# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 201 | |
| Committee: | Scientific | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

Provide clarity to the definition of abnormal milk.

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

The issue of producing colostrum for use as a human food product is a growing national issue. Colostrum is currently listed in the PMO on page one (1) under the "undesirable" sub-definition of abnormal milk which creates a regulatory loophole in allowing the production of this product. Combining this loophole with the lack of compelling scientific data for the safety and efficacy of current dairy lab testing and processing standards and you create a food product that doesn't appear to fall under any specific set of regulations. Changing the terminology will provide state regulatory agencies with a clearer sense of direction for the acceptable use of colostrum as a food product; it will also begin to mirror the definition as listed in the Code of Federal Regulations.

Justification: Other definitions of milk in the PMO (I. Camel Milk, V. Goat Milk, X. Hooved Mammals' Milk, CCC. Sheep Milk, JJJ. Water Buffalo Milk) all list the definition as "practically free of colostrum". 21 CFR 131: Milk and Cream also list the definition as:

PART 131 -- MILK AND CREAM

Subpart B - Requirements for Specific Standardized Milk and Cream

Sec. 131.110 Milk.

*(a) Description.* Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.

And 21 CFR 1210.3 also lists the definition as:

Sec. 1210.3 Definitions.

(c) *Milk.* For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 1 | **2023 PMO**<br>***Section(s):* 1, Definitions**<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed options for change:

Remove all sub-definitions and combine all into one label of ‘Abnormal Milk’.

~~A. **ABNORMALITIES OF MILK:** The following types of lacteal secretions are not suitable for sale for Grade “A” purposes.~~
~~A-1. **Abnormal Milk:** Milk that is visibly changed in color, odor and/or texture.~~
~~A-2. **Undesirable Milk:** Milk that, prior to the milking of the animal, is expected to be unsuitable for sale, such as milk containing colostrum.~~
~~A-3. **Contaminated Milk:** Milk that is unsaleable 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).~~

A. **ABNORMAL MILK:** Milk that is visibly changed in color, odor, or texture, or milk that contains biological, chemical, medicinal or radioactive agents, which may be deleterious to human health. Visible changes include ropy, stringy, clotted, thick, flakes or other gross alterations; or has changed in color due to red blood cells or appears abnormal in any way. This also includes Milk which, prior to the milking of the animal, is known to be unsaleable and unsuitable for human consumption such as colostrum, high Somatic Cell Count, mastitis and milk following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines, chemicals or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA).


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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|---|---|---|
| Proposal #: | 202 | |
| Committee: | Hauling/ MMSR | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

The proposal allows farm personnel to operate in-line samplers without being a licensed bulk milk weigher and sampler as long as they have been properly trained by a licensed bulk milk weigher and sampler on how to operate the in-line sampling device at that facility.

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

This proposal addresses the training and licensing requirements for using in-line samplers. Currently, high employee turnover requires frequent licensing and inspections by regulatory agencies for a task that for these systems may be nothing more than inserting a needle into a septum and placing a bag into a refrigerator. The proposed solution is to require at least one licensed bulk milk weigher and sampler (BMWS) in a management role on each dairy farm, who would then train designated samplers on the specific sampling requirements. The BMWS would maintain training records showing which employees are qualified to handling the sampling equipment. This approach maintains sample quality and safety while reducing the unnecessary burden for a task that does not require making judgment calls such as measuring the milk or rejection of milk due to smell or color. This change offers many benefits. It will reduce regulatory agencies' workload by limiting the number of individuals needing BMWS licenses and it provides more focused, equipment-specific training rather than broad BMWS requirements.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 2<br>142, 143, 144 | **2023 PMO**<br>***Section(s):* 1**<br>***Appendix: B*** | | **2023 EML** |
| Appendix A<br>page 117 | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change: PMO pages (142-144)

**II. REQUIREMENTS FOR USING AN ASEPTIC APPROVED IN-LINE SAMPLER**
**(For informational purposes only: Refer to M-I-06-6)**

A protocol for utilizing an in-line sampler system shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. A copy of the approved aseptic in-line sampling system's SOP shall be on file and posted for use at the location where the sampling system is utilized. As a minimum, the protocol (SOP) shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
2. A description of the means used to refrigerate the sample collection device and milk sample collection container throughout the milk sample collection period.
3. A means to monitor milk sample temperature, and the milk temperature.
4. A description of how and when the sampler is to be cleaned and sanitized, if not of a single use design.
~~5. A listing of the licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the sample collection device as well as to collect, identify, handle and store the milk sample.~~
5. At least one individual at that farm location who is a licensed bulk milk weigher and sampler. The licensed bulk milk weigher and sampler(s) is to have knowledge of as well as train all personnel who work with any part of the in-line measuring device, on how to properly maintain, operate, clean, and sanitize the sample collection device as well as to collect, identify, handle, and store the milk sample.
6. A list of all licensed bulk milk hauler/samplers as well as trained personnel.
~~6~~7. A description of the method and means that will be used to determine weight of the milk on the milk tank truck.

**III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS**
**(For informational purposes only: Refer to M-I-06-12, M-I-16-17)**

A protocol (SOP) specific to each milk plant and milk tank truck(s) in which industry plant samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk plant and FDA. As a minimum, the protocol (SOP) shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored. a. The aseptic sampler fitting shall be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
b. The aseptic sampler septum shall be installed according to the manufacturer's instructions.
c. Transfer of milk is achieved using a SOP specific to the aseptic sampler.
d. An appropriate device, i.e., a syringe, shall be used to transfer the milk.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the industry plant samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampler as well as to collect, identify, handle and store the milk sample.
A copy of the approved aseptic sampler's SOP shall be on file at the location where the aseptic sampler is utilized.

**IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND/OR SILOS**
**(For informational purposes only: Refer to M-I-06, M-I-06-12 or M-I-12-4)**

A protocol specific to obtaining a sample directly from a farm bulk milk tank/silo prior to loading the milk for transport utilizing an aseptic sampler shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. As a minimum, the protocol shall include the following.
1. A description of how the milk sample is to be collected, identified, handled and stored. a. The aseptic sampler shall be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
b. Transfer of milk is achieved using a SOP specific to the aseptic sampler.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers ~~who have been trained to maintain, operate, clean and sanitize the aseptic sampling device as well as collect, identify, handle and store the milk sample.~~ <u>along with any of the personnel who the licensed bulk milk weigher and sampler(s) has delegated, who have been trained to properly maintain, operate, clean, and sanitize the sample collection device as well as to collect, identify, handle, and store the milk sample.</u>
4. A copy of the approved aseptic sampler SOP shall be on file and posted for use at the location where the sampler is utilized.

**V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS**

1. A protocol specific to the use of an on-tanker farm bulk milk tank aseptic sampler which may be used for the acquisition of official milk samples from multiple and/or single farm pickups shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer and FDA. At a minimum, the protocol (SOP) shall include the

following: a. A description of how the milk sample is to be collected, identified, handled and stored.
b. A description of the means used to maintain the sample at the required temperature (between
0.0 (32°F) to 4.5 (40°F) degrees Celsius, as per this Appendix) during the sample collection period.

c. A description of the process used to obtain the temperature of milk being loaded from the farm bulk milk tank.
d. A description of how and when the sampler is to be cleaned and sanitized if not of a single use design.
e. A description of the method and the means used to ensure the representative nature of and integrity of the milk sample acquired from every farm bulk milk tank.
f. A description of the method and means that will be used to determine weight of the milk in the farm bulk milk tank.
2. The on-tanker farm bulk milk tank sampler shall be installed in consultation with the Regulatory Agency, according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
3. The State Regulatory Agency shall be provided a list of the licensed bulk milk hauler/samplers ~~who have been trained to maintain and operate the aseptic sampler as well as to collect, identify, handle and store the milk sample~~. along with any of the personnel who the licensed bulk milk weigher and sampler(s) has delegated, who have been trained to properly maintain, and operate the in-line sampler as well as to collect, identify, handle, and store the milk sample.
4. A copy of the approved on-tanker farm bulk milk tank aseptic sampler SOP shall be on file on the tanker.

(PMO Section 1 page 2)
F. **BULK MILK HAULER/SAMPLER:** A person responsible for the collection of official "Universal" samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this *Ordinance*, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station, who in the case of farms utilizing in-line samplers, is tasked with the responsibility of properly training any and all personal who obtains samples via the in-line sampler, and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or raw milk products. This person is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

(Methods page 117)
**Item 6. Sampling Procedures in Substantial Compliance**
a. Appraisal of each sampler's compliance done by record review.
b. Appraisal of sampler's compliance.
c. Evaluation criteria neither too stringent nor too lenient.

d. In the case of in-line samplers, appraisal is made of a BMWS if a delegated farm employee is either operating the in-line sampler improperly or without documented training.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 203 | |
| Committee: | Hauling | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal adds a definition of Direct Loading to Section 1. Definitions of the PMO.

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

NCIMS Hauling Procedures Committee found there was a lack of definition of direct loading. adding a definition will provide clarity. The proposed definition will become the new Q. and every definition thereafter will follow the new alphabetical numbering.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Page 4 | **2023 PMO**<br>***Section(s):* 1**<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change: PMO, Section 1. Definitions Page 4.

O. DAIRY FARM: A Grade "A" dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, camels or other hooved mammal) are kept for milking purposes, and from which a part or all of the raw milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station. (Refer to the NOTE on page 31.)

P. DAIRY PLANT SAMPLER: A person responsible for the collection of official samples for regulatory purposes outlined in Section 6. of this Ordinance. This person is an employee of the Regulatory Agency and is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a SSO or a properly delegated dSSO. Dairy plant samplers that are also SSOs or properly delegated dSSOs are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

Q. DIRECT LOADING: The loading of milk on a milk tank truck while bypassing the use of a farm bulk milk tank or silo.

~~Q.~~R. EGGNOG OR BOILED CUSTARD: Eggnog or boiled custard is the product defined in 21 CFR 131.170.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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|---|---|
| Proposal #: | 204 |
| Committee: | |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

Including an allowance for monthly regulatory samples required by Section 6 to be pulled by a third-party Dairy Plant Sampler who is employed by a commercial laboratory. This would NOT extend to allowing samples being pulled by the dairy production plants.

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

The regulatory agency sampling of Grade "A" dairy products is a requirement under the Pasteurized Milk Ordinance, current edition. However, there are a multitude of situations (weather, product supply, location, etc.) that create times when regulatory inspectors have difficulties obtaining the samples and maintaining other inspectional standards of the Grade "A" and non-Grade "A" dairy production facilities.

In the commonwealth of Pennsylvania, we utilize third-party commercial laboratories for the testing of all raw (commingled) milk and finished dairy products (commercial laboratories are required to be evaluated and maintain standards set forth in the Evaluation of Milk Laboratories Manual, current edition). These laboratories employ individuals who function as couriers to pick up the regulatory samples at the Grade "A" dairy plants. We also use these

couriers as Dairy Plant Samplers in our two hundred and thirty-three (233) non-Grade "A" dairy production facilities.

These dairy plant samplers/couriers allow our regulatory inspectors to focus on sanitation and equipment inspections while allowing for adequate review of sample results and enforcement activities. This year alone, forty-seven (47) warning letters and ten (10) citations were created based off sampling pulled by the third-party dairy plant samplers at non-Grade A dairy plants. Understandably this would not be needed in every state, but we have 60 Grade "A" dairy production facilities located around the state, sometimes concentrated in specific areas, that could be more efficiently sampled by the third-party laboratories.

The Grade "A" program already utilizes third-party individuals as Industry Plant Samplers under Section 5, the Certified Industry Inspection program. We would like to extend this allowance to Dairy Plant Samplers who would be certified by the RA's dSSO's or SSO's as we see no concern in their ability to pull unbiased, representative samples. The criteria required for this certification can already be found on a dairy plant sampler certification form.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Definitions 4, Section 6 page 27, Appendix B 138 | **2023 PMO**<br>***Section(s):* 6**<br>***Appendix:* B** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

Definitions, page 4

P. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6. of this *Ordinance*. This person is an employee of the Regulatory Agency or an approved dairy plant sampler employed at a third-party commercial dairy laboratory and is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a SSO or a properly delegated dSSO. Dairy plant samplers that are also SSOs or properly delegated dSSOs are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

Section 6 page 27
During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and 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 under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained ~~by the~~ under the direction of the Regulatory Agency from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra- pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected ~~by~~ under the direction of the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products shall be exempt from the sampling and testing requirements of this Item.

Appendix B page 138
The dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6. of this *Ordinance*. These persons are employees of the Regulatory Agency ~~and~~ or an approved dairy plant sampler employed at a third-party commercial dairy laboratory are evaluated at least once every twenty-four (24) month period by a SSO or a properly delegated dSSO. These individuals are evaluated using FORM NCIMS 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M. of this *Ordinance*.) Dairy plant samplers that are also SSOs or dSSOs are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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|---|---|---|
| Proposal #: | 205 | |
| Committee: | Liaison/ MMSR/ Scientific | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal would revise inspection and milk/milk product sampling frequencies at milk plants to at least once each 4-month period for inspections, and at least three (3) samples of milk and milk products within each 6-month period.

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

Grade "A" milk plants and milk products have an excellent record of safety. Regulatory agencies are under significant resource pressures and adjusting inspection and sampling activities to more closely align with food safety risk is warranted. This proposal would reduce inspection and sampling by 25% at milk plants, but would not alter frequencies for pasteurization checks or other aspects of regulatory activity. This adjustment would still provide effective food safety oversight while reducing the burden on state regulatory programs.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 21, 23, 27 | **2023 PMO**<br>***Section(s):* 5, 6**<br>***Appendix:*** | | **2023 EML** |
| 28, 30, 106, 107, 110 | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

*PMO, Section 5, (Page 21)*

**SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS**

Each dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility whose milk and/or milk products are intended for consumption within ...of...1 or its jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra- pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

….

3. Inspect each milk plant and receiving station at least once every ~~three (3)~~ four (4) months, provided:

a. For those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. of this *Ordinance*.

b. Regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, shall be conducted by the Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S of this *Ordinance*.) …

PMO, Section 5, (Page 23)

## ADMINISTRATIVE PROCEDURES

**INSPECTION FREQUENCY:** For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for all other milk plants and receiving stations, the interval shall include the designated ~~three (3)~~ four (4) month period plus the remaining days of the month in which the inspection is due.

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

For the purposes of determining the inspection frequency for milk tank trucks, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twenty-four (24) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection every twenty-four (24) months; or one (1) dairy farm, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products and/or fermented high- acid, shelf-stable processed and packaged milk and/or milk products, or milk tank truck cleaning facility inspection every six (6) months; or one (1) milk plant producing pasteurized, ultra- pasteurized, condensed or dried milk and/or milk products or receiving station inspection every ~~three (3)~~ four (4) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk and/ or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. …

PMO, Section 6 (Page 27)

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

…

…During any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging shall be collected in at least ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall

be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra- pasteurization, aseptic processing and packaging,

retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging.
During any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of pasteurized milk, ultra- pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products shall be exempt from the sampling and testing requirements of this Item.

**NOTE:** If the production of Grade "A" raw milk or any Grade "A" milk or milk product, as defined in this *Ordinance*, is not on a continuous monthly basis and; therefore, cannot meet this Section's sampling frequency requirement that during any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of the Grade "A" raw milk or Grade "A" milk or milk product shall be collected in at least ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days, then a sample of the Grade "A" raw milk or Grade "A" milk or milk product shall be collected during each month of production.

MMSR (Page 28)

## E. COMPUTATION OF ENFORCEMENT RATINGS

…

e. For ER purposes, to determine if inspections, sampling, and evaluations have been conducted at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the inspection, equipment tests or sample(s) is due:
• Dairy Farms: at least once every six (6) month period or prescribed by Appendix P.
• Transfer Stations: at least once every six (6) month period
• Milk Plants and Receiving Stations: at least once every ~~three (3)~~ four 4 month period or every six (6) months for Aseptic, Retort or Fermented High-Acid, shelf-stable or HACCP listed milk plants
• Milk Pasteurization equipment tests: at least once every three (3) month period and the holding time testing at least once every six (6) month period
• Grade "A" milk and/or milk product sampling and testing: during any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of each Grade "A" milk and milk product, as

defined in Sections 1. and 6. of the *Grade "A" PMO* shall be collected in ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days
• Dairy Farm individual water supplies: at least once every three (3) year period

• Milk plants, receiving stations and transfer stations individual water supplies: at least once every six (6) month period
….

MMSR (Page 30)

…
c. When an Item requires separate action on the part of the Regulatory Agency with respect to each Grade "A" receiving station or transfer station, compliance is based on the proportion of Grade "A" receiving stations or transfer stations that are included in the rating for which Regulatory Agency's official records show the Item to have been satisfied. If an Item requires more than one (1) test or determination, i.e., MILK PLANT-PART II, Numbers 2, 4, 6, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's official records, were made at the required frequency.

**For Example:** If only ~~six (6)~~ four (4) of the required ~~eight (8)~~ six (6) routine regulatory inspections were conducted since the last rating, the compliance would be ~~6/8 or seventy-five percent (75%)~~ 4/6 or sixty-seven 67%.

MMSR (Page 106)
…
1. All milk plant, receiving station and transfer station operators hold a valid permit (*Grade "A" PMO*, Section 3.). All or nothing Item. a. All milk plants, receiving stations and transfer stations hold a valid permit.

b. Permits retained only by those in compliance with the *Grade "A" PMO* requirements.

c. Permits not transferable with respect to persons and/or locations.

2. Milk plants and receiving stations inspected at least once every ~~three (3)~~ four (4) months (transfer stations, aseptic milk plants and retort milk plants at least once every six (6) months) (*Grade "A" PMO*, Section 5.). Prorate by the number of inspections in compliance with the required frequency.

MMSR (Page 107)
…

**For Example:**

= # of ~~three (3)~~ four (4) or six (6) month periods with an inspection conducted
Total # of ~~three (3)~~ four (4) or six (6) month periods in rating period, back to the last rating

a. Milk plants and receiving stations inspected at least once every three (3) months.

b. Transfer stations, aseptic milk plants, retort milk plants and fermented high-acid, shelf-stable milk plants at least once every six (6) months.

MMSR (Page 110)

….
7. Samples of each Grade "A" milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6). Prorate by the number of Grade "A" milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific Grade "A" milk and/or milk products.)
a. During any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of Grade "A" raw milk, after receipt by the milk plant, including aseptic, retort and fermented high-acid, shelf-stable milk plants, shall be collected, prior to pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, in ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

b. During any consecutive six (6) months, at least ~~four (4)~~ three (3) samples of each Grade "A" milk and/or milk product processed, as defined in Section 1. of the *Grade "A" PMO* shall be collected in ~~four (4)~~ three (3) separate months, except when ~~three (3)~~ two (2) months show a month containing two (2) sampling dates separated by at least twenty (20) days as cited in Section 6. of the *Grade "A" PMO*. However, if the production of any Grade "A" milk or milk product, as defined in the *Grade "A" PMO*, is not on a continuous monthly basis and; therefore, cannot meet the *Grade "A" PMO* sampling frequency requirement as cited, then a sample of the Grade "A" milk or milk product shall be collected during each month of production.
c. All required examinations performed on each Grade "A" milk and/or milk product sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature, as applicable) in an

The changes described in this proposal would become effective on the date of official FDA concurrence of Conference proposals communicated to the NCIMS Executive Board.


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 206 |
| Committee: | MMSR |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal requests an alternative re-certification procedure for certified industry personnel that conduct regulatory inspections on dairy farms in states where dairy farm numbers continue to decline.

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

Many states have limited numbers of dairy farms. At times, certified industry personnel do not have the 10 minimum required farms within their marketing organization in that state to evaluate with a regulatory sanitarian or rating officer for re-certification purposes. This situation often requires permission to travel to a contiguous state for additional farms or to evaluate farms in a competing market in the same state. This issue could be eliminated if reciprocity could be allowed in a situation where the marketing organization has less than the 10 minimum required farms in a state to evaluate for re-certification.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 25 and 26 | **2023 PMO**<br>***Section(s):* 5**<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

**Re-Certification:** The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector shall make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above except that a minimum of ten (10) randomly selected dairy farms and/or two (2) milk tank trucks, as applicable for the type of re-certification, shall be inspected. If the marketing organization does not have 10 dairy farms in that state, the Regulatory Agency and the certified industry inspector shall evaluate all the farms from their market in that state, but not less than 3 dairy farms. In addition, the certified industry inspector shall provide complete documentation to prove certification from another state that shall be maintained with the certified industry inspector's file for the Regulatory Agency. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency. In order to be re-certified, a certified industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant. Should the Regulatory Agency determine that a certified industry inspector has failed to demonstrate proficiency in the above re-certification procedures, the Regulatory Agency may require the certified industry inspector to perform the initial certification procedures.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 207 |
| Committee: | MMSR/ Liaison |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

To clarify that when multiple flavors of a milk or milk product are produced at the same fat level, only one sample from any of the flavored products is required, not each individual flavor.

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

Over the years, multiple M-Is have addressed this issue, highlighting the confusion surrounding the topic. This proposal aims to add clear language to the PMO, confirming that even if a dairy plant produces several flavored products at the same fat level, only one sample needs to be taken from the entire group of different flavors. For example, if a plant produces full-fat strawberry, full-fat raspberry, and full-fat blueberry yogurt, only one sample is required. The same applies to fluid milk. If a plant produces 1% mint, 1% strawberry, and 1% chocolate milk, only one sample is needed from the flavored category at each fat level. Sampling should rotate between products and sizes. This clarification aligns with the guidance in M-I-13-6 question #33, M-I-04-06 question #9, and M-I-12-9, question #16 which all emphasize that Section 6 of the PMO does not require each different flavored product at a

specific fat level to be sampled separately. Instead, it recommends rotating the sampling across different flavors at each fat level. Including this information in the PMO will help prevent

future questions from SROs and ensure that this long-standing practice is clearly documented in Section 6.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 27 | **2023 PMO**<br>***Section(s):* 6**<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed change; PMO Section 6 (page 27)

During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. In the case when multiple flavors of a milk and/or milk product is produced at a certain fat level, each individual flavor of milk and/or milk does not need to be sampled to be in compliance with this *Ordinance*, only one flavored product from each fat level. It is recommended that each different flavor of milk and/or milk products at each fat level be sampled on a rotational basis. All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products shall be exempt from the sampling and testing requirements of this Item.
**NOTE:** If the production of Grade "A" raw milk or any Grade "A" milk or milk product, as defined in this *Ordinance,* is not on a continuous monthly basis and; therefore, cannot meet this Section's sampling frequency requirement that during any consecutive six (6) months, at

least four (4) samples of the Grade “A” raw milk or Grade “A” milk or milk product shall be collected in at least four (4) separate months, except when three (3) months show a month

containing two (2) sampling dates separated by at least twenty (20) days, then a sample of the Grade “A” raw milk or Grade “A” milk or milk product shall be collected during each month of production.


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 208 |
| Committee: | App. N |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal moves a statement related to finished product testing from Appendix N. to Section 6.

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

Appendix N of the PMO pertains exclusively to the testing of 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 drug residues.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 28, 363 | **2023 PMO**<br>***Section(s):*** **6**<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

PMO, Section 6., page 28:

Whenever a drug residue test is Presumptive Positive or ~~confirmed~~ Confirmed ~~positive~~ Positive, using NCIMS Accepted Drug Residue Test Methods, the positive results shall be reported to the Regulatory Agency in which the testing was conducted and 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*.

PMO, Appendix N. Section I, page 363:

…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 using NCIMS Accepted Drug Residue Test Methods for drug residues on finished milk and/or milk products shall be reported to the Regulatory Agency in which the testing was conducted.~~


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 209 | |
| Committee: | Lab | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

An update to section 6 of the PMO to include wording related to the appropriate method for averaged values for bacterial (standard plate count and coliform), somatic cell count and temperature when samples from multiple bulks tanks are pulled from the same farm on the same day.

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

The current requirements found on page 28 of the PMO in a 'note' call for multiple bulk tank samples pulled from individual farms on the same day is to perform a standard average. This technique does not allow for consideration to the amount of product in each tank. A farm with 2 bulk tanks may have one tank that holds a significantly larger amount of product than the secondary smaller tank. We are asking to have the requirements amended to include review of the amount of product in each tank and calculate the answers based on an averages weight.

Definition of a weighted average: Multiplies each number by a predetermined weight, then adds the products together and divides by the total of the weights

Definition of a standard average: Adds all numbers together and divides by the total number of numbers. This method is also known as the arithmetic mean.

As an example, you may have one farm with a bulk tank that can hold 6 milkings (tank #1), but a smaller, secondary tank that only holds 2 milkings (tank #2). If samples are pulled and tank #1 is below the regulatory limits, but tank #2 is above the regulatory limits, the standard average could cause the farm to have a violation on a bacterial, somatic cell counts and temperature determinations. Whereas, if all the milk was in one bulk tank, there would be no violation.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Page 28 | **2023 PMO**<br>***Section(s):* 6**<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

**NOTE:** When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are ~~averaged arithmetically~~ calculated using a weighted average by the Regulatory Agency or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

To calculate the weighted value, multiply each data point by its corresponding weight, add up the values, then divide the sum of those values by the sum of all the weights: sum of (value x weight) / sum of weights

Example: Tank 1 = 12,000 lbs, SPC 25,000 Tank 2 = 3,000 lbs, SPC 260,000 Total volume 15,000 lbs

Tank 1 - 12,000x25,000 = 300,000,000 Tank 2 – 3,000 x 260,000 = 780,000,000

$$\frac{300{,}000{,}000 + 780{,}000{,}000}{15{,}000} = 72{,}000$$


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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 210 |
| Committee: | App. N |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal seeks to update Appendix N. of the PMO to reflect sunsetting of M-I-18-9 "*Tolerance And/Or Target Testing Levels Of Animal Drug Residues In Milk*".

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

In October 2025, M-I-18-9 "*Tolerance And/Or Target Testing Levels Of Animal Drug Residues In Milk*" will be sunsetting.

FDA has explored alternate means of communicating to stakeholders information about violative levels of drug residues and, ultimately, has decided to pursue rulemaking (e.g., notice-and-comment rulemaking). This process will allow for transparency to all stakeholders and the sharing of available scientific information to support codifying violative levels of drug residues in milk.

The current proposal updates Appendix N. of the PMO to reflect sunsetting of the M-I.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 30, 370, 378-379, 389 | **2023 PMO**<br>***Section(s):*** 6<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

*This proposal also directs FDA to incorporate editorial updates into the PMO Table of Contents.*

**Section 6. The Examination of Milk and/or Milk Products**
Page 30
…The procedures shall be those specified therein for: …

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

**Appendix N. Drug Residue Testing and Farm Surveillance**
**III. Testing Program for Beta-Lactam Drug Residues**
…
Page 370
REQUIREMENTS FOR TESTING:
Procedures Necessary to Complete Prior to Testing: Before any AGARMS samples are tested, all required equipment and drug residue test method verification must be completed. Refer to the applicable NCIMS 2400 forms for additional information.

1. Performance Tests/Controls: Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.
2. Positive Controls
All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.
(1) For NCIMS Accepted Drug Residue Test Methods that only detect penicillin, ampicillin, amoxicillin and cephapirin, the positive (+) control is penicillin @ 5 ± 0.5 ppb.
(2) For NCIMS Accepted Drug Residue Test Methods that detect cloxacillin, the positive (+) control may be cloxacillin @ 10 ± 1 ppb.
(3) For NCIMS Accepted Drug Residue Test Methods for one (1) drug residue only, the positive (+) control is ± 10% of the ~~target testing level/~~tolerance of the drug residue detected, or as established by this Appendix.
…

Page 378:
IV. ~~ESTABLISHED TOLERANCES AND/OR TARGET TESTING LEVELS OF DRUG RESIDUES~~ [RESERVED]

~~"Target testing levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the target testing levels. In short, FDA uses the "target testing levels" as prosecutorial guidelines and in full consistency with CNI v. Young. They do not dictate any result; they do not limit FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.~~
~~"Target testing levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the FFD&CA as amended. "Target testing levels":~~
~~1. Do not bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and~~
~~2. Do not have the "force of law" of tolerances, or of binding rules.~~
~~Notification, changes or additions of "target testing levels" shall be transmitted via Memoranda of Information (M-I's).~~

Page 378-379:
V. NCIMS ACCEPTED DRUG RESIDUE TEST METHODS
…
One (1) year after two (2) or more drug residue test methods have been evaluated by FDA and have been accepted by the NCIMS for a particular non-beta-lactam drug or drug family, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, other unevaluated drug residue test methods for that particular non-beta-lactam drug or drug family are not acceptable for determining a Confirmed Positive on AGARMS.

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

Page 379:
1. Drug residue test methods that detect Penicillin G at 2 ppb.
2. Drug residue test methods that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

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

VI. TEST METHODS FOR NON-BETA-LACTAM DRUG RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND HAVE NOT BEEN ACCEPTED BY THE NCIMS
…
Option 1 and 2 – General Requirements:
Drug residue test methods not evaluated by FDA and not accepted by the NCIMS may be used for screening AGARMS for non-beta-lactam drug residues provided that the following conditions are met:
1. The drug residue test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. ~~target testing levels or~~ non-zero tolerances are available, the drug residue test method manufacturer's data indicates that the sensitivity of the drug residue test method is at or below those concentrations.
…
Page 389:
…
Option 3 – General Requirements:
Test methods not evaluated by FDA and not accepted by the NCIMS may be used for screening AGARMS for non-beta-lactam drug residues provided that the following conditions are met:
1. The drug residue test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. ~~target testing levels or~~ non-zero tolerances are available, the drug residue test method manufacturer's data indicates that the sensitivity of the drug residue test method is at or below those concentrations.
…

Name: Food and Drug Administration

Agency/Organization: Human Foods Program – Division of Dairy Safety

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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 211 | |
| Committee: | Scientific | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal is to add Ozone, generated on-site, as an approved method of sanitizing clean product contact surfaces and for product sanitization.

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

Ozone is an extremely effective sanitizer / disinfectant at very low concentrations when dissolved in water. Additionally, it leaves no chemical residues following sanitizing, as the ozone dissipates quickly into $O_2$

All other current chemical sanitizers leave a residue; whereas Ozone leaves none.

Ozone is currently used in the food and biopharma industries as well as commercial applications to sanitize or disinfect bottled water, fruits and vegetables, eggs, clothing, etc., and the effectiveness of Ozone as a sanitizer is well documented.

The use of Ozone as a hard surface sanitizer would provide an effective means of sanitizing clean product contact surfaces, and reduce the risk of chemical carryover into dairy foods.

Included are attachments to support this proposal:

1. Ozone Sanitation - A Sustainable and Efficacious Approach to Food Safety

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Pages 50, 212, 213 | **2023 PMO**<br>***Section(s):* 7**<br>***Appendix:* E** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Changes:

Page 50:

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in 40 CFR 180.940 and shall be used in accordance with label directions, or the electro-chemical activation (ECA) or Ozone device manufacturer's instructions if produced onsite in accordance with Appendix F., II. of this *Ordinance*. (Refer to Appendix F. of this *Ordinance* for further discussion of approved sanitizing procedures.)

Page 212:

**I. METHODS OF SANITIZATION**
**CHEMICAL**

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in either in 40 CFR 180.940 and shall be used in accordance with label directions, or ECA or Ozone device manufacturer's instructions if produced onsite in accordance with Section II. below.

Page 213 Add / Insert Section for Ozone

**III. CRITERIA FOR THE ONSITE PRODUCTION AND USE OF OZONE FOR THE SANITIZATION OF MULTI-USE CONTAINERS, UTENSILS, AND EQUIPMENT**

The following is a list of criteria that are required for on-site generation of dissolved Ozone and used as a sanitizer for the sanitization of multi- use containers, utensils and equipment.

1. The Ozone device manufacturer shall be registered with the EPA as a pesticidal device establishment pursuant to 40 CFR 152.500 and shall comply with the labeling requirements outlined in 40 CFR 156.10.
2. The minimum dilution percentage of the sanitizer shall be 2 parts per million (ppm) dissolved Ozone with a minimum contact time of 30 seconds pursuant to the efficacy requirements for EPA DIS/TSS 4 Sanitizer rinses (https://archive.epa.gov/pesticides/oppad001/web/html/dis-04.html), for previously cleaned milk-contact surfaces. The sanitizer produced shall meet the data requirements of 40 CFR Part 158 Data Requirements for Registration, Pesticide Assessment Guidelines – Subdivision G, 91-2(f), and its test documents shall be pursuant to Good Laboratory Practices (GLPs).
3. Potable water shall be used to ensure quality and consistency of the sanitizer generated.
4. The Ozone generation device and its solution storage containers, if applicable, shall be constructed of materials that do not impart toxic materials into the sanitizing solution either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes that may occur in contact with dissolved Ozone.
5. The dissolved Ozone generation device shall be labeled with the following:
    a. Contents;
    b. EPA Establishment Number for the Ozone device manufacturer;
    c. Usage instructions (e.g., ppm of dissolved ozone), including the shelf-life (if applicable);
    d. A list of its active and inert ingredients; and
    e. Other required standard safety data disclosures, formerly referred to as Safety Data Sheet (SDS).
6. The Ozone generating device used to produce the dissolved Ozone solution shall control and record the parameters to ensure that the device is operating within its design limits and provides an effective real time notification or alarm and shall shut down when it falls out of the required range as recommended by the Ozone device manufacturer.
7. Standard measurement methods such as electronic sensors or test strips shall be used to verify that the dissolved Ozone is being applied at a minimum concentration of 2 ppm, or as defined per the application. Measurement equipment shall be checked, calibrated and measurements recorded. All records shall be accessible to the Regulatory Agency for inspection.


| | | | |
|---|---|---|---|
| Name: | Matt Lowe | | |
| Agency/Organization: | Advanced Ozone Integration, Inc. | | |
| Address: | 2580 El Camino Real | | |
| City/State/Zip: | Atascadero / CA / 93422 | | |
| Telephone No.: | 805-835-5272 | E-mail Address: | mlowe@advancedozoneintegration.com |

# Ozone Sanitation - A Sustainable and Efficacious Approach to Food Safety


## ABSTRACT

Ozone's discovery and commercial use as a disinfectant can be traced back to the late 1800s. Early on, its primary function was sanitation and disinfection for potable water. The scientific community thoroughly studied and vetted the use of ozone for these specific applications, which led to the realization that ozone could benefit countless other industries as well. Throughout the rest of the 20th Century and now well into the 21st Century, research continues to show the benefits of using ozone for disinfection and sanitation purposes across a multitude of commercial industries.


## INTRODUCTION

Since its discovery in the early 1800s, ozone has been proven to be an efficacious sanitizer, disinfectant and antimicrobial oxidizing agent. The disinfecting capability of 1 ppm (mg/L) of ozone dissolved in water (aqueous ozone) is equivalent to many times (10 to 4,000 times) the concentration of free available chlorine (Morris, 1975), depending on the pH, temperature and microorganism(s) to be destroyed. Ozone has been proven to be effective at oxidizing microorganisms such as viruses and bacteria because its method of oxidation prevents them from developing a tolerance to ozone.

In viruses, ozone oxidizes DNA and RNA which are ineffectively protected by a thin protein coat (von Sonntag & von Gunten, 2012). In bacteria, ozone rips electrons away from the disaccharides and amino acids that comprise the cell wall. This causes lysis or bursting of the wall, effectively destroying the organism. Figure 1 shows the steps leading to the destruction of bacteria in detail. Ozone begins its attack with the cell membrane (a), then continues its assault on glycoproteins, glycolipids, or certain amino acids along with sulfhydryl groups of some enzymes (b). Image (c) shows the initial damage to the membrane before break down of the cell wall becomes apparent (d). Complete perforation of the membrane (e) occurs just before the cell lysis or disintegration (f) (Rojas-Valencia, 2011).

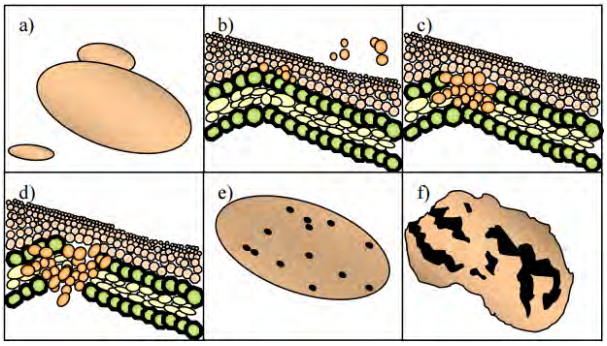


**Figure 1. Bacteria lysis during ozone disinfection**

Research has also shown ozone to be effective at oxidizing biofilms, pesticides, and pharmaceutical pollutants such as endocrine disruptors. However, it is important to note that partial oxidation of pesticides and endocrine disruptors can form ozonation byproducts that need to be further treated and removed from potable water with post filtration typically

involving Advanced Oxidation Processes (AOP) in addition to utilizing bacteria, such as biologically activated carbon (BAC) filters.

## OZONE BASICS

Ozone is a resonant molecule comprised of three oxygen atoms. The third atom is weakly bonded and electron deficient, causing the molecule to be unstable which consequently makes the ozone molecule an effective sanitizer, disinfectant, and oxidizer. Because of ozone's instability as a gas, it cannot be stored and must therefore be generated onsite near its point of use. It is produced via an ozone generator which utilizes a dry, oxygen-enriched feed gas and electricity. As the feed gas passes through the generator, the electrical energy (a plasma field) causes some of the oxygen ($O_2$) molecules to split, resulting in two singlet oxygen atoms ($O^1$). These singlet atoms ($O^1$) unite with other oxygen molecules ($O_2$) to produce ozone ($O_3$) (Figure 2).

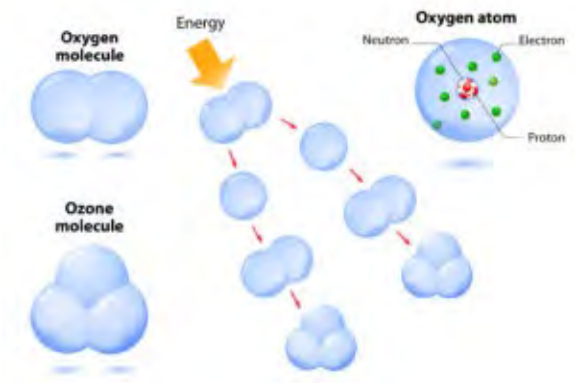


**Figure 2. Formation of Ozone**

When ozone gas is dissolved in water, its half-life can range from seconds to hours, depending upon the pH, temperature, level and type of contaminants in the water. Ozone oxidation of dissolved organic contaminants typically results in the formation of oxygen, carbon dioxide and smaller, more biodegradable molecular fragments.

## OZONE OXIDATION STRENGTH COMPARISON

Chlorine-based chemicals have long been considered the industry standard for sanitation and disinfection purposes. However, since the 1970s, it has become evident that chlorination of certain waters can form disinfection by-products (DBP) that are carcinogenic. Because of that and the greater oxidative power of ozone, it has become more widely accepted as an alternative sanitizer and disinfectant in the food industry. Ozone's antimicrobial efficacy, as measured in electron volts, is superior to commercial sanitation products commonly used in today's modern food facilities (Figure 3). No other sanitation or disinfection chemical is stronger or more efficacious than ozone in terms of its oxidative power.

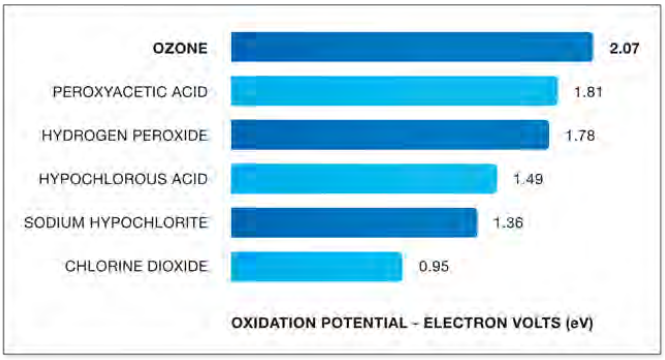


**Figure 3. Oxidation Comparison**

The Ct value term, based on models developed by Chick and Watson (Langlais, et al 1991), is used to indicate the level of ozone disinfection for specific microorganisms. The units for Ct are concentration (mg/L) multiplied by time (minutes) and is based on the empirical testing of the ozonation of various microorganisms under specific temperature and water quality conditions. The level of lethality is based on a logarithmic scale, where 1 log is equivalent to 90% kill, 2 logs is 99%, 3 logs is 99.9%, etc.

## OZONE EFFICACY AND COMPARISONS TO CHLORINE-BASED CHEMICALS

Ozone has been widely studied over the past century for its disinfection efficacy and its superior strength to commonly used chlorine-based chemicals.

**Table 1. Values of Specific Coefficients of Lethality for the Main Disinfectants (L/mg/min)**

| Disinfectant | Enterobacteria | Viruses | Bacterial Spores | Amoebic Cysts |
|---|---|---|---|---|
| $O_3$ (Ozone) | 500 | 5 | 2 | 0.5 |
| HOCl (Hypochlorous acid) | 20 | 1 & up | 0.05 | 0.05 |
| $OCl^-$ (Hypochlorite ion) | 0.2 | < 0.02 | < 0.0005 | 0.0005 |
| $NH_2Cl$ (Chloramine) | 0.1 | 0.005 | 0.001 | 0.02 |

Source: Morris (1975)

**Table 2. Ct values (mg-min/L) for 99% Inactivation of Microorganisms with Disinfectants at 5°C.**

| Microorganism | Disinfectant | | | |
|---|---|---|---|---|
| | Free Chlorine (pH 6 to 7) | Preformed Chloramine (pH 8 to 9) | Chloride Dioxide (pH 6 to 7) | Ozone (pH 6 to 7) |
| *E. coli* | 0.034-0.05 | 95-180 | 0.4-0.75 | 0.02 |
| Polio 1 | 1.1-2.5 | 770-3740 | 0.2-6.7 | 0.1-0.2 |
| Rotavirus | 0.01-0.05 | 3810-6480 | 0.2-2.1 | 0.006-0.06 |
| Phage f2 | 0.08-0.18 | -- | -- | -- |
| *G. lamblia* cysts | 47->150 | -- | -- | 0.5-0.6 |
| *G. muris* cysts | 30-630 | 1400 | 7.2-18.5 | 1.8-2.0 |

Source: Hoff (1987)

**Table 3. U.S. EPA Ct values (mg- min/L) for 3 log Inactivation of *Giardia* Cysts (99.9%) with Ozone at Different Temperatures with pH values from 6 to 9**

| Inactivation | Temperature °C (°F) | | | | | |
|---|---|---|---|---|---|---|
| | 0.5 (33) | 5 (41) | 10 (50) | 15 (59) | 20 (68) | 25 (77) |
| 1.0 log | 0.97 | 0.63 | 0.48 | 0.32 | 0.24 | 0.16 |
| 1.5 log | 1.5 | 0.95 | 0.72 | 0.48 | 0.36 | 0.24 |
| 2.0 log | 1.9 | 1.3 | 0.95 | 0.63 | 0.48 | 0.32 |
| 2.5 log | 2.4 | 1.6 | 1.2 | 0.79 | 0.60 | 0.40 |
| 3.0 log | 2.9 | 1.9 | 1.4 | 0.95 | 0.72 | 0.46 |

Source: U.S. EPA (1989a)

## OZONE APPLICATIONS

Ozone has been documented to be significantly more effective than all the commonly-used sanitation chemicals available for commercial and industrial sanitation. It is unsurpassed for its antimicrobial efficacy, and is superior in terms of microbial log reduction. Also, given proper safety, material selection and environmental controls, it demonstrates no negative impacts on the facilities, products or employees. Ozone treatment is a uniquely safe and sustainable non-thermal sanitation process and is compatible with the proper processing materials (See Ozone Safety and Material Compatibility).

For application control, gaseous ozone is dissolved in water to create "ozone-enriched water" which is commonly referred to as *aqueous ozone*. Aqueous ozone can be utilized at several points of the process, depending on the commodity. The most common uses in the food industry are direct contact with the food product and/or surface sanitation and CIP/SIP. Since ozone is an approved food additive, it has the unique capability of providing sanitation to food and equipment simultaneously (i.e. food product on a conveyor belt). Ozone creates no organoleptic changes in food products (through direct or indirect contact), as traditional chemicals can and do. Ozone helps to remove residual pesticides and microorganisms such as *E. coli, Listeria monocytogenes, Salmonella choleraesuis, Campylobacter jejuni and Bacillus subtilis, etc.* from food products.

Direct product and surface application typically consists of a low-pressure spray using fixed spray bars, drench, shower or rain-type applicators (such as the Ozone Rain Pan), or with hand-held sprayers. It can also be added to flume water which can be recirculated if the process is moderately clean, or sent to the drain. Additional uses have also included sanitizing bottles or product water prior to flavor additives. In some facilities, gaseous ozone is used in controlled atmosphere (CA) environments for microorganism control, ripening delay and spoilage reduction resulting in increased shelf-life of the product. These processes can all be performed simultaneously with a centralized ozone system.

Aqueous ozone systems are typically controlled by a dissolved ozone monitor/controller which provides automatic dose control proportional to the water flow. Depending upon the application, the ozone concentration is commonly regulated to between 1.5 – 5.0 mg/L. Most applications use cold water (<75°F) sprayed at a low pressure (10 psi or less), allowing for gentle flooding of surfaces without causing pressurized over-spray that can inadvertently spread microorganisms to other areas of the facility and/or result in excessive off-gassing of ozone into the plant environment.

Ozone-enriched water can sanitize both food contact and non-food contact surfaces, as well as any other wettable area with sanitation needs. The use of ozone can reduce levels of fat, oil and grease on surfaces, as well as break down bacterial biofilm build-up, molds and mildew (particularly in areas of high sugar products). With continued use, ozone will sanitize floor drains and rid the drains and plumbing of biofilm and other microorganisms that can migrate back into the processing area (especially *Listeria monocytogenes*) with the benefit of adding dissolved oxygen to the wastewater and no adverse effects on wastewater treatment systems.

Additional benefits of the regular use of aqueous ozone include elimination of greasy film on facility floors, pre-ozonation of Reverse Osmosis (RO) source water to prevent biofouling of the RO membranes, and keeping conveyor belts clean and free of buildup consisting of food debris, sugar, fat, grease, fungi, and biofilm that may contain human or food sourced pathogens.

## OZONE SAFETY AND MATERIAL COMPATIBILITY

Aqueous ozone systems operated per Good Manufacturing Process (GMP) are safe for workers. The systems utilize ambient ozone monitors to alert those in the area if a catastrophic equipment failure happens and the ozone concentration exceeds safe exposure limits. These monitors will also cut off power to the ozone generator to prevent further ozone gas leaking before repairs can be made to the system. If so desired, remote alarms or notifications can be linked to the monitor in the immediate vicinity of the ozone generator to prevent others from entering the area until it is safe.

Because ozone is a strong oxidizer, the use of compatible materials that can withstand prolonged exposure to ozone is important. Acceptable materials include the following:

- Stainless Steel (304, 316 and foil)
- Aluminum (all grades)
- Concrete, painted surfaces, wood
- Painted concrete
- Plastics: ECTFE, PTFE, PVC, PVDF, HDPE (Polyethylene)
- Gaskets: FPM (Viton), EPDM
- Rubber Modified Vinyl
- Glass

Natural rubber latex is not suitable for use with aqueous ozone and mild steel may experience surface rusting.

## INDUSTRY AND REGULATORY ACCEPTANCE OF OZONE

The use of ozone has had wide commercial adoption and multiple approvals from government agencies, globally, for well over one hundred years. However, in the U.S., approvals didn't start showing up until the 1970s. Since then, all the pertinent U.S. government agencies have added ozone to their lists of approved antimicrobials for multiple applications in the food industry.

With increased interest in adopting more sustainable practices, increasing consumer demand for more organic and healthy food options, as well as much stricter food safety rules (i.e. FSMA, HAACP and HARPC), the use of ozone has accelerated the move away from multi-chemical based sanitation treatments. Other events, including water availability and cost, food recalls, foodborne illnesses, waste water concerns and the need to reduce operating costs, have advanced the use of ozone-based technology either as a replacement for, or an addition to traditional chemical-based and thermal-based sanitation treatments. Ozone is an FDA, USDA and USDA Organic approved antimicrobial food additive. It is an EPA approved antimicrobial oxidizer for potable water, surface sanitation and CIP/COP/SIP.

Below is a summary of the current regulatory information on ozone use in the food industry by agency. Additional documentation further describing the regulations in detail can be found at the end of this document (Regulatory Documentation).

- **FDA** – Regulates and allows ozone contact with foods (F&V, seafood, shell eggs, bottled water)
- **USDA/FSIS** – Regulates and allows ozone contact with meat, poultry and egg products
- **USDA National Organic Program (NOP)** – Allows ozone for organic food contact
- **EPA/FIFRA** – Regulates ozone generators under their device program (sanitation and potable water)
- **OSHA** – Regulates ozone (for worker exposure) in workplace air

## DETAILED REGULATORY DOCUMENTATION

### FDA

**21 § CFR 129.80 (3/15/1977; amended 4/4/2012)**

Bottled water plant sanitizing of contact surfaces and any other critical area
0.1 ppm ozone-enriched water solution for at least five minutes (Ct value of 0.5 mg-min/L)

**21 CFR §173.368 (6/26/2001)**

FDA Secondary Direct Food Additives Permitted in Food for Human Consumption

Ozone may be safely used in the treatment, storage, and processing of foods, including meat and poultry

Ozone is used as an antimicrobial agent in accordance with current industry standards of good manufacturing practice

**21 § CFR 178.1010 (b) (1, 3, 9, 30, 38) (3/16/1977)**

"Category Three Certification": <15 cfu per cm for Yeast, Mold, Bacteria; No rinse

§178.1010 (b): "The solutions consist of one of the following, to which may be added components generally recognized as safe (GRAS) and components which are permitted by prior sanction or approval."

- (1) 200 ppm chlorine
- (3) 25 ppm iodine (iodophore)
- (9) 200 ppm quaternary ammonia compound
- (30) 400-600 ppm peroxide
- (38) 128-156 ppm peroxyacetic acid

Ozone is (GRAS) and listed under prior sanction (USEPA/FIFRA) Standard Dose 1-5 ppm Ozone

### USDA/FSIS

November 27, 2001, the American Meat Institute filed a letter with USDA/FSIS requesting interpretation of the scope of the FDA rule allowing the use of ozone as an antimicrobial agent

USDA/FSIS determined that, "The use of ozone on raw and ready-to-eat meat and poultry products just prior to packaging is acceptable," and that there are "no labeling issues in regard to treated product"

**USDA/FSIS Directive 7120.1** (12/17/02) (Revised 3/3/16)

"The attachment below identifies the substances that have been accepted since January 2000 by FSIS as safe and suitable for use in the production of meat and poultry products"

(Attachment 1) Antimicrobial - Ozone

1. All Meat and Poultry Products
2. In accordance with current industry standards of good manufacturing practice
3. Reference 21 CFR § 173.368

## USDA NATIONAL ORGANIC PROGRAM (NOP) ALLOWED SUBSTANCES

Ozone is listed in the NOP Final Rule **(§ 205.605 (b) (20)** pg. 437 - Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"

(b) Synthetics allowed: (20) ozone

Food Safety and Inspection Service New Technology Information Table Last Updates January 25, 2017

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/new-technologies/new-technology-information-table

Listed technology: Ozone

**FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products - January 2014**

A. Post-lethality Treatments and Antimicrobial Agents

Buege, D.R., Ingham, S.C. and J.A. Losinski (University of Wisconsin-Madison), "Evaluation of Del Ozone's Delzone® Sanitation System as a Post-Lethality Treatment to Control *Listeria monocytogenes* Contamination on Ready-To-Eat Meat Products", Confidential Report to Del Ozone, April 16, 2004.

I. Use of Antimicrobial Ingredients including Bacteriophages, Lactates, Acetates, Diacetates, and Ozone

*Ozone is an antimicrobial gas usually applied in an aqueous solution to products, food contact surfaces as a continuous spray (e.g., belts, moving tables), and nonfood contact environmental surfaces. Currently, the use of ozone is permitted by FDA and FSIS (21 CFR 173.368, FSIS Directive 7120.1) for use with all meat and poultry products, including RTE meat and poultry products.*

Buege et al., (2004) showed 1.0 to 2.4 log reductions (average 1.5) of *Lm* when 0.6 ppm ozone for 30 seconds was applied to ham, salami, meatloaf, natural casing wieners, and skinless wieners.

**FSIS USDA Training - Process Category Introduction 3/25/2015 Inspection**

Poultry Slaughter – Antimicrobial Interventions

Raw Product – Intact Processing Category

Common Controls - Biological

*In addition to the controls that may have already been used during the slaughter process, establishments commonly utilize additional antimicrobial interventions for pathogens of concern.*

On August 21, 2014, FSIS published the Modernization of Poultry Slaughter Inspection final rule. FSIS Notice 50-14 addresses how IPP are to verify compliance with approved online and offline

reprocessing antimicrobial intervention systems. *Establishments that slaughter poultry other than ratites are allowed to use these approved systems to clean carcasses accidentally contaminated with digestive tract contents* ***(9 CFR 381.91)****. A list of approved systems is included as an attachment to this notice.*

Ozone

*Ozone may be used in contact with food as a gas or liquid as an antimicrobial in meat and poultry products, including ground meats.*

## EPA/FIFRA OFFICE OF PESTICIDE PROGRAMS (OPP) DISINFECTANT TECHNICAL SCIENCE SECTION (DIS/TSS)

EPA regulates ozone as a pesticide- producing device

Ozone generators must be registered by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Each Ozone Generator Manufacturer has a unique EPA registered establishment number as a pesticide-producing device

For no-rinse surface sanitation compliance the USEPA/FIFRA Office of Pesticide Programs (OPP) Disinfectant Technical Science Section (DIS/TSS) requires:

1. Antimicrobial efficacy data determined by AOAC International methods
2. Toxicological profiles
3. Environmental impact information
4. Specific label information and directions for use

Ozone Generators are recognized by the EPA as antimicrobial producing devices per EPA documentation published in 1976, with an EPA Establishment Number necessary for compliance.

## VALIDATION STUDIES

**NSF International Toxicology Labs Test Results ca 2000-2001**

Ozone systems with an aqueous ozone output of 1.5-2.0 ppm dissolved ozone tested for antimicrobial efficacy

Antimicrobial Efficacy Protocols

DIS/TSS-1 (AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants, for both broad-spectrum and hospital/medical environment efficacy claims) was chosen by the Microbiology and Toxicology Groups at NSF as the best testing protocol efficacy testing of aqueous ozone sanitizing on hard surfaces

NSF also chose DIS/TSS-4 (AOAC Method 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants) for additional efficacy testing

NSF conducted studies according to EPA-established AOAC Official Methods 961.02 & 960.09, Germicidal Spray Products as Disinfectants, and Germicidal & Detergent Sanitizing Action of Disinfectants test procedures (Aqueous ozone 1.5-2.0 mg/L) (Note: log reductions are mandated by the AOAC Method)

**AOAC 961.02 Results (AOAC Method 961.02 requires a minimum log 6 reduction)**

| | | |
|---|---|---|
| *Salmonella choleraesuis* | 6 log reduction (99.9999%) | 180 seconds |
| *Staphylococcus aureus* | 6 log reduction (99.9999%) | 600 seconds |
| *Pseudomonas aeruginosa* | 6 log reduction (99.9999%) | 300 seconds |
| *Trichophyton mentagrophytes* | 6 log reduction (99.9999%) | 30 seconds |

**Additional evaluations as per AOAC 961.02 Results (AOAC 961.02 Additional evaluations require a minimum log 4 reduction)**

| | | |
|---|---|---|
| *Campylobacter jejuni* | 4 log reduction (99.99%) | 180 seconds |
| *Aspergillus flavus* | 4 log reduction (99.99%) | 300 seconds |
| *Brettanomyces bruxellensis* | 4 log reduction (99.99%) | 180 seconds |
| *Listeria monocytogenes* | 4 log reduction (99.99%) | 180 seconds |

**AOAC 960.09 Results (AOAC Method 960.09 requires a minimum log 5 reduction)**

| | | |
|---|---|---|
| *Escherichia coli* | 5 log reduction (99.999%) | 30 seconds |

**Robert Donofrio, et al, IWA Publishing 2013 Journal of Water and Health | 11.2 | 2013**

Antimicrobial Validation for *Cryptosporidium parvum* Reduction by NSF International – Low Dose Ozone (CT 0.74)

Pass compliance requires a 3 log (99.9%) reduction of *Cryptosporidium parvum*

Actual Microbial Reductions in 30 Seconds (Actual Ozone Ct value was 0.76)

*Cryptosporidium parvum* 3.0 log (>99.9%)

NSF International Validation Study

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**M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 71 (2001) 131–138**

*Bacillus subtilis*

"It is evident that ozone is superior to hydrogen peroxide in killing bacterial spores. Hydrogen peroxide at ~10,000-fold higher concentration was less effective than ozone against *Bacillus* spores. The comparatively low concentration needed to eliminate large populations of spores at ambient temperature in short time periods makes ozone best suited for industrial settings."

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**M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 66 (2001) 1247**

*B. cereus*

Aqueous Ozone 0.12 mg/L @ 5 minutes (Ct 0.6) @ 28°C = > 2 log reduction

M.A. Khadre, A.E. Yousef, International Journal of Food Microbiology 71 (2001) 131

*B. cereus*

Aqueous Ozone 11.0 mg/L @ 1 minutes (Ct 11.0) @ 22°C = > 6 log reduction

Quote per Dr. Ahmed Yousef, February 2009

"Regarding International Journal of Food Microbiology 66 (2001) 1247 and 71 (2001) 131, both studies provide statistical comparison only; therefore, the ozone was not optimized, it is very likely that ozone is more cost- efficient at lower quantities, and should be re-evaluated for optimum CT value and efficacy for *Bacillus*."

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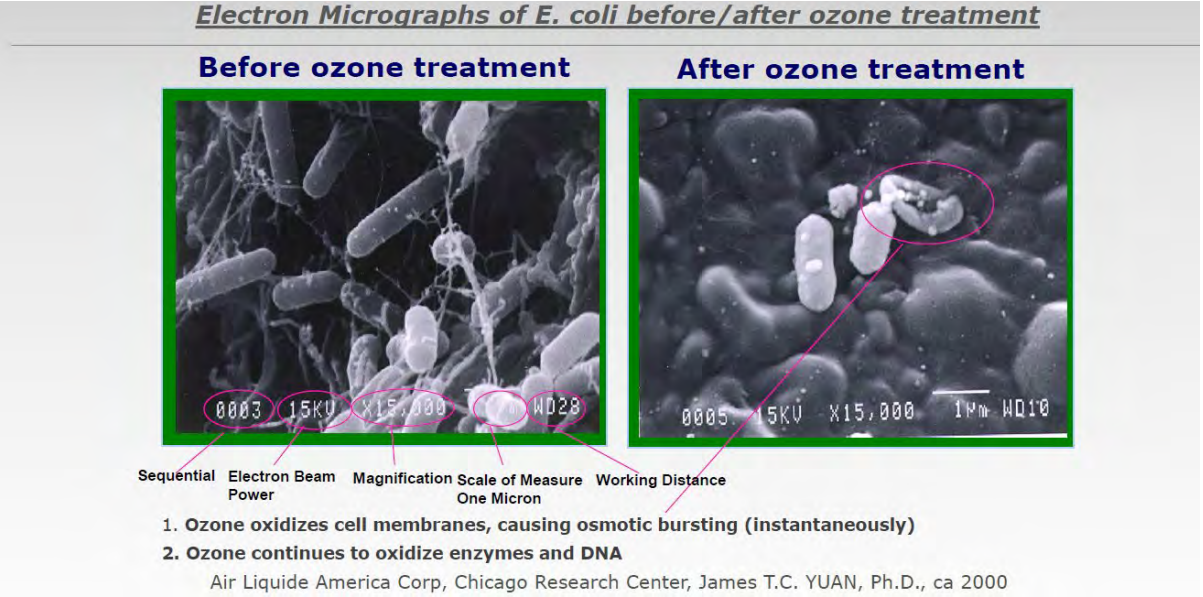
**James T.C. Yuan Ph.D., Air Liquide America Corp, Chicago Research Center, ca 2000**

Industry Apple Surface Study *E. coli* (Ct 1.0)

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**Stephanie L. Rogers, et al, Journal of Food Protection, Vol. 67, No. 4, 2004, Pages 721–731**

A Comparison of Different Chemical Sanitizers for Inactivating *Escherichia coli* O157:H7 and *Listeria monocytogenes* in Solution and on Apples, Lettuce, Strawberries, and Cantaloupe

Log reduction time (LRT): time (in seconds) required to reduce bacterial populations by log 1 at 21-23°C

| Treatment | *E. coli* O157:H7 | *L. monocytogenes* |
|---|---|---|
| Peracetic acid (80 ppm) | 65 ± 0.21 | 70 ± 0.17 |
| CTP (100 ppm chlorine) | 31 ± 0.13 | 35 ± 0.32 |
| CTP (200 ppm chlorine) | 22 ± 0.19 | 27 ± 0.18 |
| Chlorine dioxide (3 ppm) | 24 ± 0.20 | 25 ±0.21 |
| Chlorine dioxide (5 ppm) | 18 ± 0.31 | 19 ± 0.24 |
| Ozone (3 ppm) | 16 ± 0.31 | 15 ± 0.26 |

Ozone (3 ppm) was extremely effective against *L. monocytogenes* and *E. coli* O157:H7 on produce. Kim et al. *(22)* also found 1.3 ppm ozone to be highly effective on fresh lettuce, with mesophilic bacteria decreasing > 4 log after a 5-min exposure. (22) Kim, J., A. E. Yousef, and G. W. Chism. 1999. Use of ozone to inactivate microorganisms on lettuce. *J. Food Safety* 19:17–34.

**Aqueous model system studies.** Peroxyacetic acid (80 ppm) had the highest LRT (65 and 70 s), while chlorine dioxide (5 ppm) and ozone (3 ppm), which were not significantly different from each other, had the lowest LRT (15 to 19 s), respectively, for *E. coli* O157:H7 and *L. monocytogenes*. LRT values for CTP (200 ppm chlorine) and chlorine dioxide (3 ppm) (22 to 27 s) were significantly higher than those for chlorine dioxide (5 ppm) and ozone (3 ppm) for both *E. coli* O157:H7 and *L. monocytogenes*.

**Produce inoculation studies.** Chlorine dioxide (5 ppm) and ozone (3 ppm) were not significantly different from each other and had the lowest LRT (22 to 96 s), while peroxyacetic acid had the highest LRT for *L. monocytogenes* on all produce types (79 to 131 s). CTP (200 ppm chlorine) and chlorine dioxide (3 ppm) were not significantly different from each other and had similar LRT values (30 to 100 s), regardless of produce type. CTP (100 ppm chlorine) was significantly different from all other treatments on whole apples, sliced apples, and whole lettuce, but LRT values (41 to 118 s) were significantly lower than those for peroxyacetic acid. LRT values (39 to 60 s) for shredded lettuce, strawberries, and cantaloupe treated with CTP (100 ppm chlorine) were not significantly different from those treated with CTP (200 ppm chlorine). Treatment of shredded lettuce with CTP (100 and 200 ppm chlorine), chlorine dioxide (3 and 5 ppm), and ozone (3 ppm) yielded LRT values that were not significantly different from each other (96 to 104 s).

In conclusion, the results of this study indicate that peracetic acid (80 ppm), CTP (100 and 200 ppm chlorine), chlorine dioxide (3 and 5 ppm), and ozone (3 ppm) effectively decreased the numbers of *E. coli* O157:H7 and *L. monocytogenes* on fresh produce. Chlorine dioxide (3 and 5 ppm) and ozone (3 ppm) were more effective against *E. coli* O157:H7 and *L. monocytogenes* compared with the other sanitizers.

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**Laszlo Varga, et al, International Journal of Dairy Technology, Vol 69 May 2016**

Use of ozone in the dairy industry: A review

Summary

Ozone treatment is a cost-effective and eco-friendly food-processing technology. It has successfully been used for the removal of milk residues and biofilm-forming bacteria from stainless steel surfaces and in milk processing, including fluid milk, powdered milk products and cheese. Ozonation has been shown to prevent mould growth on cheese and inactivate airborne moulds in cheese ripening and storage facilities. Ozone treatment has also been found to be a promising method for reducing the concentrations of pollutants in dairy wastewaters

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**K.L. Bialka And A. Demirci Journal of Food Science—Vol. 72, Nr. 9, 2007**

Decontamination of *Escherichia coli* O157:H7 and *Salmonella enterica* on Blueberries Using Ozone and Pulsed UV-Light

The results of this study indicate that both ozone and pulsed UV-light have a potential to be used as a method of decontaminating blueberries. Maximum reductions after treatment with gaseous ozone were 3.0 and 2.2 log10 CFU/g of *Salmonella* and *E. coli* O157:H7, respectively. The maximum reductions achieved after treatment with aqueous ozone were 5.2 and 6.2 log10 CFU/g of *E. coli* O157:H7 and *Salmonella*, respectively. Furthermore, sensory analysis failed to detect a significant difference in the gaseous ozone, aqueous ozone or pulsed UV-light treated compared with untreated blueberries.

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**Mi Young Lim, Ju-Mi Kim, Jung Eun Lee, And GwangPyo Ko, Applied and Environmental Microbiology—Feb. 2010, p. 1120-1124**

*Characterization of Ozone Disinfection of Murine Norovirus*

The efficacy of ozone against human norovirus was determined using murine norovirus (MNV) as a surrogate. Under all conditions, more than 99% of MNV was inactivated by ozone at 1.0 mg/L within two minutes.

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**James B. Hudson, Manju Sharma, And Selvarani Vimalanathan, Ozone Science & Engineering—31, 216-223**

*Development of a Practical Method for Using Ozone Gas as a Virus Decontaminating Agent*

The following 12 viruses were used: influenza strain H3N2, herpes simplex virus type 1 rhinovirus types 1A and 14, Adenovirus types 3 and 11, mouse coronavirus, Sindbis virus, yellow fever virus, vesicular stomatitis virus, poliovirus, and vaccinia virus. All 12 viruses tested, on different hard and porous surfaces, and in the presence of biological fluids, could be inactivated by at least 99.9% in the laboratory and in simulated field trials. Ozone dose was 25 parts per million for 25 minutes [(Concentration X Time = 625)].

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**Jennifer L. Cannon, Grishma Kotwal, And Qing Wang, Ozone Science & Engineering—35, 217-219**

*Inactivation of Norovirus Surrogates after Exposure to Atmospheric Ozone*

Surface disinfection of norovirus surrogates, feline calicivirus and murine norovirus by 20 parts per million atmospheric ozone for 18 minutes exposure [(Concentration X Time = 360)] resulted 99.999% inactivation.

## REFERENCES

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Von Sonntag, C. & von Gunten, U. (2013). *Chemistry of Ozone in Water and Wastewater Treatment.* London, UK: IWA Publishing.

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https://www.fsis.usda.gov/

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https://www.osha.gov/

## ABOUT THE AUTHOR

Beth Hamil has over 40 years' professional experience in ozone system development, ozone applications, ozone consulting (including applications engineering), and project management, spanning a comprehensive range of commercial industries including, aquatics, food safety applications (commercial and food service), wineries, pharmaceutical and industrial uses. She is highly experienced and very adept with regulatory compliance responsibilities for the use of ozone, while staying up-to-date with emerging governmental compliance developments. Her ongoing focus continues to be developing parameters for ozone efficacy and worker/environmental safety for a broad range of applications. Visit www.bethhamilo3consulting.com for more information.

## EDITORIAL CONTRIBUTIONS

Matt Lowe has a Bachelor of Science degree from the University of California, San Diego in biochemistry with a focus in microbiology. Matt has worked in the ozone industry since 1999 in application research & development, product development, system integration and service, in multiple segments of the food and beverage industries. Matt helped develop current best practices for aqueous ozone system design to safely and effectively produce and distribute high concentrations of ozone to multiple applications. Matt has worked for two leading ozone system manufacturers in business development, marketing, and system integration roles. Matt was actively involved in early government regulatory agencies including FDA, USDA, EPA, and NSF to broaden the approvals of ozone for hard surface and direct product antimicrobial treatment.

# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 212 |
| Committee: | MMSR/ Hauling |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

Clarify that that individual maintaining, operating, cleaning and sanitizing an aseptic in-line sampler does not need to be a licensed bulk milk hauler/sampler.

The person collecting, identifying, handling and storing the milk sample does need to be a licensed bulk milk hauler/sampler.

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

The maintenance, operation, cleaning and sanitizing of aseptic in-line samplers most frequently falls to on farm personnel – the same people responsible for maintaining, operating, cleaning and sanitizing all the equipment used to collect and store milk on the farm. These personnel are trained in the standard operating procedures of the farm and should not need to be additionally licensed as bulk milk hauler/samplers unless they are collecting, identifying, handling and storing the milk samples.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 142-143 | **2023 PMO**<br>***Section(s):***<br>***Appendix: B*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:
Pages 142-143

**II. REQUIREMENTS FOR USING AN ASEPTIC APPROVED IN-LINE SAMPLER**
**(For informational purposes only: Refer to M-I-06-6)**

A protocol for utilizing an in-line sampler system shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. A copy of the approved aseptic in-line sampling system's SOP shall be on file and posted for use at the location where the sampling system is utilized. As a minimum, the protocol (SOP) shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
2. A description of the means used to refrigerate the sample collection device and milk sample collection container throughout the milk sample collection period.
3. A means to monitor milk sample temperature, and the milk temperature.
4. A description of how and when the sampler is to be cleaned and sanitized, if not of a single use design.
5. A listing of the licensed bulk milk hauler/samplers who have been trained to ~~maintain, operate, clean and sanitize the sample collection device as well as to~~ collect, identify, handle and store the milk sample.
6. A description of the method and means that will be used to determine weight of the milk on the milk tank truck.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 213 | |
| Committee: | Hauling | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal updates NCIMS Form 2399b and Appendix B, Section VIII.

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

The Hauling Procedures Committee has reviewed the NCIMS 2399b Form and proposes two updates that will address On-Tanker sample systems for farm pickup and the definition of the exterior condition of the tank as defined in Appendix B. Additional Samples and Sampling Equipment item added to reflect the proposed change on the form.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 146 | **2023 PMO**<br>***Section(s):*** **VIII**<br>***Appendix:*** **B** | | **2023 EML** |
| | **2023 MMSR** | NCIMS 2399b | **Forms**<br>***Form Number: NCIMS 2399b*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

**MILK TANK TRUCK STANDARDS:** All Items of FORM NCIMS 2399b-MILK TANK TRUCK INSPECTION REPORT fall into the categories of "Compliance", "Non-Compliance" or "Not Applicable" (NA) as determined during the inspection. The following Items relate to FORM NCIMS 2399b: (Refer to Appendix M. of this *Ordinance*.)

1. **Samples and Sampling Equipment:** (When provided)
   a. Sample containers shall be stored to preclude contamination.
   b. The sample box shall be in good repair and kept clean.
   c. Sample transfer instrument shall be cleaned and sanitized to ensure that proper samples are collected.
   d. The properly constructed sample transfer instrument container (refer to Item 9r) is provided and adequate means for maintaining sanitizer solutions is on hand.
   e. The samples are properly stored to preclude contamination.
   f. The sample storage compartment shall be clean.
   g. Samples are maintained at an acceptable temperature 0°C-4.5°C (32°F-40°F) and a temperature control sample is provided.
   h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.
   <u>i. A copy of the approved on-tanker farm bulk milk tank aseptic sampler SOP shall be on file on tanker when applicable.</u>

**National Conference on Interstate Milk Shipments**

# MILK TANK TRUCK INSPECTION REPORT

| | |
|---|---|
| TANKER SERIAL NO. | |
| TANKER PERMIT NO. | |
| STATE ISSUING PERMIT | |
| MILK TANK TRUCK OWNER | SAMPLER'S PERMIT NO. |
| ADDRESS OF OWNER | DRIVER DELIVERS TO |
| NAME OF OPERATOR / DRIVER | NAME AND ADDRESS OF INSPECTION LOCATION |
| ADDRESS OF DRIVER | |

***An inspection of your milk tank truck showed violations existing in the items checked below in the non-compliance column. You are further notified that this inspection report serves as notification of the intent to suspend this milk tank truck's permit if the violations are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)***

| | Compliance | Non-Compliance | N/A |
|---|---|---|---|
| **1. SAMPLES AND SAMPLING EQUIPMENT (PMO, Appendix B)** | | | |
| a. Storage of Sample Containers | | | |
| b. Sample Box in Good Repair; Clean | | | |
| c. Sample Transfer Instrument | | | |
| d. Sampling Transfer Instrument Container | | | |
| e. Sample Storage | | | |
| f. Sample Storage Compartments | | | |
| g. Samples 0°C - 4.4°C (32°F - 40°F), Temperature Control | | | |
| h. Approved Thermometer Available | | | |
| i. SOP available for on-tanker aseptic sample system for farm pickup | | | |
| **2. PRODUCT TEMPERATURE 7°C (45°F) OR LESS (PMO, Section 7, Items 18r and 17p)** | | | |
| a. Temperature of Product in Tank | | | |
| b. Product in External Fluid Transfer Systems that Exceeds 7°C (45°F) is Discarded | | | |
| **3. EQUIPMENT CONSTRUCTION, CLEANING, SANITIZING AND REPAIR (PMO, Section 7, Items 10p, 11p and 12p)** | | | |
| a. Dome Lid Assembly | | | |
| b. Gasket(s) | | | |
| c. Vent(s) | | | |
| d. Pump(s) | | | |
| e. Hose(s) | | | |
| f. Hose Connection(s) | | | |
| g. Hose(s) more than 8 Ft in Length Mechanically Cleaned | | | |
| h. Valve(s) | | | |
| i. Protection from Contamination | | | |
| j. Interior Condition of Tank | | | |
| k. Aseptic Sampler | | | |
| l. Other *(Specify)* | | | |

| | Compliance | Non-Compliance | N/A |
|---|---|---|---|
| **4. EXTERIOR CONDITION OF TANK (PMO, Appendix B)** The exterior of the milk tank truck is properly constructed and in good repair. | | | |
| **5. CLEANING/ SANITIZING RECORD (PMO, Section 7, Item 12p)** | | | |
| a. Is Recording Chart Available? | | | |
| b. Is Cleaning /Sanitizing Tag Available? | | | |
| 1. Recording Chart Available for Cross-Reference? | | | |
| 2. Attached to Tanker? | | | |
| 3. Date of Last Cleaning /Sanitizing (PMO, Appendix B) | | | |
| 4. Properly Completed (PMO, Appendix B) | | | |
| **6. LOCATION OF LAST CLEANING/SANITIZING** | | | |
| **7. LABELING** | | | |
| **8. VEHICLE AND MILK TANK TRUCK PROPERLY IDENTIFIED** | | | |
| **9. PREVIOUS INSPECTION SHEET OR AFFIXED LABEL AVAILABLE** | | | |
| **10. SAMPLE CHAIN-OF-CUSTODY** | | | |

REMARKS *(If additional space is required, please place information on a separate page.)*

| | |
|---|---|
| SANITARIAN | DATE |
| AGENCY | |

FORM NCIMS 2359b (10/25 23)

**MILK TANK TRUCK INSPECTION REPORT**

*REMARKS (Continued)*

| | | | |
|---|---|---|---|
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| Agency/Organization: | Hauling Procedures Committee | | |
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**National Conference on Interstate Milk Shipments**

# MILK TANK TRUCK INSPECTION REPORT

| | |
|---|---|
| TANKER SERIAL NO. | |
| TANKER PERMIT NO. | |
| STATE ISSUING PERMIT | |

| | |
|---|---|
| MILK TANK TRUCK OWNER | SAMPLER'S PERMIT NO. |
| ADDRESS OF OWNER | DRIVER DELIVERS TO |
| NAME OF OPERATOR / DRIVER | NAME AND ADDRESS OF INSPECTION LOCATION |
| ADDRESS OF DRIVER | |

***An inspection of your milk tank truck showed violations existing in the Items checked below in the non-compliance column. You are further notified that this inspection report serves as notification of the intent to suspend this milk tank truck's permit if the violations are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)***

| | Com-pliance | Non-Com-pliance | N/A |
|---|---|---|---|
| **1. SAMPLES AND SAMPLING EQUIPMENT (PMO, Appendix B)** | | | |
| a. Storage of Sample Containers | ☐ | ☐ | ☐ |
| b. Sample Box in Good Repair; Clean | ☐ | ☐ | ☐ |
| c. Sample Transfer Instrument | ☐ | ☐ | ☐ |
| d. Sampling Transfer Instrument Container | ☐ | ☐ | ☐ |
| e. Sample Storage | ☐ | ☐ | ☐ |
| f. Sample Storage Compartments | ☐ | ☐ | ☐ |
| g. Samples 0°C - 4.4°C (32°F - 40°F), Temperature Control | ☐ | ☐ | ☐ |
| h. Approved Thermometer Available | ☐ | ☐ | ☐ |
| i. SOP available for on-tanker aseptic sample system for farm pickup | ☐ | ☐ | ☐ |
| **2. PRODUCT TEMPERATURE 7°C (45°F) OR LESS (PMO, Section 7, Items 18r and 17p)** | | | |
| a. Temperature of Product in Tank | ☐ | ☐ | ☐ |
| b. Product in External Fluid Transfer Systems that Exceeds 7°C (45°F) is Discarded | ☐ | ☐ | ☐ |
| **3. EQUIPMENT CONSTRUCTION, CLEANING, SANITIZING AND REPAIR (PMO, Section 7, Items 10p, 11p and 12p)** | | | |
| a. Dome Lid Assembly | ☐ | ☐ | ☐ |
| b. Gasket(s) | ☐ | ☐ | ☐ |
| c. Vent(s) | ☐ | ☐ | ☐ |
| d. Pump(s) | ☐ | ☐ | ☐ |
| e. Hose(s) | ☐ | ☐ | ☐ |
| f. Hose Connection(s) | ☐ | ☐ | ☐ |
| g. Hose(s) more than 8 Ft in Length Mechanically Cleaned | ☐ | ☐ | ☐ |
| h. Valve(s) | ☐ | ☐ | ☐ |
| i. Protection from Contamination | ☐ | ☐ | ☐ |
| j. Interior Condition of Tank | ☐ | ☐ | ☐ |
| k. Aseptic Sampler | ☐ | ☐ | ☐ |
| l. Other *(Specify)* | ☐ | ☐ | ☐ |

| | Com-pliance | Non-Com-pliance | N/A |
|---|---|---|---|
| **4. EXTERIOR CONDITION OF TANK (PMO, Appendix B)** The exterior of the milk tank truck is properly constructed and in good repair. | ☐ | ☐ | ☐ |
| **5. CLEANING/ SANITIZING RECORD (PMO, Section 7, Item 12p)** | | | |
| a. Is Recording Chart Available? | ☐ | ☐ | ☐ |
| b. Is Cleaning /Sanitizing Tag Available? | ☐ | ☐ | ☐ |
| 1. Recording Chart Available for Cross-Reference? | ☐ | ☐ | ☐ |
| 2. Attached to Tanker? | ☐ | ☐ | ☐ |
| 3. Date of Last Cleaning /Sanitizing (PMO, Appendix B) | ☐ | ☐ | ☐ |
| 4. Properly Completed (PMO, Appendix B) | ☐ | ☐ | ☐ |
| **6. LOCATION OF LAST CLEANING/SANITIZING** | | | |
| **7. LABELING** | ☐ | ☐ | ☐ |
| **8. VEHICLE AND MILK TANK TRUCK PROPERLY IDENTIFIED** | ☐ | ☐ | ☐ |
| **9. PREVIOUS INSPECTION SHEET OR AFFIXED LABEL AVAILABLE** | ☐ | ☐ | ☐ |
| **10. SAMPLE CHAIN-OF-CUSTODY** | ☐ | ☐ | ☐ |

REMARKS *(If additional space is required, please place information on a separate page.)*

| | |
|---|---|
| SANITARIAN | DATE |
| AGENCY | |

**FORM NCIMS 2399b (10/25 ~~23~~)**

## MILK TANK TRUCK INSPECTION REPORT

REMARKS *(Continued)*

# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 214 |
| Committee: | Hauling |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal would add a Note to the Wash and Sanitize Record requirements under Appendix B of the PMO to provide a Regulatory Agency clear flexibility to exclude a milk tank truck cleaning facility operated on a dairy farm included in a valid IMS-listed BTU from the requirement to submit a list of permitted "non-IMS" listed milk tank truck cleaning facilities for publication on the NCIMS web site.

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

The Wash and Sanitize Record requirements under Section VIII of Appendix B currently require state Regulatory Agencies to submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities for purposes of publishing on the NCIMS web site. However, it is unclear if a milk tank truck cleaning facility located and operated on the premises of a permitted and inspected Grade "A" dairy farm that is officially part of an IMS-listed BTU can be appropriately considered "non-IMS listed" and subject to the web site publication requirements.

Many dairy farms across the country utilize milk tank trucks for direct loading of milk in lieu of a conventional fixed bulk milk tank in a milkhouse. These milk tank trucks used by a

producer to transport their own milk are in some cases cleaned by using truck cleaning facilities located on their own dairy farm. As a Grade "A" dairy farm, the operation is already

assigned a unique permit by the Regulatory Agency and is associated with a formal BTU designation which accompanies the load to a processor in addition to a properly completed wash and sanitize tag clearly identifying the specific location of the last cleaning. With such clear Grade "A" related identifiers on the milk tank truck, an extra step of public posting on a "non-IMS" list is unnecessary, contradictory, and creates potential security risks.

Strengthening security on dairy farms is an important and shared objective of FDA, the states, and industry. Identifying milk tank truck cleaning facilities located on dairy farm premises via a public web site raises security concerns and runs counter to the broader national objectives to harden the production sector against potential threats. States should have the flexibility to evaluate both the benefits and risks of such listings and implement procedures that are most appropriate for their industry. Additionally, regulatory requirements associated with milk tank truck cleaning facilities should be supportive of on-farm locations and use, as avoiding milk tank truck choke points for multiple trucks from diverse operations can have obvious biosecurity benefits. Furthermore, processors rejecting milk tankers of known permitted Grade "A" BTU-listed origins based solely on absence from a web site can also cause unwarranted disruption and costs to the industry. The applicability of the "non-IMS" listed reporting requirement to facilities on a Grade "A" dairy farm is also unclear and causes confusion with respect to compliance. This proposal would make clear that a permitted milk tank truck cleaning facility located on the premises of a permitted, BTU-listed Grade "A" dairy farm may be excluded from the "non-IMS listed" reporting and web publication requirements if deemed appropriate by the Regulatory Agency. The "may" instead of "shall" in the Note allows for each Regulatory Agency to implement practices that best serve their state.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Page 148 | **2023 PMO**<br>***Section(s):***<br>***Appendix: B*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

*PMO, Appendix B (Page 148)*

5. **Wash and Sanitize Record:**

a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

**NOTE:** The option to use non-IMS listed milk tank truck cleaning facilities, as cited in a. above, shall not be applicable to a TPC authorized under the ICP.

b. A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than fifteen (15) days.
c. The following information shall be recorded on the cleaning and sanitization tag: (1) Identification of the milk tank truck.
(2) Date and time (optionally, in military time (24 hour clock)) of day the milk tank truck was cleaned and sanitized.
(3) Location where the milk tank truck was cleaned and sanitized.
(4) Signature(s) or initials of the person(s) who cleaned all appurtenances and sanitized the milk tank truck.
d. The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of the bulk milk hauler/sampler or the milk tank truck operator.
e. States shall submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS web site.

NOTE: Milk tank truck cleaning facilities operated by a producer on the premises of a permitted Grade "A" dairy farm that is part of a valid IMS-listed BTU may be excluded by the Regulatory Agency from the requirements of item 5e. above.

The changes described in this proposal would become effective on the date of official FDA concurrence of Conference proposals communicated to the NCIMS Executive Board.


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 215 | |
| Committee: | Lab<br>Single Service | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

Make corrections to the PMO to update the term "officially designated lab" according to the Environmental Protection Agency (EPA) definition.

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

Update the term "officially designated lab" according to the Code of Federal Regulations.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 341 | **2023 PMO**<br>***Section(s):*** **d.7.c.**<br>***Appendix:*** J | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; at least once every twelve (12) month period thereafter; and when any repair or alteration for the individual water supply system has been made. The examination of the sample shall be conducted ~~in an Officially Designated Laboratory~~ by a laboratory certified by EPA or the State (40 CFR § 141.28).


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 216 |
| Committee: | App. N |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

Provide for producer traceback on single farm loads.

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

The current language in Appendix N repeatedly states that "Producer traceback is not required when a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be Confirmed Positive for drug residues using NCIMS Accepted Drug Residue Test Methods or Verified Screening Positive for drug residues using test methods not evaluated by FDA and not accepted by the NCIMS** is from a single producer, since the farm of origin has already been determined."

This language assumes the only impact on the quality and safety of the milk in the farm bulk milk tank, etc is the farm of origin. In reality, other factors also influence the quality and safety of the milk on the truck including the wash status of the truck – was another load of milk hauled previous to the one requiring traceback? Was the truck adequately drained and washed?

Not providing for producer traceback on confirmed positive samples leaves the marketer, sampler and tester of the milk open to legal challenge because it was not truly confirmed that the producer was the responsible party.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 363, 366, 376, 377 | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** *N* | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

Pages 363-364

~~Producer traceback is not required when a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be Confirmed Positive for drug residues using NCIMS Accepted Drug Residue Test Methods or Verified Screening Positive for drug residues using test methods not evaluated by FDA and not accepted by the NCIMS** is from a single producer, since the farm of origin has already been determined.~~

Page 366

(2) Producer trace back is not required:
~~i) 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 Confirmed Positive for drug residues using NCIMS Accepted Drug Residue Test Methods is from a single producer, since test methods, the farm of origin has already been determined. The positive producer shall be handled in accordance with Section III and VI. Options 1 and 2 of this Appendix.~~

~~ii) 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 not accepted by the NCIMS** without additional confirmation required is from a single producer, since the farm of origin has already been determined. The Verified Screening Positive producer shall be handled in accordance with Section VI. Option 3 of this Appendix.~~

Page 376

~~NOTE: Producer traceback is not required when the AGARMS sample that is found to be Confirmed Positive for drug residues using NCIMS Accepted Drug Residue Test Methods is from a single producer, since the farm of origin has already been determined.~~

Page 377 – strike through note in flow chart

Note: Producer trace back is not required when the AGARMS sample that is found to be Confirmed Positive for drug residues using NCIMS Accepted Drug Residue Test Methods is from a single producer since the farm of origin has already been determined.


| | | | |
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 217 | |
| Committee: | App. N | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

To provide clarifying guidance to existing language in the PMO Appendix N. on when states should report results to other states.

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

To stress the importance of notifying a Regulatory Agency without delay when the farm of origin is in a different state from where the testing was done.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 364 | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

PMO, Appendix N. Section II, page 364:

**II. REGULATORY AGENCY RESPONSIBILITIES NOTIFICATIONS:**

Upon receipt of notification from industry that a sample of AGARMS, which contains milk from another Regulatory Agency's jurisdiction has been found to be Presumptive Positive for drug residues using NCIMS Accepted Drug Residue Test Methods or Verified Screening Positive for drug residues using test methods not evaluated by FDA and not accepted by the NCIMS**, it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from the state in which the milk originated without delay.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 218 |
| Committee: | App. N |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal clarifies language pertaining to drug residue test methods for non-beta-lactams.

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

To make the language in Appendix N. Sections I. and VI. pertaining to drug residue test methods for non-beta lactams consistent with the Section VI flow chart.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 364, 379 | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

PMO, Appendix N. Section I, page 364:

~~** One (1) year after two (2) drug residue test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, Option one (1) or two (2) in Section VI of this Appendix shall be used for confirmation.~~

**When there are no NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, only Option 1 or 3 in Section VI of this Appendix shall be used.

When only one NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, Options 1, 2, or 3 in Section VI of this Appendix may be used.

After two or more NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, Options 1, 2, or 3 in Section VI of this Appendix may be used for an additional period of one year. The additional period of one year begins upon the effective date of the M-I associated with the FDA evaluation and NCIMS acceptance of the second test method. At the end of one year (365 days), only Options 1 or 2 shall be used. Option 3 shall no longer be used.

PMO, Appendix N. Section VI, page 379:

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

When there are no NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, only Option 1 or 3 below shall be used.

When only one NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, Options 1, 2, or 3 below may be used.

After two or more NCIMS Accepted Drug Residue Test Methods for detecting a particular non-beta-lactam drug or drug family, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, Options 1, 2, or 3 below may be used for an additional period of one year. The additional period of one year begins upon the effective date of the M-I associated with the FDA evaluation and NCIMS acceptance of the second test method. At the end of one year (365 days), only Options 1 or 2 shall be used. Option 3 shall no longer be used.


| | | | |
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 219 | |
| Committee: | App. N | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

Provide clarifying language to existing language in the PMO Appendix N. Section II.

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

To add two questions to the review of the Appendix N. Industry Monitoring and Surveillance Program.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 365 | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

PMO, Appendix N. Section II, page 365:

A review of the Industry Monitoring and Surveillance Program shall include, but not be limited to, the following:

1. Is the industry program an appropriate routine monitoring program for the detection of drug residues?
2. Is the industry program screening all incoming raw milk supplies at receiving locations for drug residues in accordance with Sections I and III of this Appendix?
3. Is the industry utilizing certified or approved analysts for screening for drug residues per Section III of this Appendix?
~~2.~~ 3. Is the industry program utilizing appropriate drug residue test methods per Sections III and VI of this Appendix?
~~3.~~ 4. Is each producer's milk represented in the industry testing program for drug residues and tested at the frequency prescribed in Section I. of this Appendix?
~~4.~~ 5. Is the industry program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the violative AGARMS and of the trace back to the farm of origin as specified in Section I?
~~5.~~ 6. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended or discontinued until subsequent testing, using the same or equivalent (M-I-96-10, latest revision)

drug residue test method that was used when the producer was initially found to be violative, establishes the milk is no longer positive for drug residues?

| | | | |
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 220 |
| Committee: | App. N |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal clarifies language pertaining to testing requirements for AGARMS (All Grade "A" Raw Milk Supplies) samples.

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

To make language in Appendix N Section III clear on the requirements for testing AGARMS samples.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 370-371 | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** N | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

PMO, Appendix N. Section III, page 370-371:

**REQUIREMENTS FOR TESTING:**
**Procedures Necessary to Complete Prior to Testing:** Before any AGARMS samples are tested, all required equipment and drug residue test method verification must be completed. Refer to the applicable NCIMS 2400 forms for additional information.
**1. Testing Facility**: Location evaluated by an LEO and found acceptable following the criteria specified in the NCIMS General Requirements 2400 form (2400-n). This may be a PMO Section 6 or PMO Appendix N CIS accredited Officially Designated Laboratory or a PMO Appendix N approved Officially Designated Screening Facility.
**2. Testing Personnel:** Individuals evaluated by an LEO to perform an NCIMS Accepted drug test method following the criteria specified in the NCIMS 2400 form for the method used. For accredited Officially Designated Laboratories personnel are certified (PMO Section 6 and CIS) and for approved screening facilities personnel are approved.
**3. Test Methods:** All testing must be completed using an NCIMS Accepted Drug Test Method. NCIMS Accepted test methods are listed in M-a-85 (latest Revision). Issuance of an M-I indicating NCIMS acceptance of a method(s) is considered recognition of the method meeting M-a-85 requirements regardless of whether the current M-a-85 list includes that method(s). All NCIMS Accepted tests must be used in compliance with the NCIMS General Requirements 2400 form (2400n) and applicable NCIMS 2400 form for the test method used.

~~1.~~ **4. Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.
~~2.~~ **5. Positive Controls**
All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.

(1) For NCIMS Accepted Drug Residue Test Methods that only detect penicillin, ampicillin, amoxicillin and cephapirin, the positive (+) control is penicillin @ 5 ± 0.5 ppb.
(2) For NCIMS Accepted Drug Residue Test Methods that detect cloxacillin, the positive (+) control may be cloxacillin @ 10 ± 1 ppb.
(3) For NCIMS Accepted Drug Residue Test Methods for one (1) drug residue only, the positive (+) control is ± 10% of the target testing level/tolerance of the drug residue detected.

**~~3.~~ 6. Work Area:**

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

**~~4.~~ 7. Test Kit Thermometers:**

a. Thermometer traceable to a NIST Certified Thermometer.
b. Graduation interval not greater than 1°C.
c. Dial thermometers are not used to determine the temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.

**~~5.~~ 8. Refrigeration:**

a. Test kit reagent storage temperature specified by manufacturer.

**~~6.~~ 9. Balance (Electronic):**

a. 0.01 g for preparation of positive (+) controls.
b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the LEO.

**~~7.~~ 10. Screening Test Method Sampling Requirements:**

a. Temperature of milk in the AGARMS determined and recorded.
b. Representative AGARMS sample for drug residue testing collected,
c. Samples tested within seventy-two (72) hours of collection.

**~~8.~~ 11. Screening Test Method Volumetric Measuring Devices:**

a. Single use devices provided by kit manufacturers are acceptable for Appendix N. screening analysis.
b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the LEO.
371
c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N. screening.

**~~9.~~ 12. 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 NCIMS Accepted Drug Residue Test Method, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is Confirmed Positive using an NCIMS Accepted Drug Residue Test Method, 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.

**~~10.~~ 13. 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 NCIMS Accepted Drug Residue Test Method, 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 NCIMS Accepted Drug

Residue Test Method, 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.


| | | | |
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 221 | |
| Committee: | Scientific | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal seeks to make modifications in wording for Appendix R, Determination of Time/Temperature Control for Safety Milk and/or Milk Products within the "Instruction for Using Tables A and B" section. The changes in wording will help clarify the process of determination.

This proposal also seeks to restructure the decision tree to help streamline and clarify the process for determining the necessity of a time/temperature control for the safety of milk and/or milk products. Specifically, it seeks to remove redundancy and make it follow the intended process more closely.

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

The decision tree should be effective in steering the user to navigate the framework to determine if time/temperature is required for safety for milk or milk product(s). The general flow of information per the 2001, IFT publication is based upon two questions: is the food treated to neutralize vegetative pathogens and is the food packaged to prevent recontamination? A "yes" to both directs you to Table A. A "no" to either or both directs you to Table B. In the context of milk and/or milk products, "treatment" is considered the pasteurization of milk and/or milk products as prescribed within the PMO or a "treatment" equivalent to pasteurization with documentation acceptable to FDA. In the current flow

diagram, if milk and/or milk product is treated with a method deemed equivalent to pasteurization, the user is not directed to ask the second question regarding immediate

packaging to prevent recontamination. Additionally, the current flow diagram tells you to place your product within the appropriate table using $a_w$ and/or pH values without telling you the specific table to use given the answers to the questions posed.

This proposal seeks to improve this flow.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| 404 - 406 | **2023 PMO**<br>***Section(s):*** **N/A**<br>***Appendix:*** *R* | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

2023 PMO, Appendix R, Pages 404 – 406:

Page 404

**INSTRUCTION FOR USING TABLES A AND B**

1. Does the operator want to hold the milk and/or milk product without using time or temperature control?
   a. No: Continue holding the milk and/or milk product at 7°C (45°F) or less as required in the *Grade "A" PMO*.
   b. Yes: Continue using the decision tree to identify which table to use to determine whether TCS is required.
2. Is the milk and/or milk product pasteurized?
   a. No: The milk and/or milk product is either raw or heat-treated. Proceed to Step #3.
   b. Yes: The milk and/or milk product is pasteurized to the required minimum time and temperature for the milk and/or milk product as specified in the definition of Pasteurization of this *Ordinance*. Proceed to Step #~~4.~~5.
3. Is the milk and/or milk product treated using some other method equivalent to pasteurization?
   a. No: The milk and/or milk product is raw or heat-treated, which may allow vegetative cells and spores to survive. Use Table B and ~~Proceed~~ proceed to Step #6.

b. Yes: If another method equivalent to pasteurization is used to destroy pathogens; such as, irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, etc.,

Page 405

the new technology shall have been recognized by FDA as providing milk and/or milk product safety equal to pasteurization, and the effectiveness of the process shall be demonstrated by sufficient evidence or other means. Proceed to Step #~~5.~~4.

~~4.~~5. Is it packaged to prevent re-contamination?

a. No: Re-contamination of the product by both pathogenic spores and vegetative cells can occur after pasteurization because it is not immediately packaged. Use Table B and ~~Proceed~~ proceed to Step #6~~. and use Table B.~~

b. Yes: If the milk and/or milk product is packaged immediately after pasteurization to prevent recontamination, higher ranges of $a_w$ and/or pH can be tolerated because spore-forming bacteria are the only microbial hazard. Use Table A and ~~Proceed~~proceed to Step #6~~. and use Table A.~~

~~5.~~4. Further PA or plant documentation required.

a. The manufacturer of this product may be able to supply evidence acceptable to FDA that indicate the milk and/or milk product can be safely held without TCS.

b. Milk and/or milk products prepared or processed using new technologies may be held without time/temperature control provided the new technology has been recognized by FDA as providing milk or milk product safety equal to pasteurization and provided the effectiveness of the use of such technologies is based on evidence accepted by FDA.

6. Using the milk and/or milk product's processing parameters, known $a_w$ and/or pH values, position the milk or milk product in the appropriate table.

a. Choose the column under "pH Values" that contains the pH value of the milk and/or milk product in question.

b. Choose the row under "$a_w$ Values" that contains the $a_w$ value of the milk and/or milk product in question.

c. Note where the row and column intersect to identify whether the milk and/or milk product is Non-TCS and therefore does not require time/temperature control, or whether further PA is required. Other factors; such as, redox potential, competitive microorganisms, salt content or processing methods, may allow the product to be held without time/temperature control; however, evidence acceptable to FDA is required.

~~7. Use Table B for milk and/or milk products that are not pasteurized or pasteurized but not immediately packaged, where both pathogenic spores and vegetative cells may be a concern or use Table A for milk and/or milk products that are pasteurized and immediately packaged, where only pathogenic spores are of concern.~~

~~8.~~7. Determine if the milk and/or milk product is Non-TCS or needs further PA.

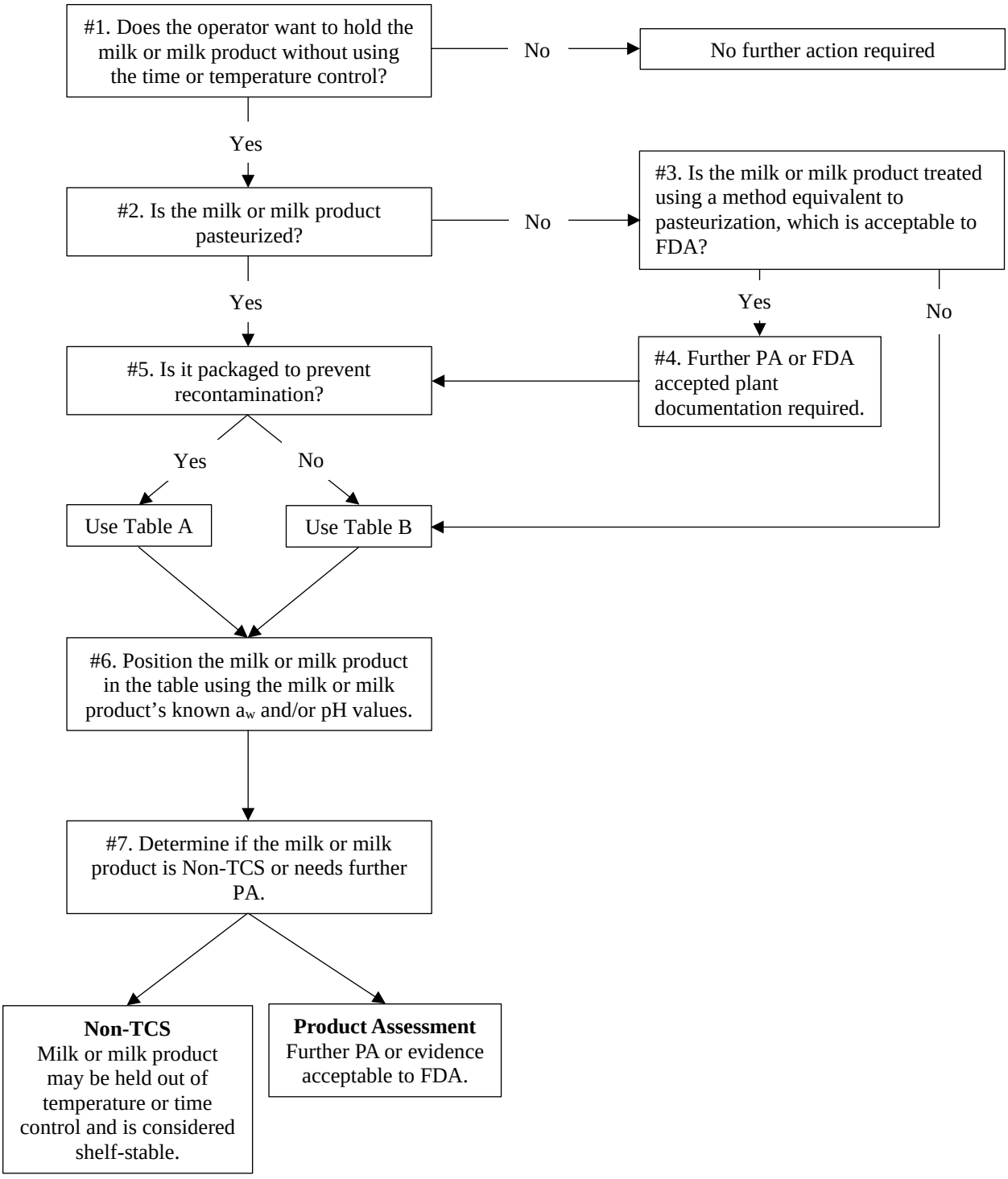


**Figure 70 . Decision Tree for Using pH, $a_w$, or the Interaction of pH and $a_w$ to Determine if a Milk and/or Milk Product Requires Time/Temperature for Safety**

Source Document: Evaluation and Definition of Potentially Hazardous Foods, IFT, 2001 available at https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous- Foods.pdf


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 222 | |
| Committee: | MMSR/ Single Service | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal aims to change the frequency of Single Service Containers &/or Closure Manufacturers ratings from a twelve (12) month frequency to a twenty-four (24) month frequency, while only requiring biannual regulatory inspections.

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

The current requirements found in the Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single Service Containers and/or Closures for Milk and/or Milk Product Manufacturers documents (MMSR) currently requires Single Service Containers &/or Closure Manufacturers either require quarterly inspections and a twenty-four (24) month rating OR a twelve (12) month rating frequency with no inspections required. I am advocating for an alternative option that would decrease the quantities of regulatory inspections and ratings.

The commonwealth of PA has thirty-one (31) Single Service Containers &/or Closure Manufacturers. These facilities require an annual state regulatory inspection as part of the requirements of a state permit. Twenty-five (25) of these facilities have been on an annual rating frequency for years where there has been little concern over regulation compliance. The

facilities that are inspected quarterly have even less concern for regulation compliance. Similar establishments (or even the same establishments) that produce containers for other manufactured foods regulated under 21 CFR 117 are not required to receive any state regulatory inspections.

I would propose the option for a lowered inspection frequency that consists of two (2) regulatory inspections per year that would allow for a twenty-four (24) month IMS listing. Increased regulatory inspections and/or IMS re-listing frequencies would be at the discretion of the RA. This lowered frequency would reduce the number of IMS ratings that need conducted each year and create mild changes to the frequency of inspections for the state regulatory staff.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| Page 40 | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

MMSR, page 40:

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating, certifying and listing single-service containers and/or closures manufacturing plants. Rating and/or Regulatory Agencies shall choose from the following list of criteria for the certification and listing of single-service containers and/or closures manufacturers:

1. Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant may be listed for twenty-four (24) months plus the remaining days of the month, if the single-service containers and/or closures manufacturing plant is inspected at least ~~quarterly~~ biannually, using FORM NCIMS 2359c, and Regulatory Agency's official records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service containers and/or closures manufacturers that operate in conjunction with an NCIMS HACCP IMS listed milk plant may be listed for twenty-four (24) months plus the remaining days of the month in which the rating is due, if the single- service containers and/or

closures manufacturing plant is integrated into the milk plant's NCIMS HACCP System and if the single-service containers and/or closures manufacturing plant is

inspected at the minimum milk plant audit frequency specified in Appendix K. of the *Grade "A " PMO,* using FORM NCIMS, and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single-service containers and/or closures manufacturing areas.

2. Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally IMS listed for twelve (12) months plus the remaining days of the month in which the rating is due.
3. Single-service containers and/or closures manufacturers that operate as a separate entity may be IMS listed for twenty-four (24) months plus the remaining days of the month, if the Regulatory Agency has a permit system and inspects the single-service containers and/or closures manufacturing plant using FORM NCIMS 2359c at least ~~quarterly~~ biannually. All testing of containers, closures and individual water supplies shall be under the direction of the Regulatory Agency and kept on file.
4. Single-service containers and/or closures manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally IMS listed for twelve (12) months plus the remaining days of the month in which the rating is due.

**NOTE:** This criterion is the only option available for use by a SSC when certifying foreign manufacturers of single-service containers and/or closures for milk and/or milk products.

5. Certification of single-service containers and/or closures manufacturing plants may be valid for a period not to exceed one (I) or two (2) years from the earliest certification listing date plus the remaining days of the month, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest certification date plus the remaining days of the month. In the case of a one (1) year certification listing with the earliest certification date of 6/15/2019, the expiration date would be 6/30/2020.


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 223 |
| Committee: | MMSR |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

To place IMS listed retort products within the same product code as aseptic products since there is currently no code assigned for them.

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

There are no product codes for retorted products on the IMS list at this time. Since they are similar to aseptic products due to their FDA filing process and lack of product sampling requirements, they fit best under the same code as aseptic products.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| 53, 82, 88 | **2023 MMSR** | 2359i, M-a-98 | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change: Methods (Pages 53, 82, and 88) 2359i

PRODUCT CODES:
1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream)
2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim
3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream)
4. Pasteurized Half & Half, Coffee Cream, Creams
5. Ultra-Pasteurized (UP) Milk and Milk Products
6. Aseptic or Retort Milk and Milk Products (Including Flavored)
7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd)
8. Cultured or Acidified Milk and Milk Products
9. Yogurt (Including Lowfat or Skim)
10. Sour Cream Products (Acidified or Cultured)


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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 224 |
| Committee: | Lab |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal establishes an NCIMS Study Committee tasked with evaluating the laboratory program, specifically program efficiency.

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

The laboratory program was established in 1950 when the first official NCIMS took place and has become an integral part of assuring the safety of Grade "A" milk products. The requirement for the evaluation of milk laboratories for interstate shipments is outlined in the *Evaluation of Milk Laboratories* (EML) and 2400 laboratory forms. These documents provide detailed guidelines for proficiency testing, certification, and auditing of laboratory personnel and methods, and ensuring that laboratories adhere to the stringent standards required for accurate and reliable testing of milk and milk products. As a result, there is reciprocity between States on acceptance of laboratory results.

This proposal would create a study committee to consider opportunities to make improvements in the NCIMS laboratory program to increase program efficiencies.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

The NCIMS Laboratory Committee and FDA request 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 assigned committee is charged to evaluate the NCIMS laboratory program, specifically program efficiency. In identifying opportunities for greater efficiency, the assigned committee may consider an assessment of the current NCIMS laboratory program to identify opportunities for modernization that include both quality and efficiency enhancements.

The assigned committee will submit a report outlining the findings and recommendations to the NCIMS Executive Board.


Name: Laura Traas and Misty Moriarty-McNutt

Agency/Organization: NCIMS Laboratory Committee and FDA

Address:

City/State/Zip:

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Telephone No.: 301-796-9668 E-mail Address: Misty.Moriarty@fda.hhs.gov

# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 225 | |
| Committee: | Lab- NEW 2400 | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

Brunelle Biotech Consulting, on behalf of Shimadzu Diagnostics, requests the Conference to consider a new method for rapid aerobic counts on dairy products.

The proposal is the submission of a new method and the subsequent updating of the 2400 series forms as appropriate to add the Shimadzu Diagnostics CompactDry TCR method for rapid aerobic counts.

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

The goal is to provide an additional testing platform for rapid aerobic counts on dairy products. The CompactDry TCR was validated in comparison to IMS #2a (Standard Plate Count, SPC) in three NCIMS certified laboratories and at Q Laboratories in Cincinnati, OH. Q Laboratories acted as the Coordinating Laboratory and prepared and shipped materials to the three NCIMS laboratories as well as providing one additional data set. The matrices evaluated in the study included raw commingled milk and pasteurized dairy products including whole milk, fat-free milk, half and half, heavy cream, chocolate milk, strawberry milk, lactose-free 2% milk, UHT 1% milk, and nonfat dry milk. A report is provided with this proposal.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | Add Form 2400a-11 | **Forms**<br>***Form Number: 2400a*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

Add new Form 2400a-11, CompactDry TCR, and incorporate any new information that may be needed in the 2400a form.


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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 226 | |
| Committee: | Lab- NEW 2400 | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

KEYENCE proposes the BC-1000 High Accuracy Automated Colony Counter to be NCIMS certified to allow this system to be used within microbiology testing labs performing colony counts.

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

KEYENCE BC-1000 High Accuracy Automated Colony Counter allows users to count bacteria colonies instantaneously with the click of a button. This system can count a variety of samples from general live bacteria to E. Coli, lactic acid bacteria, and many more. It counts different sample holders as well from petridish cultures, to petrifilm, and even membrane filter or compact dry plates. Settings for counts can be saved a reproduced by all users giving reliable results. After counting, the BC-1000 can digitize data in report templates, document counts, and export data amongst labs and users. We're proposing the BC-1000 to be a solution to microbial testing labs to aid in the count process, data repeatability and reliability, and exporting results.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

KEYENCE proposes BC-1000 High Accuracy Automated Colony Counter to be NCIMS certified to be used within microbiology labs performing colony counts. Data of the systems performance in the dairy industry will be submitted prior to the conference for the Lab Committee to review.


| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 227 |
| Committee: | Lab |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal rectifies a discrepancy between the Pasteurized Milk Ordinance (PMO) and the Evaluation of Milk Laboratories (EML) documents concerning Certified Industry Supervisor training and supervising Industry Analysts in their laboratories. This proposal also includes the addition of the AGARMS definition to the EML.

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

Discrepancies in Conference documents create confusion and may lead to complicated enforcement issues not intended by NCIMS. As updates are made to conference documents, discrepancies may appear despite the best efforts of all parties. These discrepancies need to be rectified when found to ensure the smooth function of our national Grade "A" dairy industry.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | 3, 4, 11, 13, 14 | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

EML pg 3:

1. **ALL GRADE "A" RAW MILK SUPPLIES (AGARMS):** all Grade "A" raw milk supplies transported in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers.

… (renumber each definition as appropriate)

~~2~~3. **CERTIFIED INDUSTRY SPERVISOR (CIS):** An industry supervisor (IS) who is evaluated and listed by an LEO as certified to conduct drug residue screening tests using NCIMS Accepted Drug Residue Test Methods at industry drug residue screening sites for Grade "A" *PMO*, and Appendix N. ~~regulatory~~ enforcement actions (confirmation of ~~milk tank trucks~~ AGARMS, producer trace back and/or permit actions). A CIS may also supervise and train Industry Analysts (IAs) to screen AGARMS for Appendix N. drug residue testing requirements.

…

~~5~~6. **INDUSTRY ANALYST (IA):** A person under the supervision of a CIS or IS who is assigned to conduct screening of ~~milk tank trucks~~ AGARMS for *PMO,* Appendix N. drug residue requirements.

~~6~~7. **INDUSTRY SUPERVISOR (IS):** An individual trained by an LEO who is responsible for the supervision and training of IAs who screen ~~milk tank trucks~~ AGARMS for *PMO,* Appendix N. drug residue requirements.

EML pg 4:

~~10~~11. **OFFICIALLY DESIGNATED LABORATORY:** A commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid shelf-stable processing and packaging; and ~~bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues~~AGARMS.

EML pg 11:

of approved ISs/IAs are not approved to ~~test raw, commingled, bulk milk~~AGARMS in the *PMO*, Appendix N. program.

EML pg 13:

4. When a CIS examines ~~commingled raw bulk milk tanker milk or its equivalent~~AGARMS for *PMO*, Appendix N. purposes,…

EML pg 14:

5. When an IS or an IA examines ~~commingled raw bulk milk tanker milk or its equivalent~~AGARMS for *PMO*, Appendix N. purposes,…


| | | | |
|---|---|---|---|
| Name: | Laura Traas, Chair | | |
| Agency/Organization: | NCIMS Laboratory Committee | | |
| Address: | | | |
| City/State/Zip: | | | |
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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 228 | |
| Committee: | Lab | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

This proposal adds language to the definition of an Officially Designated Laboratory in the EML and PMO to clearly specify that a commercial laboratory that is properly authorized by the Regulatory Agency may conduct official work for the examination of pasteurized milk and milk products, single-service containers/closures, and dairy waters, in addition to producer samples. This will make the definition consistent with current use of the term in the EML, MMSR, and PMO and ensure important flexibility to resource constrained state regulatory programs to meet official laboratory testing requirements of the Grade "A" program.

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

State milk regulatory programs are facing significant resource challenges (e.g., budget, personnel, facilities, equipment) that can impact completion of inspection, sampling and laboratory testing activities required by the PMO. Properly authorized Officially Designated Laboratories have long been an important and highly effective resource for states to meet analytical testing obligations under the national Grade "A" program. Importantly, Officially Designated Laboratories are overseen by a robust laboratory accreditation and analyst

proficiency monitoring system as specified in the EML including, but not limited to, direct on-site engagement by state Laboratory Evaluation Officers (LEOs) certified by the FDA/LPET to ensure the integrity of laboratory services important for monitoring of milk and milk product safety and the protection of public health.

Current Conference documents reference Officially Designated Laboratories as acceptable sources of official testing data beyond producer samples alone. For example, Section C, "Rating Methods for Grade "A" Milk Plants, Receiving Stations and Transfer Stations" in the MMSR (page 17) currently describes that when conducting a state rating or PHS/FDA check rating of a milk plant, the Regulatory Agency's official records are used to determine compliance with bacterial, coliform, phosphatase, drug residue and cooling temperature requirements; and that acceptance of data from Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Acceptance of data from "Officially Designated Laboratories" is also clearly stated for milk product samples in the evaluation of state enforcement under Milk Plant-Part II, Item 7(c) of the MMSR (page 110-111) where the parenthetical (Commercial, if acceptable to the Regulatory Agency) is also shown. Officially Designated Laboratories are likewise cited as acceptable under IMS listing methods applicable to single-service containers and closures in the MMSR (page 25); and for official water microbiological testing in the EML (page 19) and PMO (page 341).

While all of the above references clearly indicate that regulatory agencies may use properly authorized Officially Designated Laboratories for official tests on records associated with milk plants, the definition of an Officially Designated Laboratory as currently written does not explicitly indicate official work includes pasteurized milk products, dairy waters or single-service containers and/or closures. This proposal would revise the definition of an Officially Designated Laboratory to be consistent with its overall usage in the text of the EML, MMSR, and PMO, and remove any ambiguity regarding the official acceptability of testing data from commercial laboratories properly authorized and overseen as Official Designated Laboratories under the proven procedures of the EML and national Grade "A" milk program of NCIMS.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| Page 10 | **2023 PMO**<br>***Section(s):* 1**<br>***Appendix:*** | Page 4 | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

*EML, Section 1, (Page 4)*

10. **OFFICIALLY DESIGNATED LABORATORY:** A commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid shelf-stable processing and packaging; ~~and~~ bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues; and pasteurized milk and milk products, single-service containers and/or closures, and dairy waters.

*PMO, Section 1, (Page 10)*

QQ. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging; ~~and~~ bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues; and pasteurized milk and milk products, single-service containers and/or closures, and dairy waters.

The changes described in this proposal would become effective on the date of official FDA concurrence of Conference proposals communicated to the NCIMS Executive Board.


| | | | |
|---|---|---|---|
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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 229 |
| Committee: | Lab |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal seeks to add the language from M-I-18-11, *Alternate Procedure For Granting Conditional Certification For New Or Existing Laboratory Methods To Milk Analysts That Are Currently Certified For A Similar Existing Laboratory Method,* to the *Evaluation of Milk Laboratories* (EML).

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

M-I-18-11, *Alternate Procedure For Granting Conditional Certification For New Or Existing Laboratory Methods To Milk Analysts That Are Currently Certified For A Similar Existing Laboratory Method*, was issued in 2018 and (per the M-I) the procedure outlined within that document was to be submitted as a proposal to the 2019 NCIMS Conference, which did not happen as anticipated.

The procedure outlined in M-I-18-11 allows an LEO to conditionally certify an analyst(s) in a dairy laboratory for a new method before undergoing an on-site survey or split sample performance evaluation, provided the analyst(s) is already certified on a similar existing method and meets the criteria specified in M-I-18-11. The document identifies several method parings with very similar analytical procedures that are approved for this process. Adding this language

to the EML will allow dairy labs to bring on new methods (as long as they are similar and identified pairings) more efficiently, without waiting for an on-site evaluation or proficiency testing.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | 8 | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

EML Page 8, add the following language after the section titled
**CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS**
and before the section titled
**ACCREDITATION/APPROVAL OF MILK LABORATORIES**
with direction to FDA to use editorial authority to update the Table of Contents**.**

**CONDITIONAL CERTIFICATION FOR NEW OR EXISTING LABORATORY METHODS TO MILK ANALYSTS THAT ARE CURRENTLY APPROVED/CERTIFIED FOR A SIMILAR EXISTING LABORATORY METHOD**

Conditional certification will be recognized for specifically identified and linked current and newly accepted or similar existing laboratory methods when the following criteria are met. Refer to the laboratory methods list below.

1. The analyst shall have conditional, provisional or full certification status for the currently accepted/approved laboratory method.

2. If analysts do not have certification status for the current laboratory method, then the traditional route of certification as specified in the *EML* will be required to be followed to gain conditional certification for the new laboratory method or similar existing laboratory method.

3. If laboratories have one (1) or more analysts certified for the current laboratory method and are seeking conditional certification for the new laboratory method or similar existing

laboratory method, then the laboratory shall contact their Laboratory Evaluation Officer (LEO) to request conditional certification for the new or other similar existing laboratory method and provide a list of analysts for which the laboratory is seeking conditional certification.

4. The laboratory shall provide documentation, e.g. training records, showing that analysts have been trained on the laboratory method for which conditional certification is being requested and assure that they understand any differences that may exist between the laboratory method and similar existing laboratory method. Verification of technique and understanding will take place at the next on-site laboratory survey.

5. Conditional status of the analyst will remain in effect until the analyst has satisfactorily participated in an on-site laboratory survey AND has satisfactory results in a milk split sample performance evaluation for the new laboratory method or similar existing laboratory method, at which time the analyst will be granted full certification.

6. If an on-site laboratory survey or milk split sample performance evaluation results are unsatisfactory prior to gaining full certification, then conditional certification status shall be revoked until the next on-site is satisfactory or the analyst has satisfactory results in the next milk split sample performance evaluation for the new laboratory method or similar existing laboratory method, at which time conditional status will be regained. As before, regaining conditional certification shall be by the route that certification was lost.

7. The laboratory shall agree to these conditions or the traditional procedure/route of certification will be required to be followed.

8. LEOs will need to submit a Laboratory Status Change Summary Template to LPET to include the new laboratory method for the laboratory. An on-site survey and evaluation report will not be required if conditional certification is granted by meeting Items 3 and 4 above.

9. Should a supplemental or the biennial on-site laboratory survey take place at any time up until the laboratory's expiration date, then an evaluation report and summary template will be required to be submitted to LPET. The new laboratory method or similar existing laboratory method shall be part of the on-site laboratory evaluation or certification shall be removed or reduced as appropriate.

To initiate this process, the following pairings will be recognized:

| # | Currently Accepted/Approved | New/Other Similar |
|---|---|---|
| 1 | Petrifilm Aerobic Count (PAC) | Petrifilm Rapid Aerobic Count (RAC) |
| 2 | Charm Beta lactam SL or SL3 | Charm ROSA SULF, ROSA TET or TRIO |
| 3 | Neogen Advanced for Tetracycline or B-I | Neogen Advanced for Beta lactams or Tet |
| 4 | Any currently approved Electronic Somatic Cell Count (ESCC) | Any other curent or new ESCC (excluding Foss BacSomatic) |
| 5 | Idexx Colilert or Colisure | Idexx Colilert or Colisure |


Name: Food and Drug Administration

Agency/Organization: Human Foods Program – Division of Dairy Safety

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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 230 |
| Committee: | Lab |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal aligns the requirement for the recommended minimum number of samples of an analyst testing the plate count of raw milk and the minimum number samples required to be used for proficiency tests of analysts operating the BactoCount IBC, BactoCount IBCm and BactoScan™ FC.

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

The 2023 EML specifies that the recommended minimum number of samples for a split sample proficiency test of the plate count of raw milk to be six (See table 1 on page 33). On page 14 and 17 it specifies that analysts being certified for BactoCount IBC, BactoCount IBCm and BactoScan™ FC must be tested with a minimum of 14 samples. This proposal aligns the minimum number of samples for testing plate counts of raw milk samples to six for all plate count test methods.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | 14, 17 | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:
Modify the 2023 EML, pages 14 and 17 to reduce the number of minimum number of samples to be tested from fourteen (14) down to six (6) for analysts being certified for BactoCount IBC, BactoCount IBCm and BactoScan™ FC.

Pg. 14
7. An acceptable annual proficiency testing program for the BactoCount IBC, BactoCount IBCm and BactoScan™ FC (all NCIMS approved models) shall meet the following applicable criteria.
(a) The BactoCount IBC, BactoCount IBCm and BactoScan™ FC (all NCIMS approved models) shall be used to examine a minimum of ~~fourteen (14)~~ six (6) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan™ FC and for which the analyst or BIO has been certified/approved, respectively.
(b) Split samples (minimum of ~~fourteen (14)~~ six (6)) shall…

Pg. 17
2. An acceptable annual proficiency testing program for the BCC, BCMC and BSC (all NCIMS approved models) shall meet the following applicable criteria.
(a) BCC, BCMC and BSC (all NCIMS approved models) shall be used to examine a minimum of ~~fourteen (14)~~ six (6) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the Bentley BactoCount IBC, Bentley BactoCount IBCm or Foss BactoScan™ FC Count and for which the analyst or BIO has been certified/approved, respectively.
(b) Split samples (minimum of ~~fourteen (14)~~ six (6)) shall…

| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

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|---|---|
| Proposal #: | 231 |
| Committee: | Lab |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

To remove items in Section 5 of the Evaluation of Milk Laboratory list of items to bring during an evaluation.

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

Many of the items that are being removed are required to be housed in the laboratory and are unnecessary for the laboratory evaluation officers (LEO) to bring. A few of the items are considered hazardous materials and should not be carried with the LEO.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | 25 | **2023 EML** |
| | **2023 MMSR** | | **Forms**<br>***Form Number:*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

## SECTION 5: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

While conducting laboratory on-site surveys, the FDA/LPET or LEO may find it extremely useful to have in their possession different types of equipment which shall enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some LEOs currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy.

~~1. Brom thymol blue solution.~~
~~2. Chlorine test kit (chloramine or free chlorine).~~
~~3. Conductivity meter.~~
4. Anemometer.
5. Level (or cross test level).
6. Light meter (in foot-candles).
~~7. Maximum registering thermometer (MRT) for autoclaves.~~
~~8. Reference books (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater).~~
9. Ruler, pocket - metric.
~~10. Special measuring flask (calibrated at 97-99-101-ml).~~
~~11. Taper gauge or drill bits for PLC loops.~~
12. Thermometer(s).
~~13. Weights - accurate (S/S1 or ASTM 1, 2 or 3).~~

(Renumber each item as appropriate)

| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 232 | |
| Committee: | Lab-2400/ Scientific | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

To change the autoclave temperature required from 120±1°C for all items to the temperature specified by the manufacturer of the media.

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

Most media manufacturers specify 121±1°C as the temperature for properly autoclaving their media. Therefore, most autoclaves are set to autoclave media at 121±1°C. There are only a few media that recommend a lower temperature. Requiring all labs to operate their autoclaves at the lower temperature for all media is unnecessary – only those labs that use the more temperature sensitive media should be required to use the lower temperature for those media.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | 8 | **Forms**<br>***Form Number:***<br>**NCIMS 2400** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

Form 2400 Cultural Procedures

**14. Sterilization by Moist Heat** _____

a Autoclave media at ~~120±1°C~~ the temperature specified by the manufacturer _____

1. Dilution buffer blanks for 15 min (30 min optional) _____

2. Media for 15 min (sugar broths as per manufacturer instructions) _____

b. Autoclave media within 1 hour of preparation _____

c. Autoclave dilution buffer on same day prepared _____

d. Loosen stoppers or caps slightly to permit passage of steam and air _____

e. All air expelled from autoclave before pressure allowed to rise _____

f. Autoclave will reach ~~120±1°C~~specified temperature within 15 min (5 min pref.) of starting air-exhaust _____

g. Properly operating and calibrated temperature gauge (not a pressure gauge) relied on to insure sterilization _____

| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 233 |
| Committee: | Lab- 2400 |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

Update the NCIMS 2400 Cultural Procedures – General Requirement form to allow verification of prepared dilution blanks by weight.

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

The current 2400 from requires that 1 in every 25 dilution water blank be verified for volume using at Class A graduated cylinder. This requires the dilution water to be poured into the cylinder for verification making it unusable to the laboratory. For commercially prepared blanks that are purchased by the laboratory this wastes considerable resources. A study was done by the Maine Department of Agriculture and New York State Department of Agriculture and Markets in which the purchased dilution blanks were checked by weight instead of volume. No statistical difference was found between the two methods. Data was sent to the NCIMS Laboratory Committee for review.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | X | **Forms**<br>***Form Number:***<br>***NCIMS 2400 Cultural Procedures – General Requirements*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:
NCIMS Cultural Procedures – General Requirements (pg. 13)

**26. Dilution Buffer and Blanks**

f. Alternatively, use commercially prepared dilution buffer blanks.

Brand: _____

Lot#: _____ Exp. Date: _____

1. Maintain volume records ~~as above~~ using one of the following methods:

a. Pour each blank into a Class A graduated cylinder (or equivalent) to check volume as described in 26.d.1-4.

OR

b. Visually observe and discard any blanks with < 97 or >101 mL. Of the remaining blanks appearing to have correct volume, verify 1 out of every 25 bottles. Of the bottles set aside for verification, pour three of these blanks into a class A graduated cylinder (or equivalent) to verify volume of each. Allow emptied bottles to dry completely (including any tops/seals) and determine an average weight. Weigh remaining bottles set aside for verification, subtracting average weight of the bottles. Records maintained. If any blanks are out of tolerance, discard entire lot and record lot as discarded.

2. Check toxicity as above on each new lot received

3. Check pH and record

| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | |
|---|---|
| Proposal #: | 234 |
| Committee: | Lab- 2400 |
| New Procedure | |
| Procedure Change | |
| Const./Bylaws Change | |

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

## A. Summary of Proposal

This proposal requests revisions to the Petrifilm® 2400 forms to remove the obsolete Advanced Instruments® PetriScan® Reader and make minor editorial corrections to the counting aids sections.

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

Advanced Instruments stopped production of the PetriScan® Reader in 2005. The company provided service and maintenance support for 10 years after production stopped. The product was fully obsoleted in 2015. Advanced Instruments does not offer a replacement product and does not have any objections to removing the PetriScan® Reader as the equipment has been fully obsoleted.

Information regarding the status of the PetriScan Reader, was provided January 2025 by Russel Walker, Technical Support Specialist at Advanced Instruments (Russellw@aicompanies.com).

Minor editorial revisions are needed to correct typos and clarify some of the general instructions in the “Counting Aids” section following the approval to removal an obsolete

reader (PIMS) and addition of the Petrifilm® Plate Reader Advanced following the 2023 NCIMS Conference.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | 9 and 6 respectively | **Forms**<br>***Form Number: 2400a-4 and 2400a-5*** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

Form 2400a-4 Page 9

~~4. Advanced Instruments® PetriScan® Reader~~
~~[Approved for use with PAC only]~~

~~a. Inspect scanner glass for spots and if necessary clean using a soft, lint-free cloth with a mild glass cleaner~~
~~b. Place templates 1 and 2, and two PAC plates with no growth in the PetriScan grid and scan~~
~~c. Count and record all results prior to the start of and at the end of each operation period~~
~~d. Scan, count and record template and no growth PAC plate results hourly with continuous operation~~
~~e. Template 1 gives count between 27 and 33~~
~~f. Template 2 gives count between 190 and 210~~
~~g. No growth PAC plates give a count of zero~~
~~h. If any results out of range~~

~~1. Inspect templates and PAC plates for defects and scanner glass for spots~~
~~2. If defect(s) found, replace template or PAC plates and scan, count and record new result(s)~~
~~3. Do not proceed until template and no growth PAC plates give acceptable results, seek technical assistance~~

~~6~~4. Maintain records

~~d~~a. Examine each test plate visually prior to placing into the reader

1. For plates with no growth, assure reader count is Zero

2. For atypical ~~plates;~~ plates: ~~spreader colonies, confluent growth, excessive growth around edge of plate, etc., do not count with reader, record as appropriate using items 15 & 16~~
   a. Confluent growth, excessive growth around edge of plate, etc., record as appropriate using item 16.
   b. For plates with spreader colonies do not use reader if liquefied colonies exceed 25% of plate. Record as appropriate using item 16.

Form 2400a-5 Page 6

~~4. Advanced Instruments® PetriScan® Reader~~
~~[Approved for use with PAC only]~~
~~a. Inspect scanner glass for spots and if necessary clean using a soft, lint-free cloth with a mild glass cleaner~~
~~b. Place templates 1 and 2, and two PAC plates with no growth in the PetriScan grid and scan~~
~~c. Count and record all results prior to the start of and at the end of each operation period~~
~~d. Scan, count and record template and no growth PAC plate results hourly with continuous operation~~
~~e. Template 1 gives count between 27 and 33~~
~~f. Template 2 gives count between 190 and 210~~
~~g. No growth PAC plates give a count of zero~~
~~h. If any results out of range~~
~~1. Inspect templates and PAC plates for defects and scanner glass for spots~~
~~2. If defect(s) found, replace template or PAC plates and scan, count and record new result(s)~~
~~3. Do not proceed until template and no growth PAC plates give acceptable results, seek technical assistance~~

~~6~~4. Maintain records
~~d~~a. Examine each test plate visually prior to placing into the reader
1. For plates with no growth, assure reader count is Zero
2. For atypical ~~plates;~~ plates: ~~spreader colonies, confluent growth, excessive growth around edge of plate, etc., do not count with reader, record as appropriate using item 17~~
   a. Confluent growth, excessive growth around edge of plate, etc., record as appropriate using item 17.
   b. For plates with spreader colonies do not use reader if liquefied colonies exceed 25% of plate. Record as appropriate using item 17.

| | | | |
|---|---|---|---|
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# 39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

| | | |
|---|---|---|
| Proposal #: | 235 | |
| Committee: | Lab-2400/ Other Species | |
| New Procedure | | |
| Procedure Change | | |
| Const./Bylaws Change | | |

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

## A. Summary of Proposal

Change FORM NCIMS 2400d Direct Somatic Cell Count

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

To add the Atlanta (O'Keefe) modification to the form for the staining of goat smears.

## C. Proposed Solution

Changes to be made on the following NCIMS Documents:

| Page Number(s) | Document | Page Numbers(s) | Document |
|---|---|---|---|
| | **2023 PMO**<br>***Section(s):***<br>***Appendix:*** | | **2023 EML** |
| | **2023 MMSR** | 5, 6, 7, and 8 | **Forms**<br>***Form Number:*** **NCIMS 2400d** |
| | **2023 Procedures** | | **2023 Constitution and Bylaws** |

Proposed Change:

FORM NCIMS 2400d – Direct Microscopic Cell Count
Rev 03/2024

Page 5

**21. Sample Measurement and Smear Preparation (Metal Syringe)**

f. When preparing multiple smears, complete steps 21.a through 21.e.4 before starting the next smear

g. After spreading test portion, dry smears at 40-45ºC within 5 min on level surface (item 6). <u>If staining using the Atlanta modification (item b. 2.) place smears on a level surface at room temperature (do not heat) and allow to air dry (~ 10 min).</u>

h. To prevent smears from cracking and peeling from slide during staining, do not heat too rapidly

Page 6

**23. Sample Measurement and Smear Preparation (Micropipettor)**

g. When preparing multiple smears, complete steps 23.a through 23.f before starting next smear

h. After spreading test portion, dry smears at 40-45ºC withing 5 min on level surface (item 6). <u>If staining using the Atlanta modification (item b. 2.) place smears on a level surface at room temperature (do not heat) and allow to air dry (~ 10 min).</u>

i. To prevent smears from cracking and peeling from slide during staining, do not heart too quickly

**Staining Films**

a. Levowitz-Weber and methylene Blue Stains

1. Use ventilated hood for steps 24.a.2-4

2. Submerge or flood slides in stain for 2 min (timer used)

3. drain off excess stain by resting edge of slide on absorbent paper

4. Dry thoroughly (air dry or use cool forced air)

5. Dip dry stained slide in 3 changes of tap water at 35-45$^{o}$C

6. Drain and air dry slide before examining smears

b. Pyronin Y-Methyl Green Stain ~~(New York Modification)~~

Note: Stain is light sensitive and must be protected from overexposure to light

1. Slide is run through the following staining scheme <u>(New York Modification)</u>

| | |
|---|---|
| Carnoy's Fixative | 5 min |
| 50% Ethanol | 1 min |
| 30% Ethanol | 1 min |
| DI or MS Water | 1 min |
| Stain | 6 min |
| N-Butyl Alcohol | flush briefly |
| Xylene | flush briefly |

a. Optionally, if smears will not adhere to slides:

1. Allow slide to dry, (appox. 10 min) protected from overexposure to light, after Carnoy's fixative step but before the 50% ethanol step OR

2. Allow slide to dry (approx. 10 min) protected from overexposure to light, after stain step but before flush with N-Butyl alcohol

<u>OR</u>

<u>2. Slide is run through the following staining scheme (Atlanta Modification)</u>

<u>Carnoy's Fixative 6 min</u>
<u>Let air dry (≥ 10 min until visually dry – protected from exposure to light)</u>
<u>30% Ethanol 2 min</u>
<u>DI or MS Water 2 min</u>
<u>Stain 2 min</u>
<u>Let air dry (≥ 10 min or until visually dry protected from exposure to light)</u>

Xylene flush briefly (10 seconds)

3. Cells stain blue or blue-green; RNA and background stain pink

Page 8

**25. Examination**

h. After examination of each smear record strip count

i. Conduct monthly comparative counting between analysts (see plate count procedure ~~FDA/~~NCIMS 2400 forms, Identifying Counting Errors)


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