accepted for Appendix N testing. The 90/95 detection levels for chlortetracycline for the currently accepted test kit meet the 50% rule.

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

This Proposal would delete the word “safe” from the 50% rule. Safe levels were largely developed to provide test method developers with a target to insure adequate sensitivity of the test method in part based on available technology. These levels are not legally binding as noted in Appendix N. The current list of drugs with safe level given in M-I-05-5 are:

Drug	Safe Level ppb
Erythromycin	50
Gentamicin	30
Penicillin	5
Sulfamethazine	10

Sulfamethizole	10
Sulfanilamide	10
Sulfachloropyridazine	10
Sulfapyridine	10
Sulfadiazine	10
Sulfaquinoxaline	10
Sulfamerazine	10
Sulfathiazole	10

Reference:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm287572.htm>

Under 21 CFR 530.41, sulfonamide drugs are prohibited for extra label use in lactating dairy cattle except for the approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxy pyridazine.

The Proposal would not change the exception for Penicillin.

Outside of Penicillin, there is only one (1) NCIMS approved test for any of the drugs listed. This test is not widely used by the dairy industry or States and is not based on the most current technologies used in the dairy industry for testing. New test methods for non-Beta lactam drugs have not been submitted for approval other than the combination Beta lactam-flunixin test method.

The listed safe levels should represent an upper limit for these drugs to ensure the safety of the milk supply. Removing the 50% rule requirement for drugs with safe levels will give greater flexibility to test method manufacturers to develop test methods for these drugs which are not approved for use in lactating dairy animals. The greater availability of non-Beta lactam test methods is a key need to allow the NCIMS to improve testing and implement changes to the current testing program as mandated within Appendix N of the PMO.

**NOTE:** The 50% detection level of the safe/tolerance rule is cited in IMS-a-43 (Actions of the 2001 National Conference on Interstate Milk Shipments): Proposal 264.

**C. Proposed Solution**

Changes to be made on page(s):		xiv and 374	of the (X - one of the following):
<input checked="" type="checkbox"/>	2013 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2013 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2013 Procedures	<input type="checkbox"/>	2013 Constitution and Bylaws

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

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

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

**V. APPROVED TEST METHODS ...**

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

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**V. APPROVED TEST METHODS**

Regulatory Agencies and industry shall use ~~tests~~ test methods from ~~the most recent revision of 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, 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~~ Ordinance. ~~Drug residue detection methods shall be evaluated at the safe level or tolerance.~~ Regulatory Enforcement action based on each test ~~kit~~ 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~~ Ordinance.

One (1) year after a drug test(s) test method(s) have ~~has~~ been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated drug tests test methods are not acceptable for screening milk. The acceptance of evaluated drug tests test methods does not mandate any additional screening by industry with the evaluated drug test method.

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 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.

Name: CFSAN

Agency/Organization: Food and Drug Administration

Address: 5100 Paint Branch Parkway

City/State/Zip: College Park, MD 20740

Telephone No.: (240) 402-2175

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

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal:	217
Committee:	Appendix N/Lab

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

**A. Summary of Proposal**

This Proposal combines the text from the three (3) Appendix N Proposals that FDA submitted to provide an all-encompassing Proposal to indicate how Section 6 and Appendix N of the PMO would read with the potential passage of these three (3) Proposals.

This Proposal addresses Appendix N testing to require that at least one (1) of the following drug families (Beta-lactams, Amphenicols (florfenicol) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins) be conducted on each milk tank truck and/or each raw milk supply that has not been transported in bulk milk pickup tankers; or on a statistical basis calculated by FDA statisticians (the number of milk tank truck loads (percentage) based on the total number of milk tank truck loads received and/or each raw milk supply that has not been transported in bulk milk pickup tankers utilized from the previous year) employing a random testing program.

This Proposal addresses Proposal 220 from the 2013 NCIMS Conference that was assigned to the Appendix N Modification Committee addressing the procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is a drug testing method **AVAILABLE** that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11).

It further addresses a request from FDA to the Appendix N Modification Committee and accepted by the Appendix N Modification Committee to develop a procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is **NOT** a drug testing method that has been evaluated and accepted by FDA and the NCIMS available.

This Proposal also seeks to modify the minimum sensitivity requirement, the 50% detection level of the safe/tolerance level rule, for the acceptance of test methods for drug residue analysis by making safe levels of drugs not applicable with the exception of penicillin G. The proposal would delete the word “safe” from the 50% rule and from the text of the PMO, where appropriate.

For test methods for tetracycline drugs, this Proposal seeks to modify the minimum sensitivity requirement. Test methods that meet or exceed the 90/95 detection levels for oxytetracycline and tetracycline of the currently accepted test kit may be accepted for Appendix N testing. The 90/95 detection levels for chlortetracycline for the currently accepted test kit meet the 50% rule.

<p style="text-align: center;"><b>B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission</b></p>
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Proposal 243 from the 2005 NCIMS Conference directed the NCIMS Executive Board to create a NCIMS Ad-hoc Study Committee (Appendix N Modification Committee) to evaluate the potential to modify Appendix N of the PMO to require that raw milk be tested for drug residues on a statistically designed basis that will consider the volume of use for the drug(s); its toxicity; and other public health risk factors. The review shall include Beta lactam drugs and other drugs used in dairy animals.

FDA developed a Veterinary Drug Risk Ranking Model incorporating the factors cited above and the findings from this Risk Ranking Model have indicated that the following drug families (Beta-lactams, NSAIDs (flunixin), Sulfonamides, Macrolides, Amphenicols (florfenicol), Tetracyclines, Aminoglycosides, and Avermectins) should be tested for in raw milk. FDA proposes the testing of at least one (1) of the following drug families (Beta-lactams, Amphenicols (florfenicol) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins) on each milk tank truck and/or each raw milk supply that has not been transported in bulk milk pickup tankers on a statistical basis calculated by FDA statisticians (the number of milk tank truck loads (percentage) based on the total number of milk tank truck loads received and/or each raw milk supply that has not been transported in bulk milk pickup tankers utilized from the previous year) employing a random testing program.

Proposal 220 at the 2013 NCIMS Conference was assigned to the Appendix N Modification Committee. The Committee was assigned to address the procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is a drug testing method **AVAILABLE** that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11). This Appendix N violation has been occurring for a period of time and was brought to the attention of all parties four (4) years ago. NMPF submitted Proposal 220 to the 2013 NCIMS Conference that proposed a study committee to address this Appendix N violation. The authors and other dairy industry sponsors of Proposal 220 stated to FDA at the 2013 NCIMS Conference that the Committee would come back to the 2015 NCIMS Conference, if not before by going through the M-a process, with a solution to this identified Appendix N violation. Based on this promise, FDA

agreed to provide Regulatory Discretion up to the 2015 NCIMS Conference with the understanding that this issue would be resolved to the satisfaction of FDA before or at the 2015 NCIMS Conference. With the Appendix N Modification Committee submitting a Proposal to have a voluntary pilot program to continue to look at options that were agreed to and are currently being utilized by the Committee and several States to address this situation, FDA believes that a voluntary pilot program is not warranted and that the options that are currently utilized by several States adequately addresses the issues raised by FDA. Any concerns that may arise with the adoption of this Proposal can be adequately addressed utilizing the proposed text in the Committee's Proposal that states: In advance of using such a test kit, 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 method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11.

FDA also made a request to the Appendix N Modification Committee, which was accepted by the Committee, to develop a procedure to follow when using a drug testing method that has **NOT** been evaluated and accepted by FDA and the NCIMS when there is **NOT** a drug testing method that has been evaluated and accepted by FDA and the NCIMS available. Based on this acceptance, FDA agreed to provide Regulatory Discretion up to the 2015 NCIMS Conference with the understanding that this issue would be resolved to the satisfaction of FDA before or at the 2015 NCIMS Conference. With the Appendix N Modification Committee submitting a Proposal to have a voluntary pilot program to continue to look at an option that was developed by the Committee to address this situation, FDA believes that a voluntary pilot program is not warranted and that the option that has been developed by the Committee adequately addresses the issues raised by FDA. Any concerns that may arise with the adoption of this Proposal can be adequately addressed by utilizing the proposed text in the Committee's Proposal that states: In advance of using such a test kit, 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.

This Proposal would also delete the word "safe" from the 50% rule. Safe levels were largely developed to provide test developers with a target to insure adequate sensitivity of the test in part based on available technology. These levels are not legally binding as noted in Appendix N.

The Proposal would not change the exception for Penicillin.

Outside of Penicillin, there is only one (1) NCIMS approved test for any of the drugs listed with safe levels as cited in M-I-05-5 (Sulfonamides). This test is not widely used by the dairy industry or States and is not based on the most current technologies used in the dairy industry for testing. New test methods for non-Beta lactam drugs have not been submitted for approval other than the combination Beta lactam-flunixin test method.

The listed safe levels should represent an upper limit for these drugs to ensure the safety of the milk supply. Removing the 50% rule requirement for drugs with safe levels will give greater flexibility to test method manufacturers to develop test methods for these drugs which are not approved for use in lactating dairy animals. The greater availability of non-Beta lactam test methods is a key need to allow the NCIMS to improve testing and implement changes to the

current testing program as mandated within Appendix N of the PMO.

**NOTE:** The 50% detection level of the safe/tolerance rule is cited in IMS-a-43 (Actions of the 2001 National Conference on Interstate Milk Shipments): Proposal 264.

**C. Proposed Solution**

Changes to be made on page(s): xiv, 26-30 and 363-374 of the (X - one of the following):

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

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

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

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**V. APPROVED TEST METHODS**

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

*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, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

It shall be the responsibility of the industry plant sampler to collect a representative sample of milk for Appendix N testing. Appendix N testing shall be conducted for at least one (1) of the following drug families (Beta-lactams, Amphenicols (florfenicol) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins) from the following:

1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is

approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or

2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk from 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. for processing at that location. ...

*Page 28:*

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, aseptic processing and packaging, or retort processed after packaging. In addition, drug tests for Beta lactams on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests for Beta lactams, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) ...

Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using a test method which has not been evaluated and accepted by FDA and the NCIMS, without additional confirmation required, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N of this Ordinance. ...

## ADMINISTRATIVE PROCEDURES ...

### LABORATORY TECHNIQUES: ...

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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 safe 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 ~~drug test kits~~ methods available. (Refer to M-a-85, latest revision, for the approved Beta lactam drug tests test methods and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved Beta lactam drug tests test methods available.) Regulatory Enforcement action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N of this Ordinance.) A result shall be considered confirmed positive for ~~Beta lactam~~ 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.

Once a drug test method(s) for Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins has been independently evaluated, or evaluated by FDA, and has been found acceptable by FDA and the NCIMS, only those accepted Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins test methods shall be used for detecting the particular drug or drug family residues in raw milk for Appendix N testing at current tolerance levels. (Refer to M-a-85, latest revision, and M-I-92-11 for the approved test methods.) Enforcement action shall be taken on all confirmed positive results. (Refer to Appendix N of this Ordinance.) A result shall be considered confirmed positive 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.

One (1) year after a test method(s) has been evaluated by FDA and accepted by the NCIMS for Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins, other unevaluated test methods for that particular drug or drug family are not acceptable for determining a Screening Test Positive (Confirmation) of a milk tank truck load of milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers. The acceptance of evaluated test methods by FDA and the NCIMS for drugs other than Beta lactams, Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, and Avermectins, does not mandate any additional screening by industry or Regulatory Agencies with the evaluated 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.

Provided, that until an additional test method is 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 for the required Appendix N testing at current tolerance levels, 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. tolerance levels. (Refer to Section VI of Appendix N of this Ordinance.) Non-Beta lactam test methods which have been evaluated by FDA and have been found acceptable by FDA and the NCIMS as cited in M-a-85, latest revision, and M-I-92-11 for detecting non-Beta lactam drug residues in raw milk shall be used during the confirmation step. (Refer to M-a-85, latest revision, and M-I-92-11, for the approved non-Beta lactam test methods and M-a-98, latest revision, for the specific raw milk for which there are approved non-Beta lactam test methods available.) Enforcement action shall be taken on all confirmed positive non-Beta lactam results. (Refer to Section II of Appendix N of this Ordinance.) A result shall be considered confirmed positive for Beta lactams, Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, and Avermectins drug residues if it has been obtained by using a test method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS established in memoranda transmitted periodically by FDA.

Provided further, that until a test method is found acceptable by FDA and the NCIMS for Amphenicols (florfenicol), Macrolides, Aminoglycosides, or Avermectins in raw milk for the required Appendix N testing at current tolerance levels, screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening and verified screening positive steps, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. tolerance levels. Enforcement action as

cited in Appendix N of this Ordinance shall be taken on all verified screening positive Amphenicols (florfenicol), Macrolides, Aminoglycosides, and Avermectins results. (Refer to Section VI of Appendix N of this Ordinance.) ...

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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 at least one (1) of the following drug families (Beta lactams, Amphenicols (florfenicol) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins drug residues employing a random testing program. 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:

1. Alternating test method per bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers; or  
2. A statistical basis, which is calculated by FDA statisticians utilizing drug families identified from FDA's Veterinary Drug Risk Ranking Model. The number of milk tank truck loads or percentage based on the total number of milk tank truck loads received and/or each raw milk supply that has not been transported in bulk milk pickup tankers utilized from the previous year's data based on the drug family being tested are as follows:

- a. Beta-lactams: (Every bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers that is not being tested for one (1) of the drug families listed below);
- b. Amphenicols (florfenicol): (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%);
- c. NSAIDs (flunixin): (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%);
- d. Sulfonamides: (One (1) in seven (7) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (14%);
- e. Macrolides: (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%);
- f. Tetracyclines: (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%);
- g. Aminoglycosides: (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%); or
- h. Avermectins: (One (1) in fifteen (15) bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers (7%).

Additionally, other drug residues shall be ~~screened~~ tested for by employing a random sampling and testing 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*.)

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.

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

**NOTE:** On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted by the Regulatory Agency where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency in which the dairy farm is located as specified in Appendix B of this Ordinance and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues using approved test methods or verified screening positive test results using test methods not evaluated by FDA and accepted by the NCIMS from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers; or farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be retained or disposed of as determined by the Regulatory Agency.

All presumptive positive test results for drug residues on finished milk and/or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

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### **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 (~~confirmed~~) 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.

Further pickups or 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.

### **RECORD REQUIREMENTS:**

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested\*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if the initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load using approved test methods or a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS.

\*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above

information.

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Records of all sample test results shall be maintained for a minimum of six (6) months by the industry at the location where the ~~tests~~ test methods were run, and/or another location as directed by the Regulatory Agency.

## II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another Regulatory Agency's jurisdiction, 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, it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from which the milk originated.

### MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The test method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the test method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the ~~industry analyst~~ Industry Analyst (IA) test the samples. Receiving locations that choose to certify all receiving ~~analysts~~ IAs, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving ~~Industry Analysts~~ IAs and Industry Supervisors (ISs) successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I. INDUSTRY RESPONSIBILITIES of this Appendix for drug residues?
4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers and of the trace back to the farm of origin?
5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended

until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

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a. There should be ~~an~~ a documented agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be “timely” for example by telephone or fax, and supported in writing.

b. The ultimate disposition should either be prearranged in ~~an~~ a documented agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted ~~Beta lactam~~ specified drug residue milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CSI). Positive producers shall be handled in accordance with this Appendix.

d. All verified screening test positive loads using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

~~e.~~ 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 (~~confirmed~~) for drug residues using approved test methods, 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. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS. Positive producers shall be handled in accordance with this Appendix.

f. 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 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. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

eg. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry, under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records ~~should~~ shall be maintained by

industry and/or the Regulatory Agency that:

- (1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and
- (2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. ENFORCEMENT of this Appendix, as applicable, based on the test method utilized, and has cleared the milk for pick up and/or use.

Sufficient records ~~should~~ shall be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance*.

#### **ENFORCEMENT:**

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

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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.

**Prevention of the Sale of Milk:** Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, the Regulatory Agency shall immediately take effective measures to prevent the sale of milk containing drug residues.

**Penalties:** Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

**Reinstatement:** When the permit has been suspended as required, The the Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

**Follow-Up:** Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and

actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance*.

**Permit Revocation:** After a third violation for a drug residue using approved test methods in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

### **REGULATORY AGENCY RECORDS:**

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records shall indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?
4. What screening and/or confirmatory ~~test(s)~~ test method(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?
6. Which producer(s) was responsible?
7. Record of negative test results prior to subsequent milk pickup from the violative producer(s).

### **III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED**

#### **DEFINITIONS:**

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For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85<sub>2</sub> (latest revision), or M-I-92-11 approved test method, which has been promptly repeated 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.
2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive (confirmation) result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method as that used for the presumptive positive,

with a positive (+) and negative (-) control that give the proper results, and either or both of the duplicates are positive. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be performed by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ (CIS) using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Suspension Action:** A producer trace back/permit suspension action test is performed after a screening test positive load (confirmation) is identified by an Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS using the same or an equivalent (M-I-96-10, latest revision) test method as was used to obtain the screening test positive (load (confirmation)). A confirmed producer test positive result is obtained in the same manner as a ~~confirmation~~-(screening test positive (confirmation)) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the producer presumptive positive result. This testing is performed with a positive (+) and negative (-) control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

**NOTE:** 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 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 (~~confirmed~~) for drug residues using approved test methods, 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.

4. **Individual Producer Load:** An individual producer bulk milk pickup tanker is a bulk milk pickup tanker, or a compartment(s) of a bulk milk pickup tanker, that contains milk from only one (1) dairy farm.

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 feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system; and/or other raw milk storage containers.

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6. **Industry Analyst (IA):** A person under the supervision of a Certified Industry Supervisor (CIS) or Industry Supervisor (IS) who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

7. **Industry Supervisor/Certified Industry Supervisor (IS/CIS):** An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts (IAs) who test milk tank trucks and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N drug residue requirements.

8. **Certified Industry Supervisor (CIS):** An Industry Supervisor (IS) who is evaluated and

listed by a LEO as certified to conduct drug residue screening tests using approved test methods at industry drug residue screening sites for *Grade "A" PMO*, Appendix N regulatory enforcement actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit actions).

**9. Verified Screening Positive:** A verified screening positive test is a positive result from an initial testing using test methods not evaluated by FDA and accepted by the NCIMS of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers, which has been promptly repeated 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.

**10. Producer Trace Back With Permit Suspension Action Not Required:** A producer trace back test is performed after a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, is identified by an industry laboratory using the same test method as was used to obtain the verified screening positive load. A verified screening positive producer test result is obtained in the same manner as a verified screening positive for a bulk milk pickup tanker. After an initial positive result is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the initial producer positive result. This testing is performed with a positive (+) and negative (-) control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is verified as screening positive. (Refer to Section VI of this Appendix.)

**NOTE:** 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 used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be 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.

## **CERTIFIED INDUSTRY SUPERVISORS (CISs); EVALUATION AND RECORDS:**

Reference: *EML*

**1. Certified Industry Supervisors (CISs)/Industry Supervisors (ISs)/Industry Analysts (IAs):** Regulatory Agencies may choose to allow ~~Industry Supervisors ISs~~ to be certified. Under this program, these ~~Certified Industry Supervisors CISs~~ may officially confirm using approved test methods presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO shall use the appropriate Appendix N. FDA/NCIMS 2400 Form when evaluating Official Laboratories, Officially Designated Laboratories or ~~Certified Industry Supervisors CISs, Industry Supervisors ISs and Industry Analysts IAs.~~ The ~~Certified Industry Supervisor/Industry Supervisor CIS/IS~~ shall report to the LEO the results of all competency evaluations performed on ~~Industry Analysts IAs.~~ The names of all ~~Certified Industry Supervisors CISs, Industry Supervisors ISs and Industry Analysts IAs,~~ as well as their training and evaluation status, shall be maintained by the LEO and updated as replacement, additions and/or removals occur. The LEO shall verify (document) that each

~~Certified Industry Supervisor CIS~~ and/or ~~Industry Supervisor IS~~ has established a program that ensures the proficiency of the ~~Industry Analysts IAs~~ they supervise. The LEO shall also verify that each ~~Industry Supervisor IS~~ and ~~Industry Analysts IA~~ has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the ~~Industry Supervisor IS~~ or ~~Industry Analysts IA~~ to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of ~~Industry Supervisors ISs~~ and/or ~~Industry Analysts IAs~~. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for ~~Certified Industry Supervisors CISs~~ and the training requirements for ~~Industry Supervisors ISs~~ and ~~Industry Analysts IAs~~.)

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2. **Sampling and Testing of Bulk Milk Pickup Tankers:** The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample shall be representative. The sample analysis shall be completed before the milk is processed.

3. **Sampling and Testing of Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers:** All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s) supply. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

4. **Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

5. **Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results:** If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of

under the supervision of the Regulatory Agency.

**BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST:**

1. **Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, as defined in the SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN RAW BULK MILK PICKUP TANKERS of this Section, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. ~~Industry analysts IAs~~ may screen tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the ~~Industry Supervisor IS~~ Certification Program.

a. Industry Presumptive Positive Options Using Approved Test Methods: There are two (2) industry options for the milk represented by a presumptive positive sample using approved test methods:

(1) 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 in an Official Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor CIS~~ at a location acceptable to the Regulatory Agency. Documentation of 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 tankers 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 the same or equivalent test method (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. 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 correct reactions, the sample is deemed a Screening Test Positive (~~Confirmed~~ Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers 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.

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(2) The owner of the presumptive positive milk may reject the load and/or raw milk

supply that has not been transported in bulk milk pickup tankers without further testing. At that time the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

**NOTE:** 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 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 (~~confirmed~~) for drug residues using an approved test method, 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.

### 3. **Re-Sampling:**

a. Presumptive Results Using Approved Test Methods: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained using approved test methods. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results Using Approved Test Methods: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP*, FDA/NCIMS 2400 Forms, Appendix N and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency shall be based on objective evidence. A Regulatory Agency allowing re-sampling shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is are necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

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### 4. **Producer Trace Back:**

a. All screening test confirmed positive (~~confirmed~~) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official Laboratory, Officially Designated Laboratory or by a ~~Certified Industry Supervisor~~ CIS. Positive producers shall be handled in accordance with this Appendix.

**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 (~~confirmed~~) for drug residues using an approved test method, 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.

b. All screening verified positive loads using test methods not evaluated by FDA and accepted by the NCIMS, without additional confirmation required, shall be broken down (producer trace back) using the same test method. Verification producer trace back tests shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

**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 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.

Assuring Representative Samples From Individual-Producer Loads And Multiple-Farm Tank Loads From An Individual Producer: Representative samples shall be secured from each farm storage tank(s)/silo(s) of milk prior to loading onto a bulk milk pickup tanker and/or other raw milk supply transportation method at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker and/or other raw milk supply transportation method to a designated location acceptable to the Regulatory Agency.

**Record Requirements:** Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo, or other raw milk storage container(s), etc. used for the storage of raw milk supplies that have not been transported in bulk milk pickup tankers being tested\* ;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test method performed/lot #/any and all controls (+/-);
5. Results of the test, if the analysis results are positive the record shall show:
  - a. The identity of each producer contributing to the positive load;
  - b. Who at the Regulatory Agency was notified;
  - c. When did this notification take place; and
  - d. How was this notification accomplished.
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed; and
8. Prior test documentation shall be provided for a presumptive positive load when using an approved test method or a verified screening positive load when using test methods not

evaluated by FDA and accepted by the NCIMS.

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\*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

**SCREENING TESTS TEST METHODS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:**

**1. Performance Tests/Controls (+/-):**

- a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
- b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
- c. All NCIMS Approved Confirmation Test Methods for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers ~~Screening Tests~~ Include the Following Format:

All presumptive positive test results shall be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with ~~single~~ positive (+) and negative (-) controls by a certified analyst (Official Laboratory, Officially Designated Laboratory or ~~Certified Industry Supervisor~~ CIS) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control results, the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency in which the testing was conducted, as a screening test positive (confirmed).

- d. All Test Methods Used by Industry, which have Not been Evaluated by FDA and Accepted by the NCIMS for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Include the Following Format:

One (1) of the options provided for in Section VI of this Appendix shall be followed.

- ~~e.~~ All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.

(1) For tests that have been validated and only detect Penicillin, Ampicillin, Amoxicillin and Cephapirin, the positive (+) control is Pen G @  $5 \pm 0.5$  ppb.

(2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @  $10 \pm 1$  ppb.

(3) For test kits validated for one (1) drug residue only, the positive (+) control is  $\pm 10\%$  of the safe level/tolerance of the drug residue detected.

**2. Work Area:**

- a. Temperature within specifications of the test kit manufacturer's labeling.
- b. Adequate lighting for conducting the test kit procedure.

**3. Test Kit Thermometers:**

- a. Thermometer traceable to a NIST Certified Thermometer.
- b. Graduation interval not greater than  $1^{\circ}\text{C}$ .
- c. Dial thermometers are not used to determine the temperatures of samples, reagents,

refrigerators, or incubators in milk laboratories.

4. **Refrigeration:**

a. Test kit reagent storage temperature specified by manufacturer.

5. **Balance (Electronic):**

a. 0.01 g for preparation of positive (+) controls.

b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of  $\pm 5\%$ . These devices may be calibrated at another location acceptable to the LEO.

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6. **Screening Test Method Sampling Requirements:**

a. Temperature of milk in the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers determined and recorded.

b. Representative bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sample for drug residue testing collected.

c. Samples tested within seventy-two (72) hours of collection.

7. **Screening Test Method Volumetric Measuring Devices:**

a. Single use devices provided by kit manufacturers are acceptable for Appendix N screening analysts.

b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the LEO.

c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N screening. ...

#### **IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES**

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutorial guidelines and in full consistency with *CNI v. Young* stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and

2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes or additions of "safe levels" shall be transmitted via Memoranda of Information (M-I's).

#### **V. APPROVED TEST METHODS**

Regulatory Agencies and industry shall use tests test methods from ~~the most recent revision of M-a-85, latest revision, and M-I-92-11~~ 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 the

following drug families: Beta lactams, NSAIDs (flunixin), Sulfonamides, Macrolides, Amphenicols (florfenicol), Tetracyclines, Aminoglycosides, and Avermectins 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 Ordinance. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory Enforcement action based on each test kit 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 Ordinance.

One (1) year after a drug test(s) test method(s) have has been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family Amphenicols (florfenicol), NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins, other unevaluated drug tests test method(s) for that particular drug or drug family are not acceptable for screening milk 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 tests test methods by FDA and the NCIMS for drugs other than Beta lactams, NSAIDs (flunixin), Sulfonamides, Macrolides, Amphenicols (florfenicol), Tetracyclines, Aminoglycosides, and Avermectins, 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 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.

## **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):**

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 tankers 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 Tankers 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.

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 tankers 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 Tankers 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.

**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 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. 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. Enforcement action involves the penalty of the removal of the adulterated milk 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 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 shall be made to determine the cause. The farm inspection is 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)/silo(s), 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.

*Note: Section VI of Appendix N of the PMO contained within this Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2015 National Conference on Interstate Milk Shipment following FDA's concurrence with the NCIMS Executive Board.*

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



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 218  
Committee: Appendix N/Lab

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

**A. Summary of Proposal**

This proposal clarifies the scope of the current drug residue test kit requirements contained in Appendix N for drug residue testing.

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

This proposal clarifies that the drug residue test kit requirements as currently outlined in Appendix N apply only to those drug residues for which testing is mandated by the Grade "A" PMO (currently the beta-lactams).

This proposal does not change current drug residue testing requirements and responsibilities as required by the PMO.

**C. Proposed Solution**

Changes to be made on page(s): 374 of the (X - one of the following):

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

## V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 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 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. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit 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 test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk for compliance with Section 6 of this Ordinance. The acceptance of evaluated tests does not mandate any additional screening by industry with the evaluated method.

Name:	NMPF NCIMS Committee		
Agency/Organization:	National Milk Producers Federation		
Address:	2101 Wilson Blvd, Suite 400		
City/State/Zip:	Arlington, VA 22201		
Telephone No.:	703-243-6111	E-mail Address:	bbriczinski@nmpf.org

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 219

Committee: Lab

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

**A. Summary of Proposal**

The PMO requires the Regulatory Agency to do the arithmetical averaging of sample results from producers shipping multiple tanks/loads of raw milk in a day. This proposal is to allow personnel in an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency to do the arithmetical averaging.

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

The PMO requires collection of a representative raw milk sample from each farm bulk milk tank and/or silo. Each sample must be delivered to an approved location for analysis to evaluate compliance with bacterial count and somatic cell count standards. Personnel at the testing laboratory report test results to the Regulatory Agency. It is increasingly common for a milk producer to ship more than one load of milk to a milk plant and, thus multiple samples from a producer are collected and analyzed in a day. The PMO currently requires the individual daily analytical results to be arithmetically averaged by the Regulatory Agency. It is not difficult to calculate an arithmetic average, either manually or by computer. The same types of safeguards already in place to ensure the integrity of laboratory analyses and reported results would ensure the integrity of calculated arithmetic averages.

**C. Proposed Solution**

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

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

**Make the following change to page 28 of the 2013 PMO (citation starts at line 13:**  
**NOTE:** When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency or by personnel at an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency and recorded as the official results for that day.

Name:	Steve Ingham		
Agency/Organization:	Wisconsin Department of Agriculture, Trade and Consumer Protection; Division of Food Safety		
Address:	P.O. Box 8911		
City/State/Zip:	Madison, WI 53708-8911		
Telephone No.:	608-224-4701	E-mail Address:	Steve.Ingham@wisconsin.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 220  
Committee: Other Species

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

**A. Summary of Proposal**

For sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year: the sample history of somatic cell counts will not carry forward through the months where no product was available to sample and instead the sampling counts will begin afresh with each new milking season.

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

Just like dairy goats, dairy sheep are seasonal breeders and due to the physiology of the sheep secretory system, the Somatic Sell Count (“SCC”) increases as the stage of lactation progresses.

Seasonal sheep milk producers begin each spring with all ewes entering the milking season at the same exact time. The flock is substantially different than the one last tested in the fall of the previous year. These ewes have all recently lambed. Many older ewes were culled or have died and a significant number of younger replacements are introduced into the milking parlor. New ewes rarely enter the milking parlor once the season is underway.

Therefore, for seasonal producers, the entire flock is at the same stage of

lactation as the count elevates, resulting in counts in excess of 750,000/mL which then causes these sheep dairies to be cited for violations of the SCC Standard.

This phenomenon will leave the seasonal dairies with a high potential for ending the season in a 2 out of 4 or even a 3 out of 5 violation. Now, even though this seasonal dairy will suspend milking operations for more than 6 months and will restart in the spring with a significantly different flock, they are still in the same exact violation status as they were in the fall and will remain in perpetual peril of suspension of permit or court action. In effect, the new flock carries forward the violations of the old flock.

Large sheep milk producers who utilize confinement systems milk year round. They are constantly managing their flocks by adding and culling ewes throughout the year. This allows them to maintain different lactation stages throughout the flock and yield SCC results at consistent numbers at any point of the calendar and meet the current 750,000/mL Standard.

But for smaller, seasonal flocks that are only in one and the same stage of lactation at a certain sampling date, the probability of exceeding that SCC Standard is increased. And those violations will likely occur more frequently as the season progresses. When the new milking season begins again in the spring, the seasonal producer is likely to be already in some stage of violation of the SCC Standard. Thus, it becomes a constant ordeal to meet the SCC Standard because any new violation may trigger additional violations and/or greater penalties.

Given that the seasonal producer begins each new season with a substantially different flock after a significant amount of time has passed, it is logical and reasonable to simply begin the sampling counts afresh and disregard the sample history from the previous flock results from the prior year.

Crucially, the sheep milk derived from elevated SCC is neither a human nor animal health issue. The proven scholarship presented by the National Mastitis Council, the National Conference on Interstate Milk Shipments, and so many others who, more than a decade ago, concluded “consuming milk with high SCC does not appear to pose direct, specific health risks to humans.” Furthermore, “there is no evidence that any particular cell count *per se* has any significant effect on human health.” It’s now settled that elevated SCC is not, and never was, a human health issue.

Regarding animal health, notable members of the NCIMS, Other Species Milk Committee, such as Daniel Scruton and Judy Kapture agree that sheep have a much more acute response to a minor udder infection than cows: “A slight infection that might cause a cow’s SCC to rise to 200,000 might cause...sheep [SCC to] have an even more acute response. A sheep might respond to the same infection with a SCC of 4.0 million.” (Daniel L. Scruton, NCIMS, Other Species Milk Committee and Vermont Department of Agriculture, Food and Markets, as quoted in “Goat Dairies Lower SCC Significantly in Vermont”, by Judy Kapture, Industry Technical Advisor, NCIMS Other Species Milk Committee)

Said another way, “Mastitic conditions affect milk composition in sheep as it does in cow or goat milk, except that monitoring the indirect parameter of somatic cell counts (SCC) in milk is much less related to pathogenic conditions in sheep as it is in goat udders compared to cow udders, and that high SCC (>1 million/ml) do occur in normal sheep and goat milk, especially towards the end of lactation” (Bufano et. al., 1996).

Thus, sheep may present elevated SCC and be perfectly healthy. In fact, the SCC of the flock may rise and fall unpredictably and erratically during the lactation cycle and yet be healthy producers throughout. (To be clear: truly mastitic sheep are easily identifiable, quickly treated, or culled.) Although it is true that elevated SCC in cows is a clear indicator of a health problem, it is not necessarily true for sheep or goats. These are undisputed facts. Therefore, not carrying forward the SCC sample history for sheep is neither a human nor an animal concern.

It’s worth noting that sheep milk cheese produced with elevated SCC milk retains the same standards of quality and taste with no diminution in value. It’s also worth noting that the facilities and final products of all milk producers and dairies are constantly inspected and tested by both the FDA and State Agriculture & Markets Agencies. These inspections provide the ultimate check on the output of any dairy and can be relied upon to ensure that high quality product enters the market.

It should be mentioned that, at one time, the FDA responded to the question: “Does the Regulatory Agency carry the sample history forward through the months where no product was available to sample?” And, at that time, the FDA offered a one-word response: “Yes”. This question was included in the “Questions and Answers from FY’03 Regional Milk Seminars” dating back to December 11, 2003.

However, the question was asked in the context of a hypothetical “farm that dries off (discontinues production) for an extended period of time (**60 days or more**).”

This proposal seeks to not carry forward the sample history only for farms that discontinue production in excess of **6 months** which is a much more significant amount of time. During this time, the sheep flock will be dried off and bred, a gestation period of 5 months will elapse, many older ewes will die or be culled and many younger replacement ewes will enter the milking parlor. In other words, during this significant period of time, the composition of the flock has changed substantially. This presents quite a different scenario than the original question.

Equally important, this question was asked over a decade ago. Since that time, the goat and sheep dairy industries have evolved and steadily grown driven by the rise of seasonal producers. Of course, dairy goat producers have resolved the issue of elevated SCC counts by successfully raising the SCC Standard to 1,500,000/mL effectively avoiding any potential violations at any point of the lactation cycle. Dairy sheep producers have not been so lucky. Thus, they continue to suffer violations of the SCC Standard. Given the increased numbers of small, seasonal sheep dairies since the FDA last addressed the ‘carry forward’ question, it is appropriate to revisit this issue now.

The American sheep dairy industry has steadily grown over the last 20 years. But, it is still in its infancy compared to the rest of the world. According to Dave Thomas (Department of Animal Sciences, University of Wisconsin-Madison), the USA still imports approximately 70 million pounds of sheep milk cheese each year but only produces less than 2 million pounds at home. This presents a huge opportunity for USA sheep dairy expansion. Presumably, the American Regulatory Agencies are not in the business of suppressing and discouraging this expansion, but rather they support and encourage sheep dairies and are responsive to rule changes that support the seasonal producers who make this industry so successful. To that end, this proposal seeks a simple modification to facilitate continued expansion of these smaller seasonal sheep dairies.

Please note that this proposal is very narrowly drawn to affect only sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year. And, it only impacts SCC samples; it has no effect on bacterial counts, coliform determinations or cooling temperatures all of which can be carried forward to the next milking season.

**C. Proposed Solution**

Changes to be made on page(s):		28	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

**Modify the 2013 PMO, Section 6, The Examination of Milk and/or Milk Products, page 28:**

Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts, somatic cell counts, coliform determinations or cooling temperatures. For sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year: the sample history of somatic cell counts will not carry forward through the months where no product was available to sample and instead the sampling counts will begin afresh with each new milking season.

Name:	Paul Borghard		
Agency/Organization:	Three Corner Field Farm, LLC		
Address:	1311 County Route 64		
City/State/Zip:	Shushan/NY/12873		
Telephone No.:	518-222-6694	E-mail Address:	paulborghard@aol.com



# 35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 221  
Committee: Lab

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

## A. Summary of Proposal

This proposal introduces a new method, the TEMPO laboratory instrument, used for the enumeration of aerobic mesophilic flora in pasteurized milk and milk products. The TEMPO AC method utilizes a vial of culture medium and card with transfer tube specific to this test. The culture medium is inoculated with the sample and the inoculated medium is transferred into a card containing 48 wells of three different volumes: 2.25µl, 22.5µl, and 225µl. The card is hermetically sealed and incubated for 22-28 hours at 32 ±1°C. The microorganisms present in the card reduce the substrate in the culture medium which results in the appearance of a fluorescent signal. The TEMPO Reader detects the signal and calculates the amount of microorganisms present in the sample, in accordance with calculations based on the Most Probable Number (MPN) method, and converts to a corresponding CFU/mL.

An internal and independent study was previously conducted through the *AOAC Research Institute Performance Tested Method program*, comparing the TEMPO AC method to the AOAC 966.23 (non-dairy) and the Standard Methods for the Examination of Dairy Products (SMEDP) (dairy) Standard Plate Count Method for enumeration of aerobic microorganisms in food. Based on the results of these studies, the TEMPO® AC for the Enumeration of Aerobic Mesophilic Flora in Foods was granted AOAC RI PTM status ( Certificate #121204).

In addition, the TEMPO AC is included in the newest revision to the USDA MLG. See statement below from the USDA.

The FSIS laboratory system has validated the TEMPO® system for analysis of four indicator organisms of sanitary conditions. The automated Most Probable Number system can be used to examine aerobic plate count, coliforms, generic *E. coli*, and Enterobacteriaceae as sanitary indicators in poultry rinses, raw pork, raw poultry and raw beef products. The methods, which will be included in Microbiology Laboratory Guidebook (MLG) 3.02, will be available on or after Jan. 5, 2015, for studies and regulatory programs identified as needing analysis of one or more of these sanitary indicators.

A collaborative study was also performed in conjunction with the FDA Milk Split samples. Eight labs and a total of 18 analysts participated in this study comparing TEMPO AC to Petrifilm for the Milk Splits. Five of the eight participating labs are NCIMS approved laboratories. Statistical analysis of the TEMPO AC results compared to the Petrifilm indicated that there is no statistically significant bias between the two methods for these data. A data summary will be forwarded to the NCIMS Lab Committee for review.

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

Because of the interest in developing rapid and less labor intensive alternative tests, the TEMPO<sup>®</sup> AC is being proposed as an alternative method to the SPC. The TEMPO<sup>®</sup> AC test provides an automated alternative to the current SPC method, resulting in significant savings in time and labor costs. This method also reduces the opportunity for subjectivity associated with current plate count methods, and allows direct input of data into the user's data management system.

**C. Proposed Solution**

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

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

Changes suggested:

- A. 1. 2013 PMO Section 6, Page 29, "**Laboratory Techniques**", Item 1: Amend to read: Standard plate count at 32°C (agar, Petrifilm method or *TEMPO AC method*).
  
- B. 1. 2011 EML, Section 2: **Proficiency Testing Programs**, page 10, Split Sample Analysis: add *TEMPO AC method* to the list of methods listed in the introductory paragraph
- 2. 2011 EML, Section 2: **Proficiency Testing Programs**, page 10, Split Sample Analysis, Item 2: Amend to read: Calculate the logarithmic mean for the Standard Plate Count, Plate Loop Count, BactoScan FC Count (BSC), *TEMPO AC method*, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase Count and Vitamin A and D<sup>3</sup> results of each test sample; .....
- 3. 2011 EML, Section 2: **Proficiency Testing Programs**, page 11, Analyst Performance Level, Item 1: add *TEMPO AC method* to the list of methods listed.

A draft 2400 form will also be submitted to the NCIMS Laboratory Committee

Name: John Mills, Senior Staff Scientist

Agency/Organization: bioMérieux, Inc.

Address: 595 Anglum Rd

City/State/Zip: Hazelwood, MO 63042

Telephone No.: 314 731-8691

E-mail Address: john.mills@biomerieux.com



# 35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 222

Committee: Lab

No  
Action

Passed as  
Submitted

Passed as  
Amended

COUNCIL ACTION

FINAL ACTION

## A. Summary of Proposal

This proposal introduces a new method, the TEMPO laboratory instrument, used for the enumeration of coliform bacteria in pasteurized milk and milk products. The TEMPO CC method utilizes a vial of culture medium and card with transfer tube specific to this test. The culture medium is inoculated with the sample and the inoculated medium is transferred into a card containing 48 wells of three different volumes: 2.25µl, 22.5µl, and 225µl. The card is hermetically sealed and incubated for 22-28 hours at 32 ±1°C. The microorganisms present in the card reduce the substrate in the culture medium which results in the appearance of a fluorescent signal. The TEMPO Reader detects the signal and calculates the amount of microorganisms present in the sample, in accordance with calculations based on the Most Probable Number (MPN) method, and converts to a corresponding CFU/mL.

The TEMPO CC method was previously validated according to AOAC RI Guidelines in a harmonized PTM study. For the PTM study, eighteen foods were evaluated including pasteurized milk, powered milk and ice cream. CC was granted AOAC RI PTM status (Certificate #060702).

In addition, the TEMPO CC is included in the newest revision to the USDA MLG. See statement below from the USDA.

**The FSIS laboratory system has validated the TEMPO® system for analysis of four indicator organisms of sanitary conditions. The automated Most Probable Number system can be used to examine aerobic plate count, coliforms, generic *E. coli*, and Enterobacteriaceae as sanitary indicators in poultry rinses, raw pork, raw poultry and raw beef products. The methods, which will be included in Microbiology Laboratory Guidebook (MLG) 3.02, will be available on or after Jan. 5, 2015, for studies and regulatory programs identified as needing analysis of one or more of these sanitary indicators.**

A collaborative study was also performed in conjunction with the FDA Milk Split samples. Eight labs and a total of 18 analysts participated in this study comparing TEMPO CC to Petrifilm for the Milk Splits. Five of the eight participating labs are NCIMS approved laboratories. A data summary will be forwarded to the NCIMS Lab Committee for review.

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

Because of the interest in developing rapid and less labor intensive alternative tests, the TEMPO<sup>®</sup> CC is being proposed as an alternative method to the coliform count. The TEMPO<sup>®</sup> CC test provides an automated alternative to the current coliform count method, resulting in significant savings in time and labor costs. This method also reduces the opportunity for subjectivity associated with current plate count methods, and allows direct input of data into the user's data management system.

**C. Proposed Solution**

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

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

Changes suggested:

1. 2013 PMO Section 6, Page 29, "**Laboratory Techniques**", Item 3: Amend to read: Coliform test with solid media, Petrifilm method *or TEMPO CC method* at 32°C for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products, except unflavored whole, reduced or low fat and nonfat (skim) milk.

A draft 2400 form will also be submitted to the NCIMS Laboratory Committee

Name:	John Mills, Senior Staff Scientist		
Agency/Organization:	bioMérieux, Inc.		
Address:	595 Anglum Rd		
City/State/Zip:	Hazelwood, MO 63042		
Telephone No.:	314 731-8691	E-mail Address:	john.mills@biomerieux.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #:	223
Committee:	Other Species/Lab

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

**A. Summary of Proposal**

To raise the Somatic Cell Count (“SCC”) limit for sheep milk from the current 750,000/mL to 1,000,000/mL for sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year.

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

In 1993, the dairy cow Somatic Sell Count (“SCC”) Standard was lowered to 750,000/mL. Simultaneously, the dairy sheep SCC Standard was also lowered to 750,000/mL. The goat Standard remained at 1,000,000/mL and was later raised to 1,500,000/mL.

At that time, the dairy goat industry was large and expanding and benefited from funding by the American Dairy Goat Association. But, the dairy sheep industry was still fledgling and developing and did not have the support or funding from any centralized organization. In fact, there were very few sheep milk producers at all. Thus, there was a dearth of data and research for sheep. Coupled with the lack of any organized voice for the very few sheep milk dairy producers, the NCIMS apparently made the easiest and most conservative decision to lower the

SCC Standard for sheep to the same Standard as cows.

The question arises why the sheep SCC Standard was set to the cows SCC Standard and not to the goats SCC Standard. The similarities between goats and sheep are well established. Sheep and goats are closely related. Both are in the same subfamily, Caprinae, and it is sometimes difficult to tell if a specific breed or strain is a goat or a sheep. Both goats and sheep share obvious physical characteristics: similar in size, hoofed ruminants, possessing similar gestation periods, etc.

But, most importantly as it relates to SCC, sheep and goats share the same apocrine milk secretion system. Cows have a completely different merocrine system. The apocrine system results in cytoplasmic particles being present in the milk of both goats and sheep. There is a potential for these particles to increase for both goats and sheep during later stages of lactation due to the decrease in milk volume.

Because both goats and sheep exhibit increased cytoplasmic particles, the traditional methods of counting SCC were initially inaccurate. As a result, the method of staining was officially changed to an alternative stain, Pyronin Y-Methyl Green, which can distinguish cytoplasmic particles and insure these are not counted. This is now the Standard Method used across the United States for both goats and sheep...but not for cows.

The common secretion systems of goats and sheep and the change in counting methodology for both goats and sheep offer direct evidence of how closely goats and sheep are similar and how significantly cows and sheep differ.

It has been claimed that historically there have been no problems for sheep milk producers meeting the 750,000/mL SCC standard for cows so no one requested an exception for sheep. Of course, at the time the Standard was lowered in 1993, there were virtually no sheep dairy operations to voice an objection. In any case, the argument that a low SCC is attainable is not sufficient for setting the Standard. Many cow dairies can achieve consistent SCC results below 200,000/mL. But, nobody would suggest lowering the Standard to 200,000/mL. Just because it is possible for some does not make the case that it must now be required for all.

And, today, large sheep milk producers may accept and meet the Standard, but that is certainly not true for small seasonal producers. The sheep milk industry is now expanding rapidly and some producers...especially smaller seasonal producers...are finding high counts an issue.

The single biggest difference between the larger and smaller operations is the age of the flock. Larger operations follow the traditional confinement system model and older ewes...who have a propensity for higher SCC levels...are routinely culled whether they are healthy or not. This allows them to maintain SCC results at consistent numbers at any point of the calendar and meet the 750,000/mL SCC Standard. Smaller operations simply cannot afford to cull otherwise healthy, older ewes with elevated SCC to avoid violating the Standard. These older ewes are valuable producers of milk, wool and lambs and can be productive for years.

The other major factor affecting SCC is seasonality. Just like dairy goats, the basic problem is that dairy sheep are seasonal breeders and due to the physiology of the sheep secretory system, the somatic cell count increases as the stage of lactation progresses. Therefore, for seasonal producers, the entire flock is at the same stage of lactation as the count elevates, resulting in counts in excess of 750,000/mL which then causes these sheep dairies to be cited for violations of the Standard.

Crucially, the sheep milk derived from elevated SCC is neither a human nor animal health issue. The proven scholarship presented by the National Mastitis Council to the National Conference on Interstate Milk Shipments, and so many others who, more than a decade ago, concluded “consuming milk with high SCC does not appear to pose direct, specific health risks to humans.” Furthermore, “there is no evidence that any particular cell count *per se* has any significant effect on human health.” It’s now settled that elevated SCC is not, and never was, a human health issue.

Regarding animal health, notable members of the NCIMS, Other Species Milk Committee, such as Daniel Scruton and Judy Kapture agree that sheep have a much more acute response to a minor udder infection than cows: “A slight infection that might cause a cow’s SCC to rise to 200,000 might cause...sheep [SCC to] have an even more acute response. A sheep might respond to the same infection with a SCC of 4.0 million.” (Daniel L. Scruton, NCIMS, Other Species Milk Committee and Vermont Department of Agriculture, Food and Markets, as quoted in “Goat Dairies Lower SCC Significantly in Vermont”, by Judy Kapture, Industry Technical Advisor, NCIMS Other Species Milk Committee)

Said another way, “Mastitic conditions affect milk composition in sheep as it does in cow or goat milk, except that monitoring the indirect parameter of somatic cell counts (SCC) in milk is much less related to pathogenic conditions in sheep as it is in goat udders compared to cow udders, and that high SCC (>1 million/ml) do occur in normal sheep and goat milk, especially towards the end of lactation” (Bufano et. al., 1996).

Thus, sheep may present elevated SCC and be perfectly healthy. In fact, the SCC of the flock may rise and fall unpredictably and erratically throughout the lactation cycle and yet be healthy producers throughout. (To be clear: truly mastitic sheep are easily identifiable, quickly treated, or culled.) Although it is true that elevated SCC in cows is a clear indicator of a health problem, it is not necessarily true for sheep or goats. These are undisputed facts. Therefore, a higher SCC Standard for sheep is neither a human nor an animal concern.

On the other hand, there is an abundance of evidence that elevated SCC in milk reduces yield. So, it is important to milk buyers that the SCC Standard is low to increase yield and, therefore, profits. In other words, elevated SCC is an economic issue. So, it is perfectly understandable that milk buyers seek the lowest possible SCC Standard. But, seasonal sheep milk producers who do not sell their milk should not be held to the same SCC Standard milk buyers demand. Instead, these seasonal sheep milk producers who are not driven by quantity and who use all of their own milk for their own cheese-making should be afforded a slightly higher yet previously acceptable Standard.

It's worth noting that sheep milk cheese produced with elevated SCC milk retains the same standards of quality and taste with no diminution in value. It's also worth noting that the facilities and final products of all milk producers and dairies are constantly inspected and tested by both the FDA and State Agriculture & Markets Agencies. These inspections provide the ultimate check on the output of any dairy and can be relied upon to ensure that high quality product enters the market.

The American sheep dairy industry has steadily grown over the last 20 years. But, it is still in its infancy compared to the rest of the world. According to Dave Thomas (Department of Animal Sciences, University of Wisconsin-Madison), the USA imports approximately 70 million pounds of sheep milk cheese each year but only produces less than 2 million pounds at home. This presents a huge opportunity for USA sheep dairy expansion. Presumably, the American Regulatory Agencies are not in the business of suppressing and discouraging this expansion, but rather they support and encourage sheep dairies and are responsive to rule changes that support the seasonal producers who make this industry so successful. To that end, this proposal seeks a simple modification to facilitate continued expansion of these seasonal sheep dairies.

Please note that this proposal does not request that the sheep milk SCC Standard be raised as high as the goat milk SCC Standard of 1,500,000/mL. It is understood that further research would be required to support that elevation. This proposal is very narrowly drawn and merely seeks a return to the previously

acceptable SCC Standard of 1,000,000/mL which provides a reasonable cushion throughout the lactation cycle but only for sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year.

In conclusion, there was no science to support setting the sheep SCC Standard to the cows SCC Standard in 1993. There is no science today supporting this connection. To the contrary, all the observable facts, objective data, and considered science should lead to the conclusion that sheep are much more closely aligned with goats and not cows. Rather than arbitrarily linking sheep to cows, it would have been more rational to link sheep to goats. The sheep SCC Standard should have logically remained the same as goats at 1,000,000/mL when the dairy cow standard was lowered to 750,000/mL. Until there is research that establishes some sort of link between cows and sheep, the Standard should be returned to 1,000,000/mL at least for sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year.

**C. Proposed Solution**

Changes to be made on page(s): 30 and 34 of the (X - one of the following):

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

**Modify the 2013 PMO, Section 6, The Examination of Milk and/or Milk Products, Laboratory Techniques, page 30, item 6c:**

6c. Sheep Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results from the Single Strip DMSCC procedure exceed the 750,000/mL standard set forth in this *Ordinance*, the count shall have been derived from, or be confirmed by, the Pyronine Y Methyl-Green Stain or the "New York modification". For sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year: the SCC Standard will be

1,000,000/mL.

**Modify the 2013 PMO, Section 7, Standards for Grade “A” Milk and /or Milk Products, page 34, Table 1, footnote \*:**

\*Goat Milk 1,500,00/mL; For sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year: 1,000,000/mL.

Name:	Paul Borghard		
Agency/Organization:	Three Corner Field Farm, LLC		
Address:	1311 County Route 64		
City/State/Zip:	Shushan/NY/12873		
Telephone No.:	518-222-6694	E-mail Address:	paulborghard@aol.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 224

Committee: Lab

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

**A. Summary of Proposal**

Revise wording in Section 6, Laboratory Techniques, of the PMO to allow new simplified methods for bacterial detection that have been FDA/NCIMS evaluated published in M-a-98, latest revision, and accepted into a 2400 series form.

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

Current bacterial standards in the PMO use brand name products. Wording can be made more generic to allow future development. The use of new evaluated and approved bacterial detection methods with 2400 forms, and for matrices communicated in M-a-98, latest revision, can be allowed without needing to revise the PMO each time a new method is developed.

**C. Proposed Solution**

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

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

p.29

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 Forms, SMEDP and OMA. The procedures shall be those specified therein for:

p.30

1. Bacterial count at 32°C (89.6°F) (Standard Plate Count (SPC) or ~~Petrifilm Aerobic Count (PAC)~~ other approved simplified aerobic count methods for milk and milk products communicated in M-a-98 latest revision).
2. Alternate methods, for bacterial counts at 32°C (89.6°F), including the Plate Loop Count (PLC), ~~Spiral Plate Count and the BactoScan FC~~ and other approved alternative methods for raw milk communicated in M-a-98, latest revision.
3. Coliform count at 32°C (89.6°F) (Coliform Plate Count, ~~Petrifilm Coliform Count (PCC)~~ and/or High Sensitivity Coliform Count (HSCC) or other approved simplified coliform count methods) for all milk and/or milk products communicated in M-a-98 latest revision.

Name:	Robert Salter		
Agency/Organization:	Charm Sciences, Inc.		
Address:	659 Andover St.		
City/State/Zip:	Lawrence, MA 01843		
Telephone No.:	978-687-9200 x134	E-mail Address:	bobs@charm.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 225  
Committee: Other  
Species/Lab

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

**A. Summary of Proposal**

The Proposal is to include in Section 6, The Examination of Milk and/or Dairy Products, the appropriate somatic cell counting method and appropriate somatic cell count standard for use with camel milk.

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

The demand for camel milk is expanding across the country. Currently unregulated camel milk is being purchased and shipped. A large part of this niche market milk supply is for use by autistic children. The fact that unregulated camel milk is being consumed by children, or by any part of the population, is of extreme public health significance. Since 2009, the NCIMS Other Species Milk Committee has assisted in collecting science based data pertinent to the goal of including dromedary camel milk in the PMO. At this time there is sufficient data available to determine that camels have an apocrine lactation system as do sheep and goats; whereas bovines have a merocrine lactation system. There is sufficient data available to determine that the appropriate somatic cell counting method for camel milk would be the Direct Microscopic Somatic Cell Count (DMSCC) done with the Pyronine Y Methyl Green (PYMG) stain, which is the method used with the other apocrine species, sheep and goats. Therefore, camel milk cell count should be derived from, or confirmed by Single Strip DMSCC done with the PYMG stain.

There is also sufficient data to determine the current bovine somatic cell count standard of 750,000 /mL, is the appropriate cell count standard for camel milk, as it is for sheep milk.

**C. Proposed Solution**

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

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

Section 6. Examination of Milk and/or Dairy Products, under 6. Screening and Confirmatory Methods for the Detection of Abnormal Milk. Addition of section d.

d. Camel Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results exceed the 750,000/mL standard set forth in this Ordinance, the count shall have been derived from, or be confirmed by, the Single Strip DMSCC using the Pyronine Y Methyl-Green Stain or the "New York modification", and conducted by analysts certified for that procedure.

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

Name:	Lynn Hinckley		
Agency/Organization:	NCIMS, Other Species Milk Committee, Chairperson		
Address:	148 Jordan Road		
City/State/Zip:	Willimantic, CT 06226		
Telephone No.:	860-208-6210	E-mail Address:	lshinckley@yahoo.com

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 226

Committee: Lab

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

**A. Summary of Proposal**

Change PMO bacteriological water standards to address EPA elimination of the MCL for Total Coliform and implementation of an E. coli MCL

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

Proposal 222 approved at the 2013 NCIMS Conference asked that a committee look at the changes to the EPA total coliform rule and report to the 2015 NCIMS Conference. This was assigned to the Laboratory Committee at the Executive Board Meeting following the 2013 Conference. The Laboratory Committee determined they could add E. coli testing to the Dairy Waters 2400 form but, most of the issues were beyond the purview of the committee. The authors of this proposal are submitting solely to provide the delegates to the 2015 conference a vehicle to address this issue as they see fit.

EPA Final Revised Total Coliform Rules (RTCR) effective April 1, 2016 eliminates the Maximum Contaminate Level (MCL) for Total Coliform and shifts to an MCL for *E. coli*.

Below is information from the EPA's fact sheet explaining the changes:

***How has the standard for total coliform changed?***

*The proposed rule establishes a health goal (Maximum Contaminant Level Goal, or MCLG) and an MCL for E. coli and eliminates the MCLG and MCL for total coliform, replacing it with a treatment technique for coliform that requires assessment and corrective action.*

*The proposed rule is establishing an MCLG and an MCL of 0 for E. coli, a more specific indicator of fecal contamination and potential harmful pathogens than total coliform. EPA is proposing to remove the current MCLG and MCL of zero for total coliform. Many of the organisms detected by total coliform methods are not of fecal origin and do not have any direct public health implication.*

*Under the proposed treatment technique for coliform, total coliform serves as an indicator of a potential pathway of contamination into the distribution system. A PWS that exceeds a specified frequency of total coliform occurrence must conduct an assessment to determine if any sanitary defects exist and, if found, correct them. In addition, under the proposed treatment technique requirements, a PWS that incurs an E. coli MCL violation must conduct an assessment and correct any sanitary defects found.*

***How has the public notification requirement changed?***

*The proposed rule is eliminating monthly public notification requirements based only on the presence of total coliforms. Total coliforms in the distribution system may indicate a potential pathway for contamination but in and of themselves do not indicate a health threat. Instead, the proposed rule requires public notification when an E. coli MCL violation occurs, indicating a potential health threat, or when a PWS fails to conduct the required assessment and corrective action.*

This means that under the new RTCR that a farm or plant on a public water supply potentially can have positive coliform water from now on and never reach the level of a boil order or a debit on a survey or check rating.

While a farm or plant with an individual supply will need to meet water standard found in Appendix G

A plant or a farm that has a positive water sample on their individual supply for total coliform at the time of a survey or check rating will lose 4 or 5 points respectively, while a plant or farm down the road will not lose points even though they have the same water quality because they are on a public system.

## OPTIONS

1. Do nothing and have a different standard for water at dairy facilities based on if the water supply is a public or an individual system.
2. Establish a standard that water supplies at all dairy facilities be sampled at PMO frequencies (both individual and public supplies)
3. Establish an E. coli standard to replace the current total coliform standard in PMO Appendix G.

## ONGOING CONCERNS

1. Many known pathogens of concerns to the dairy industry are not detected when using E. coli as the indicator for water bacteriological safety. (including E. coli O157H7)

2. For large public water systems up to 5% of the water samples may be E. coli positive without public notification.(Boil Order)
3. Some facilities (both farms and dairy plants) utilize single pass public water for the cooling of milk and/or milk products. Currently there is no requirement for plate heat exchanges to have more pressure on the milk side of the system than on the cooling media side this means that if there are leaks from a potable water system or a chill water system into pasteurized milk coliform could be detected in the finished milk product.
4. Does Cottage Cheese Curd wash water that is only acidified provide adequate protection to the curd if the public (or individual water supply contains coliform bacteria)?

**C. Proposed Solution**

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

**Option 1:**

Defeat this proposal and have different bacteriological water quality standards for public and private water supplies

**Option 2:**

PMO Section 7 Item 8r Administrative Procedures 1. Page 46

1. The water supply for milkhouse and milking operations meets the Bacteriological Standards outlined in Appendix G and is approved as safe by the applicable Government Water Control Authority ~~and or~~, in the case of individual water systems, complies with the specifications outlined in Appendix D. ~~and the Bacteriological Standards outlined in Appendix G.~~

PMO Section 7 Item 7p Administrative Procedures 8. Page 67

2. The water supply meets the Bacteriological Standards outlined in Appendix G and is approved as safe by the applicable Government Water Control Authority ~~and or~~, in the case of individual water systems, complies with the specification outlined in Appendix D. ~~and the Bacteriological Standards outlined in Appendix G.~~

Samples for bacteriological testing of ~~individual~~ all water supplies are taken upon the initial approval of the physical structure; each six (6) months 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. 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.

PMO Appendix D Page 169

The *Grade "A" PMO*, formal FDA interpretations of the *Grade "A" PMO* and other written USPHS/FDA opinions shall be used in evaluating the acceptability of individual water supplies and water system construction requirements at dairy farms, milk plants, and single-service container manufacturing facilities.

The applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. The applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits. For example, the *Grade "A" PMO* requires a satisfactory farm water sample every three (3) years. If State law required such samples to be taken annually, a SRO conducting a sanitation rating, which includes that farm, will give that farm full credit for water sample frequency, if the *Grade "A" PMO* three (3) year requirement is met, even though, the State required annual frequency is not met.

All Supplies shall be sampled in accordance with the requirements of Section 7 and Appendix J. Supplies other than individual water supplies, which have been approved as safe by the applicable Government Water Control Authority, shall be considered to be acceptable sources as provided in Section 7 of this *Ordinance* for Grade "A" inspections, as well as for all other IMS purposes without further inspection of the spring, well or reservoir treatment facility(ies), ~~testing records~~, etc.

PMO Appendix J Item 7. Water Supply Page 341

a. The water supply shall meet the Bacteriological Standards outlined in Appendix G and if from a public system, shall be approved as safe by the applicable Government Water Control Authority responsible for water quality, ~~and or~~ in the case of individual water systems, comply with at least the specifications outlined in Appendix D. ~~and the bacteriological standards outlined in Appendix G. of this Ordinance.~~

b. There shall be no cross-connection between a safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated.

c. Samples for bacteriological testing of ~~individual~~ all water supplies are taken upon the initial approval of the physical structure; each twelve (12) months thereafter; and when any repair or alteration of the water supply system has been made. The examination of the sample shall be conducted in an Officially Designated Laboratory.

### **Option 3:**

PMO Section 7 Item 8r Administrative Procedures 7. page 47

Samples for bacteriological examination are taken upon the initial approval of the physical structure, based upon the requirements of this Ordinance; when any repair or alteration of the water supply system has been made; and at least every three (3) years. Provided, that water supplies with buried well casing seals, installed prior to the adoption of this Section, shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either the presence of E. coli bacteria ~~of the coliform group~~ 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. 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 period plus the remaining days of the month in which the sample is due.

PMO Section 7 Item 15p (B) 2. d. page 87 After the current (6) insert the following:

Note: Pasteurized Equivalent Water treatment systems that have undergone the “Hazard Evaluation and Safety Assessment” of subpart d. of this section prior to December 31, 2015 shall review their assessment based on the new E. coli water standards and submit any revisions or a statement that no revisions were needed to the Regulatory Agency by April 1, 2016.

PMO Appendix G, page 223

## **I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER -BACTERIOLOGICAL**

**Reference:** Section 7, Items 8r, 18r, 7p, ~~and~~ 17p and Appendix D.

**Application:** To ~~private~~ individual water supplies, used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and to recirculated cooling water, used in milk plants, receiving stations and dairy farms.

**Frequency:** Water shall be tested for the presence of total coliform and E. coli Initially; after repair, modification or disinfection of the ~~private~~ individual water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and thereafter; semiannually for all milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities water supplies and at least every three (3) years on dairy farms. Recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually.

**Criteria:** A 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 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 vessel containing 100 mL is tested using the MTF technique or one of the Chromogenic Substrate procedures.

The Chromogenic Substrate procedures are not acceptable for recirculated cooling water.

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 Membrane Filter (MF) Fluorogenic Substrate technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL is tested using the Fluorogenic Substrate procedures.

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 the sample is positive for total coliform but negative for the presence of E. coli or indicates a Heterotrophic Plate Count of greater than 500 CFU per mL on a sample that had previously been invalidated, unsatisfactory, the water supply in question shall be considered at risk for pathogenic contamination and shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory. This inspection shall be completed with 30 days of the date of the positive test result. If the inspection and corrective action are complete, but the water supply in question is still testing positive for total coliform but negative for E. coli the facility shall continue to investigate and correct problems until subsequent samples are bacteriologically satisfactory. When the laboratory report on the sample is positive for both total coliform and E. coli, or the facility has failed to complete the water supply inspection within 30 day of the initial positive test result, the water supply is unsatisfactory.

The Laboratory Committee is requested to update the NCIMS/FDA Form 2400m Dairy Waters to include the methodology for E. coli testing.

Name:	R. Lynn Young	Laura Traas
Agency/Organization:	Milk Regulatory Consultants, LLC	WI DATCP
Address:	56820 HWY A	2601 Agriculture Drive
City/State/Zip:	Russellville, MO 65074	Madison, WI 53718
Telephone No.:	(573) 338-1785	<a href="mailto:rlynnyoung@cs.com">rlynnyoung@cs.com</a>
	(608) 267-3504	E-mail Address: <a href="mailto:Laura.Traas@wisconsin.gov">Laura.Traas@wisconsin.gov</a>

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 227

Committee: Hauling

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

**A. Summary of Proposal**

To change the annual tank inspection to a 3 year inspection

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

To better align the PMO with changes in how milk is moved throughout the country combined with the lessened inspector staff in states, this proposal seeks to assist with the difficulty of satisfying the current requirement that is difficult for all parties. There are a larger number of milk tank trucks that operate in multiple states due to loading at farms and then transporting those loads to other states, as well as from plant to plant locations that have to be transported to various states. There are a limited number of inspectors in states who can perform timely inspections as required by the current PMO. This limitation does not allow inspectors to maintain the current annual required inspection. These limitations then cause the loss of milk or milk product to not get loaded and the potential for it to be dumped. The milk or milk product can also potentially be rejected and sold at a discounted price or disposed of at a total loss to the milk hauler. This potential dumping of milk is an environmental and safety concern. The economic impact of the loss to a hauler can reach as high as \$70,000.00. Changing the requirement of the tank truck inspections to a 3 year cycle would allow the tanks to be inspected between 2 and 3 years, which would also allow a milk hauler and the state inspector enough time to keep the inspection current. This would give an inspector a broader timeframe to inspect a milk tank truck when they have the opportunity at a plant or the milk hauler's place of business.

**C. Proposed Solution**

Changes to be made on page(s): 135, 136 of the (X - one of the following):

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

Milk tank trucks shall be evaluated ~~annually~~ every 3 years using the requirements established in Sections 3 and 5 of this *Ordinance* using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M.)

**PERMITTING:** Each milk tank truck shall bear a permit for the purpose of transporting milk and milk products. (Refer to Section 3 of this *Ordinance*.) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and State issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed ~~each year~~ every three years pending satisfactory completion of an inspection as outlined in the following **INSPECTION** Section.

**INSPECTION:** Each milk tank truck shall be inspected at least once ~~each year~~ every three years by a Regulatory Agency. (Refer to Section 5 of this *Ordinance*.) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead. When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of ~~annual~~ inspection as required in the **PERMITTING** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.

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



35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 228

Committee: MMSR

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

**A. Summary of Proposal**

This proposal would limit the number of consecutive bacteriologically unsatisfactory water sample test results to three (3) before a farm and/or plant would lose their Grade A permit.

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

The PMO currently requires farms and/or plants that have unsatisfactory water sample results to be re-sampled until a satisfactory sample is obtained, with no limit to how long this process could continue without penalty. The Methods of Making Sanitation Ratings of Milk Shippers (Methods), on pages 84 and 91, requires re-sampling within 30 days of unsatisfactory water test results for farms and plants, but again sets no limit to how long this process could continue without penalty. Plants or farms with non-compliant water samples can continue to sell milk or milk products (without penalty) as long as the water supply is re-sampled every 30 days.

**C. Proposed Solution**

Changes to be made on page(s): 223 (PMO), 87 and 95 (Methods) of the (X - one of the following):

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

On page 223 of the PMO near the bottom of the page, after the sentence

“Corrective Action: When the laboratory report on the sample is unsatisfactory, the water supply in question shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory.”

Add the following sentence: Any farm or plant with three (3) consecutive bacteriologically unsatisfactory water sample results shall have their permit suspended.

On page 87 of Methods under Category II: Permit Suspension, section c. after 2.),

“ iii. If pesticide contaminated milk is not withheld from sale.” add the following:

3) Appendix G for three (3) consecutive bacteriologically unsatisfactory water samples

On page 95 of Methods under Category II: Permit Suspension, item g., after

“ 2.) Section 6 for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld.” add the following:

3) Appendix G for three (3) consecutive bacteriologically unsatisfactory water samples.

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

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 229

Committee: Lab

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

**A. Summary of Proposal**

A proposal to require records of all sample results shall be maintained for a minimum of two (2) years by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

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

To align the requirements of the PMO with the FDA/NCIMS 2400n Appendix N General Requirements (rev. 10/13) Item 14d and the FDA/NCIMS 2400 Cultural Procedures (rev. 10/13) Item 2a2 which both state that laboratory records are to be maintained for a minimum of two (2) years.

**C. Proposed Solution**

Changes to be made on page(s): 365 of the (X - one of the following):

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

Records of all sample results shall be maintained for a minimum of ~~six (6) months~~ two (2) years by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

Name:	Paula Dankert, Food and Dairy Division Lab Evaluation Officer		
Agency/Organization:	Michigan Department of Agriculture & Rural Development		
Address:	525 W. Allegan Street		
City/State/Zip:	Lansing, MI 48909		
Telephone No.:	231-357-3514	E-mail Address:	Dankertp@michigan.gov

35th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 230

Committee: MMSR

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

**A. Summary of Proposal**

This proposal would add a clarification to the Methods of Making Sanitation Ratings of Milk Shippers (Methods) (2013 Revision) that, when a Grade A milk plant is de-listed for inadequate sampling, only one re-sample (within the limits) of each debited product would be needed prior to the re-survey.

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

Grade A plants are required to have their products sampled at least 4 times each 6 months. As currently written in Methods, if a plant fails an IMS survey due to inadequate sampling, the plant would need to have 4 samples (of each product) taken prior to a re-survey to avoid being debited. Depending on how many samples were missing on the initial survey, this could keep the plant off the IMS list for 3 or 4 months.

There is no public health significance regarding this proposal.

**C. Proposed Solution**

Changes to be made on page(s): 14 of the (X - one of the following):

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

On page 14, after the first paragraph “sample result is within the limit(s).” add the following sentence:

Plants which have lost their IMS certification due to inadequate sampling must (after the initial survey) have at least one sample examination (within the limits) of each debited product to avoid being debited on the re-survey.

Name: Joe Dittrich

Agency/Organization: Minnesota Department of Agriculture

Address: 625 Robert Street North

City/State/Zip: St Paul, Minnesota 55155-2538

Telephone No.: 507-932-0663

E-mail Address: Joe.dittrich@state.mn.us