

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	201
Committee:	Scientific Advisory/Lab

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

A. Summary of Proposal

Require testing of milk and/or milk products for glyphosate residues.

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

Glyphosate is a known endocrine disrupter. There have not been animal studies evaluating the effect of glyphosate on fetuses in-utero, or through growth to adults. Levels allowed in milk should be at least as low as those for drinking water.

The most commonly used pesticide in America, glyphosate, is nearly the only one not tested for residues in the human food supply. The dairy industry should not allow the integrity, purity, and safety of their products to be compromised by this lapse in cautionary testing of human foods.

C. Proposed Solution

Changes to be made on page(s): 1, 33, and 224-225 of the (X - one of the following):

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

Modify the 2013 PMO, page 1, SECTION 1. DEFINITIONS, A. Abnormalities of Milk, A-3. Contaminated Milk.

A-3. Contaminated Milk: Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA), or from residual pesticides from animal feed.

Modify the 2013 PMO, page 33, SECTION 7. STANDARDS FOR GRADE “A” MILK AND/OR MILK PRODUCTS, Table 1. Chemical, Physical, Bacteriological, and Temperature Standards.

GRADE “A” RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRAPASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING	Drugs*****	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.
	<u>Pesticides.....</u>	<u>No pesticides may be present in milk at levels above those established by the EPA for drinking water.</u>

GRADE “A” PASTEURIZED MILK AND/OR MILK PRODUCTS	Drugs*****	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)
	<u>Pesticides.....</u>	<u>No pesticides may be present in milk at levels above those established by the EPA for drinking water.</u>

Modify the 2013 PMO, page 224-225, APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS, IV. Detection of Pesticides in Milk

~~At the present time,~~ In the past, chlorinated hydrocarbon pesticides ~~are~~ have been the chief concern. Now that glyphosate has become the most used pesticide, and is being used in increasing quantities to combat resistant weeds, and to kill and desiccate animal feed before harvest, we should understand the levels now occurring in milk. While there are other pest control compounds that are more toxic than the chlorinated hydrocarbons, many of the 225 agents in this latter group tend to accumulate in the body fat of both lactating animals and human beings, and are secreted in the milk of contaminated lactating animals. The accumulation of these toxic agents in persons continually consuming contaminated milk may

reach hazardous concentrations.

Name:	Warren Taylor		
Agency/Organization:	Snowville Creamery LLC		
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 #: 202
Committee: Scientific
Advisory/Lab

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

A. Summary of Proposal

Require testing for glyphosate residues in the feed and forage used as a feed ingredient for any portion of the total ration of the lactating dairy animal. Confirm: that feed and forage do not contain levels of glyphosate which result in glyphosate being secreted in the milk at any level, which may be deleterious to human health.

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

Increasing use of pesticides on dairy cattle feed and forage, including spraying for killing and desiccation of plants before harvest, are raising glyphosate levels in dairy cattle feed and forage, with resultant likelihood of higher glyphosate levels in the American milk supply. This proposal is to require new testing protocols to ensure that no measurable residue of those toxic chemicals are present in the milk supply.

The most commonly used pesticide in America, glyphosate, is nearly the only one not tested for residues in the human food supply. The dairy industry should not allow the integrity, purity, and safety of their products to be compromised by this lapse in cautionary testing of human foods.

C. Proposed Solution

Changes to be made on page(s): 1 and 36 of the (X - one of the following):

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

Modify the 2013 PMO, page 1, SECTION 1. DEFINITIONS, A. Abnormalities of Milk, A-3. Contaminated Milk.

A-3. Contaminated Milk: Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA), or from residual pesticides from animal feed.

Modify the 2013 PMO, page 36, STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, Item 1r. Abnormal Milk, Administrative Procedures.

7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:
 - a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and
 - b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances, which are secreted in the milk at any level, which may be deleterious to human health.
8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.
9. Feed and forage used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall be tested for glyphosate residues.

Warren Taylor	
Agency/Organization:	Snowville Creamery LLC
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 #: 203
Committee:

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

A. Summary of Proposal

A proposal to add the definition for “inspection/audit report”.

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

The term “inspection/audit report” is not defined in the 2013 PMO. Traditionally, inspection/audit reports were hand written. With the advancement in technology, electronically generated reports are needed as part of an electronic management system to be used by state regulatory agencies. This proposal is being submitted to provide clarification of terminology used in another proposal submitted by the Michigan Department of Agriculture & Rural Development (MDARD) regarding electronically generated inspection/audit reports.

C. Proposed Solution

Changes to be made on page(s): 6 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 |

Inspection/audit report: A hand written or electronically generated official regulatory form used for documentation of findings during an inspection/audit. Electronically generated official regulatory reports must be in a Write Once, Read Many (WORM) format.

Name:	Terrance Philibeck, Food & Dairy Deputy Director		
Agency/Organization:	Michigan Department of Agriculture & Rural Development		
Address:	525 W. Allegan Street		
City/State/Zip:	Lansing, MI 48909		
Telephone No.:	517-284-5699	E-mail Address:	Philibeck1@michigan.gov

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 204

Committee:

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

A. Summary of Proposal

To allow the States the *option* of having dairy plants collect finished product samples for regulatory purposes. The dairy plant personnel must be certified as a dairy plant sampler by delegation of a State Rating Officer. A permit shall be issued upon satisfactorily completing the dairy plant sampling procedures. A list of these samplers shall be maintained by the regulatory agency. The regulatory agency shall notify the dairy plant when and what samples to collect.

The notification shall be the same day the samples are collected. There shall be no advanced warning as to when the samples are to be collected. Periodically, the State Regulatory Agency shall review the sample collections performed by industry. Whenever there is a sample has been issued a warning letter, the subsequent sample shall be collected by the Regulatory Agency. Samples shall be accompanied with documentation of chain of custody and tamper evident tape or seals when necessary.

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

With State workforce reduction due to retirement and job turnover, along with budgets constraints, it is becoming increasing more difficult to manage mandated regulatory workload in an effective manner. In States where the inspector performs both dairy and food regulated inspections, it places an extra burden of accomplishing the work in the required time frame. Collecting finished product samples can be very time consuming, and work time could be better spent conducting other regulatory-type work tasks, such as inspecting plants and farms. In some cases, collecting samples can take one day to complete the sample run. There is also the occasional problem where a particular product is not available, and the inspector must go back to the dairy plant for one sample. This is outside of the scheduled routine sample

collection, which delays completion of regulatory routine work.

States currently allow industry to collect raw milk and water samples from the dairy farms, and some States even allow industry to inspect the dairy farms. This practice has been documented for years without any significant incidences. In Illinois, we have written only four enforcement letters dealing with finished product samples in the last two years. Over 6,000 samples have been collected and tested over the two year period.

C. Proposed Solution

Changes to be made on page(s): 6,27, 138 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 |

Page 6, U. **INDUSTRY DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this Ordinance. This person is an employee of the dairy plant and is evaluated at least once every two (2)-year period by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

A. **INDUSTRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Page 27, 2nd paragraph, During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging, shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency or shall be obtained under the direction of the Regulatory Agency and delivered in accordance with this Section, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging. The Regulatory Agency shall notify the dairy plant on the day of collection without any advance warning when and what samples to collect. Periodically, the State Regulatory Agency shall review the sample collections performed by industry. Whenever there is a sample has been issued a warning letter, the subsequent sample shall be collected by the Regulatory Agency. Samples shall be accompanied with documentation of chain of custody and tamper evident tape or seals when necessary.

Page 138, The dairy plant sampler or industry dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. These persons are employees of the Regulatory Agency or of the dairy plant and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official (dSSO). These individuals are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

Name:	Guy Sprouls and Steve DiVincenzo		
Agency/Organization:	Illinois Department of Public Health		
Address:	525 West Jefferson Street		
City/State/Zip:	Springfield, Illinois 62761		
Telephone No.:	217-785-2439	E-mail Address:	Steve.divincenzo@illinois.gov

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 205

Committee:

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

A. Summary of Proposal

This Proposal would eliminate Footnote #2 from the text of the PMO and from the listing of Footnotes on page 135 of the PMO and renumber the remaining Footnotes accordingly.

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

Footnote #2 provides for Regulatory Agencies desiring to not regulate cottage cheese and dry curd cottage cheese under the PMO to delete cottage cheese and dry curd cottage cheese from the definition of Milk Products. This provision and footnote was added to the PMO in the early 1960's when cottage cheese was added to the PMO. FDA is only aware of two (2) States (IA and OR) that have chosen this provision for the intrastate sale of cottage cheese and dry curd cottage cheese. IA and OR Regulatory Agency Officials were specifically asked if they could support this Proposal and both States replied that their State laws states "may be labeled Grade "A" and that they would not have an objection to deleting Footnote #2 and that they could support this Proposal.

FDA believes that this provision is no longer warranted as today all cottage cheese shipped in interstate commerce is labeled as Grade "A" and is being produced in IMS listed milk plants.

C. Proposed Solution

Changes to be made on page(s): 7, 9, 135 and 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

MAKE THE FOLLOWING CHANGES TO THE 2013 PMO.

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

SECTION 1. DEFINITIONS ...

Page 7:

EE. MILK PRODUCTS: ...

2. Cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)². ...

Page 9:

8. Cheese (standardized, except cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)², or non-standardized); or ...

Page 135:

FOOTNOTES ...

2. ~~Regulatory Agencies desiring to not regulate cottage cheese and dry curd cottage cheese under the terms of this Ordinance should delete the following from the definition of Milk Products:~~

~~Cottage cheese (21 CFR 133.128).~~

~~Dry curd cottage cheese (21 CFR 133.129).~~

Renumber remaining FOOTNOTES accordingly.

Page 136:

- ~~16~~15. A certified copy may be secured from the Food and Drug Administration, HFS-316, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

NOTE: In reference to Footnotes ~~2, 76, 87, 98, 109, 110, 121, and 132~~, for the purposes of the ICP, cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese shall be Grade “A” and shall be regulated under the terms of this *Ordinance*.

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 #: 206
Committee: Scientific
Advisory

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

A. Summary of Proposal

This proposal is to identify acceptable uses for milk and milk products rinsed from farm bulk trucks, over-the-road tankers, transfer-station, receiving station and milk plant storage silos and similar vessels by adding a definition to the PMO which identifies “Reclaimed Milk & Milk Products” and establishes conditions for their use in Grade “A” Milk and Milk Products.

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

The nature of milk and milk products during their storage, transport, and pumping is to stick to the surfaces they come into contact with. These surfaces are then required to be rinsed and cleaned, with significant amounts of the milk or milk product being captured in the rinse water and cleaning solution water. These “waters” are then either pre-treated by the milk plant and sent to municipal or dairy plant owned wastewater treatment systems (or not pretreated) and discharged directly into a sanitary sewer. Either way, the increased BOD, COD and suspended solids load from these milk and milk products ends up costing dairy plants additional surcharges for their wastewater discharges and places extra strain on municipal wastewater treatment systems.

It would be beneficial for the dairy industry and for municipal treatment systems if the milk and milk product rinsings could be safely captured and reprocessed in a manner that would allow their use as an ingredient in a Grade “A” milk or milk product.

Since the rinsing of the storage tanks, silos, pump interiors and milk pipeline interiors is done with potable water and reverse osmosis (RO) technology has the capability of removing just the rinse water to bring the components of the milk or milk product back to their original levels, the process of “reclaiming” the value of the milk or milk products would benefit the dairy industry and the

environment, meet existing standards of identity for Grade "A" dairy product and slightly decrease raw material costs which in turn could decrease retail dairy prices to consumers.

The PMO in Section 7, 16p, #3b of the Administrative Procedure (page 91 and 92) already recognizes the conditions and criteria for the proper use of reverse osmosis (RO) technology. The addition of a definition for "Reclaimed Milk and Milk Products" would not modify these RO conditions and criteria. This definition would make it clear that any captured milk and milk products rinsed from storage vessels, pumps and pipelines could be processed through an RO membrane unit using the conditions and criteria in 16p of the PMO, then reused as a "milk", "cream", or other dairy ingredient. These "RO-Processed" dairy ingredients would be required to meet the compositional requirements for a raw material or dairy ingredient from which it originated and not result in adulteration of the Grade "A" finished milk or milk product with water.

RO units remove only water, not minerals, vitamins, milkfat or milk proteins. Based on this, essentially any Grade "A" product with a standard of identity would allow for the use of the "Reclaimed Milk and Milk Product" since it would meet the compositional requirements of the original product from which it originated.

It would be relatively easy for any dairy plant or Regulatory Agency to test the Grade "A" product for the level of milkfat, milk protein and solids-not-fat levels to ensure that these products were not adulterated with water resulting from the use of "Reclaimed Milk and Milk Products".

Existing FDA Interpretations found in various "Question and Answer" documents are listed below and do not prohibit the rinsing, capture, storage and RO'ing of "Reclaimed Milk and Milk Products."

45. PMO-Section 7, Item 15pB and Appendix L

a. May a Grade "A" dairy plant perform a water flush in order to flush raw milk from bulk milk tankers to the raw milk silos?

Yes. The water-milk mixture may be flushed directly to the raw milk silo if the milk plant condenses, concentrates or dries the milk or milk product, or if the milk plant takes other appropriate actions to prevent the dilution or adulteration of milk with the added water. An example of an appropriate method to accomplish this is to flush the bulk milk tanker with potable water to a separate tank or vessel and capture this raw milk slurry for further processing. Other examples might include the use of a system or process designed, constructed and controlled that manually or automatically prevents the addition of water. The efficacy of this system should be verifiable if challenged.

b. How may this recovered water-milk mixture be used in Grade "A" milk products?

This recovered milk mixture may be used in cultured milk, 21 CFR 131.112 (d), and eggnog, 21 CFR 131.170 (e), as an "other optional ingredient", to reconstitute dried milk and condensed ingredients. Additionally, it may be used in yogurt and in cottage cheese creaming mixtures.

27. PMO-Section 7, Items 15p(A) and 15p(B)

a. May plants flush the raw cream out of storage tanks and pipelines with potable water from a water hose when loading a milk tank truck for transport?

Yes. The water-raw cream mixture may be flushed directly to the milk tank truck if the receiving milk plant condenses, concentrates or dries the cream, or if the shipping milk plant takes other

appropriate actions to prevent the dilution or adulteration of the raw cream with added water, as set forth in Administrative Procedure #18. An example of an appropriate method to accomplish this is to flush the storage tanks and pipelines with potable water to a separate tank or vessel and capture this water-raw cream mixture for further processing. Other examples might include the use of a system or process designed, constructed and controlled that manually or automatically prevents the addition of water. The efficacy of this system should be verifiable if challenged.

In summary, a clear definition for “Reclaimed Milk and Milk Products” using the criteria already in the PMO for RO systems would allow a more complete use of the raw materials used for Grade “A” dairy products, reduce the environmental burden of disposing of these products and potentially slightly decrease Grade “A” finished product prices.

C. Proposed Solution

Changes to be made on page(s):		11	of the (X - one of the following):	
X	2013 PMO		2011 EML	
	2013 MMSR		2400 Forms	
	2013 Procedures		2013 Constitution and Bylaws	

Inserted the underlined text as the new Definition titled, “QQ” and retitle all subsequent definitions after the newly added definition as appropriate.

QQ: RECLAIMED MILK AND MILK PRODUCTS: Any milk or milk product:

- originating from a Grade “A” source, and
- collected through the rinsing with potable water from PMO-compliant product contact surfaces, and
- captured and stored in PMO-compliant storage vessels, and
- processed using reverse osmosis technology compliant with Section 7, Item 16p to achieve a composition similar to the milk or milk product it originated from

will be acceptable as an ingredient in any Grade “A” milk or milk product.

Name:	Allen R. Sayler		
Agency/Organization:	CFSRS		
Address:	3511 Powells Crossing Ct.		
City/State/Zip:	Woodbridge, Virginia 22193		
Telephone No.:	571-931-6763	E-mail Address:	asayler@cfsrs.com

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	207
Committee:	Other Species

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

A. Summary of Proposal

Defining camel milk.
Proposal to add the definition of camel milk to the PMO.

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

Demand for camel milk is growing rapidly. Consumers can readily purchase and have shipped to them unregulated camel milk. In 2009 the NCIMS Other Species Milk Committee began collecting and reviewing research to qualify and include camel milk in the PMO. M-I-10 -6 addressed pasteurization times and temperature of camel milk and, the definition of Hooved Mammal’s Milk was revised to include Family Camelidae in the 2011 Revision of the PMO. M-I-12-13 approved an antibiotic residue test for camel milk, as required by Appendix N. The M-a-98 included laboratory methods and standards for camel milk. NCIMS Other Species Milk Committee believes that sufficient work has been completed to allow camel milk to be pasteurized, and marketed interstate safely under the regulatory guidelines of the PMO.

C. Proposed Solution

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

- 2013 PMO 2011 EML
- 2013 MMSR 2400 Forms

To modify the 2013 PMO, page 14, SECTION 1. DEFINITIONS.

CCC. CAMEL MILK: Camel milk is the normal lacteal secretion practically free of colostrums, obtained by the complete milking of one (1) or more healthy camels. Camel milk shall be produced according to the sanitary standards of this Ordinance. The word "milk" shall be interpreted to include camel milk. (Refer to the NOTE: on page 31.)

Name: Gene Wiseman

Agency/Organization: Missouri Milk Board

Address: 1616 Missouri Blvd. PO Box 630

City/State/Zip: Jefferson City, MO 65102

Telephone No.: 573 522-3206

E-mail Address: gene.wiseman@mda.mo.gov

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 208

Committee:

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

A. Summary of Proposal

A proposal to allow electronically generated or hand written inspection/audit reports of all dairy facility inspections to be provided to the establishment, operator, or other responsible person.

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

Technology allows state regulatory agencies to generate inspection/audit reports electronically as part of an electronic management system. Inspection/audit reports are electronically generated by these systems in place of the traditional hand written inspection/audit reports. This proposal would allow for the use of electronically generated inspection/audit reports without removing the option for use of hand written inspection/audit reports.

C. Proposed Solution

Changes to be made on page(s): 22 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 |

One (1) copy of the inspection/audit report shall be electronically provided or handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.

Name:	Terrance Philibeck, Food & Dairy Deputy Director		
Agency/Organization:	Michigan Department of Agriculture & Rural Development		
Address:	525 W. Allegan Street		
City/State/Zip:	Lansing, MI 48909		
Telephone No.:	517-284-5699	E-mail Address:	Philibeck1@michigan.gov

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 209

Committee:

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

A. Summary of Proposal

To allow the Regulatory Agency discretion, in accordance with the Regulatory Agency's State administrative procedures and hearing proceedings, in the enforcement procedures which currently require automatic permit suspension if the same non-critical requirement is found on two (2) successive inspections of a dairy farm, bulk milk/hauler sampler, milk tank truck milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor. Many states are unable to comply with this provision because their administrative procedures do not allow for this type of enforcement action.

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

State regulatory personnel conducting routine inspections are frequently presented with the requirement to suspend the permit of a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor over the violation of the same requirement listed in items 1R thru 19R and 1P thru 22P. When an inspection reveals a repeat violation of the requirements listed above, but can be attributed to a new occurrence as documented on the inspection, action should not be taken to immediately suspend the permit unless the item is a critical process element. Non critical items such as floor and wall construction and repair are best handled by administrative procedures set forth by the Regulatory Agency. Removal of the absolute requirement for permit suspension would allow inspectors to thoroughly document all violations of the PMO, develop corrective action plans when necessary while allowing the regulated entity to focus immediate attention to factors effecting milk safety and public health while looking to long term corrective solutions of non-critical items.

The repeat violations should be specific in nature as practiced by the United States Department

of Agriculture (USDA). The USDA breaks their violations out by specific areas. For example, a violation concerning walls in a processing area, followed by a violation concerning walls in a filling area would not constitute a repeat violation because two different areas were involved even though walls were involved in both violations.

C. Proposed Solution

Changes to be made on page(s):		23	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall be subject to notice of intent of suspension of permit, permit suspension and/or court action at the discretion of the Regulatory Agency if two (2) successive inspections disclose a violation of the same requirement.

Name:	Guy Sprouls and Steve DiVincenzo		
Agency/Organization:	Illinois Department of Public Health		
Address:	525 West Jefferson		
City/State/Zip:	Springfield, IL 62761		
Telephone No.:	217-785-2439	E-mail Address:	Steve.divincenzo@illinois.gov

34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal: 210
Committee: Appendix N/Lab

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

A. Summary of Proposal

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.

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

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.

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.

TABLE OF CONTENTS ...

Page xiv:

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

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: ...

Page 30:

5. Drug Testing: Beta lactam test methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current 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~~ test 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 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, Aminogylcosides, 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, Aminogylcosides, 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, Aminogylcosides, 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, Aminogylcosides, and Avermectins, does not mandate any additional screening by industry or Regulatory Agencies with the evaluated 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-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 Amphenicols (florfenicol), Macrolides, Aminogylcosides, 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.) ...

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 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*.

Page 364:

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. ...

Page 365:

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: ...

To satisfy these requirements:

Page 366:

- 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.

d. 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.

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:

Page 368:

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. ...

Page 369:

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~~.) ...

Page 370:

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. ...

Page 371:

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.

Page 372:

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. ...

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. ...

Page 373:

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.
 - ~~d~~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 ± 0.5 ppb.
 - (2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @ 10 ± 1 ppb.
 - (3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected. ...

Page 374:

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, 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.

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.

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 #: 211
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, and implemented with approval of the NCIMS Executive Board. The pilot program will develop **the regulatory requirements by which testing raw milk for drugs other than beta-lactams would be required**, the premise of which is primarily grounded on the FDA's risk ranking analysis that is as yet to be finalized.

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

There is no known public health significance related to the testing of drugs other than beta-lactams as there does not exist significant analytical data. The rationale for the submission of this proposal is to create a pilot program to develop **the regulatory framework by which testing raw milk for the presence of drugs other than beta-lactams would be required**. A pilot program would validate the need for this testing prior to arbitrarily changing the current drug testing requirements in the PMO.

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

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.

The Appendix N Modification Committee is charged to develop a pilot program, establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*. The pilot program, when finalized, would include, but is not limited to, consideration of the following criteria:

1. **Veterinary drugs required to be tested:** The Appendix N Modification Committee shall define the drugs other than beta-lactams for which raw milk is required to be tested. This will be dependent primarily on the availability of the FDA risk ranking model and final data for review.
2. **Testing methodology required to be used:** Methods evaluated by FDA and accepted by NCIMS shall be used for consistency and reliability. 2400 Forms shall be developed by the Laboratory Committee. Official Laboratories, Officially Designated Laboratories, and Certified Industry Supervisors shall be certified in appropriate testing methods.
3. **Availability of suitable test methods:** The pilot shall account for method availability, accessibility, logistical feasibility (including practicality and timeliness of results) and cost.
4. **Number of samples to be collected and assayed:** The pilot shall determine the number of samples to test based on a statistical analysis.
5. **Reduction of required Beta-Lactam testing:** The pilot shall consider the potential for reducing beta-lactam testing of both incoming raw milk and finished product, based on statistical data and feasibility.
6. **National Milk Drug Residue Database:** Results of testing for veterinary drugs other than beta-lactams shall be reported to the National Milk Drug Residue Database. The pilot shall require for timely reporting of results to the NCIMS Executive Board. This requirement will have to determine resources needed, how data shall be collected, and reported.
7. **Report of challenges of program implementation:** The committee shall review the framework of the pilot program for hurdles likely to be encountered by stakeholders in implementing this new program and report back to the 2017 Conference with potential solutions to address these challenges.
8. A complete report of the pilot program, including all test results and recommendations for a future testing framework, will be shared at the 2017 Conference. Based on this report, a proposal may be submitted to formalize the requirements of the program into the PMO as a required program (potentially, but not limited to in Appendix N, in a subpart to Appendix N, or as a separate appendix in the PMO).

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: NCIMS 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

