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M-I-20-3

March 11, 2020

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Answers to Questions Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Year 2017

Following are answers to questions received from the field; Milk Seminars; and FDA training courses (Special Problems in Milk Protection, Milk Plant Sanitation and Inspection, Milk Pasteurization Controls and Tests, and Dairy Farm Sanitation and Inspection) held during fiscal year 2017.

In accordance with procedures established through the National Conference on Interstate Milk Shipments (NCIMS), if an answer to these questions results in a new understanding of a long-standing situation or installation, and the condition as it exists does not present an immediate public health hazard, reasonable judgment should be exercised and adequate time provided for modification and correction.

An electronic version of this memorandum is available for distribution to Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and also will be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to monica.metz@fda.hhs.gov.

Monica Metz
Branch Chief
Milk and Milk Products Branch

1. **PMO-Sections 1 and 4**

Is clotted cream considered a Grade "A" milk product?

Yes. FDA has evaluated this type of product under various product names, i.e. English Double Devon Cream, Cornish Clotted Cream, Devon Clotted Cream, etc. FDA has consistently stated that this is a Grade "A" milk product, and that it meets the standard of identity found in 21 CFR 131.150 "Heavy Cream".

2. **PMO-Sections 1 and 4**

May the term "Gently Pasteurized Milk" or "Low Temperature Pasteurized" be used in the labeling on containers of milk and/or milk products? May the term "Vat Pasteurized" be used in the labeling on containers of milk and/or milk products?

1. *No. The terms "gently" and "low temperature" are undefined terms when used in conjunction with the word "pasteurized" and would be considered false or misleading to a consumer under Section 4 - Labeling of the PMO. The PMO and 21 CFR 1240.61(b) definition of "Pasteurization'" specifies minimum times and temperatures. To use the term "Gently Pasteurized" or "Low Temperature Pasteurized" for either batch (vat) pasteurization or high-temperature-short-time (HTST) pasteurization appears to imply that the milk and/or milk product is somehow "better" than a milk and/or milk product that is pasteurized at a different time and temperature.*

2. *Yes. The term "Vat Pasteurized" may be used as it is a defined term.*

3. **PMO-Sections 1 and 4; and Appendix L**

May Milk Protein Concentrate (MPC) be added to a milk product that is labeled as "High Protein Chocolate Lowfat Milk"?

The following answer was provided by CFSAN's ONFL:

Yes. While standardized milk is a good source of protein, this milk product is modified through the addition of MPC to qualify as "high protein". The use of MPC in a "high protein chocolate lowfat milk" is appropriate under the regulation for standardized foods modified by the use of a nutrient content

claim in 21 CFR 130.10. The MPC shall be from an IMS listed source and shall be labeled as Grade "A".

4. **PMO-Sections 1 and 4; and Appendix L**

a) The wording in Section 1-Definitions of the PMO for Milk Products states: "Milk and milk products which have been retort processed after packaging, or which have been concentrated (condensed) or dried are only included in this definition if they are used as an ingredient to produce any milk or milk product defined above or if they are labeled as Grade "A" as described in Section 4. of this *Ordinance*." Does this also include a milk product meeting the SOI for "Evaporated Milk" found in 21 CFR 131.130?

No. "Evaporated Milk" and "Concentrated (condensed) Milk" are distinctly defined and separate milk products. The SOI for "Evaporated milk" is found in 21 CFR 131.130. The SOI for "Condensed milk" is found in 21 CFR 131.115, and a definition of "Concentrated (Condensed) Milk" is also found in Section 1-Definitions of the PMO. The excerpt referenced from the PMO states "… Concentrated (condensed) milk …"; but does not include the milk product "Evaporated milk". A milk product meeting the SOI for "Evaporated milk" found in 21 CFR 131.130 that is pasteurized at 250 ^{0}F for two (2) minutes and extended shelf life (ESL) packaged for storage under refrigerated conditions would be considered a Grade "A" milk product. However, a milk product meeting the SOI for "Evaporated milk" found in 21 CFR 131.130 would not be considered Grade "A" if the "Evaporated milk" is retort processed after packaging with a filed process meeting the requirements of 21 CFR Part 113. Unless the retorted "Evaporated milk" is labeled as Grade "A" or will be used as an ingredient in a Grade "A" milk or milk product, then the retorted "Evaporated milk" would be considered a Grade "A" milk product.

b) The milk product will contain at least 6.5% butterfat, 16.5% milk solids not fat (MSNF) (by subtraction), at least 23% total milk solids (TMS), the requisite amount of vitamin D and will be homogenized as cited in 21 CFR 131.130. Would this milk product be correctly labeled by naming this milk product "Evaporated Milk"?

Yes.

5. **PMO-Sections 1 and 4; and Appendix L**

Does the PMO or any federal regulation (Federal Food, Drug and Cosmetic Act (FFD&CA) or CFR) require pasteurized or ultra-pasteurized milk and/or milk products to be labeled "Keep Refrigerated"?

No.

6. **PMO-Sections 1 and 4; and Appendix L**

Sodium benzoate is considered generally recognized as safe (GRAS). May sodium benzoate be used as an ingredient in the processing of cottage cheese and in other milk and milk products?

Sodium benzoate is considered GRAS and this designation can be found in 21 CFR 184.1733. The CFR defines it as an anti-microbial agent and/or as a flavoring agent.

1) *Sodium benzoate can be used in the processing of cottage cheese as long as it serves a useful function other than building the total solids content of the finished food and shall be used in a quantity not greater than is reasonably required to accomplish their intended effect (SOI for Cottage Cheese 21 CFR Part 133.128(b)). Sodium benzoate shall function to extend the shelf-life or act as a flavoring agent in cottage cheese and must be declared on the label in accordance with applicable sections of 21 CFR Parts 101 and 130.*

2) *Sodium benzoate may be used in other milk and milk product whose Standard of Identity (SOI) permits the use of an ingredient to extend the shelf-life of the milk product or permits its use as a flavoring ingredient. It must be declared on the label in accordance with applicable sections of 21 CFR Parts 101 and 130.*

7. **PMO-Sections 1, 4 and 9**

Under the PMO may raw milk for retail sale in final package form for human consumption be labeled as “Grade A”?

No. Section 9-Milk and/or Milk Products Which May Be Sold of the PMO requires that twelve (12) months from the date on which the PMO is adopted, only Grade “A” pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products or retort processed after packaging low-acid milk and/or milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. In addition, 21 CFR 1240.61- requires mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption, prohibits the sale of raw milk in interstate commerce intended for direct human consumption whether or not it is labeled “Grade A”.

NOTE: *Some State laws allow for the sale of raw milk for retail sale in final package form for direct human consumption within their jurisdiction. Some of these State laws, which adopt the PMO as their dairy regulations, allow this raw milk to be labeled "Grade A". Raw milk for retail sale in the final package form under State law, whether or not it is labeled "Grade A", is limited to the jurisdiction of that State.*

8. **PMO-Sections 1 and 6; and Evaluation of Milk Laboratories (EML)-Section 1**

a) May an Officially Designated (Industry) Laboratory be IMS accredited to conduct official Section 6-The Examination of Milk and/or Milk Products of the PMO testing of the following:

- Raw commingled milk samples collected at a milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging;
- Samples of finished pasteurized and/or ultra-pasteurized milk and/or milk products;
- A milk plant's individual water supply/source samples;
- A milk plant's recirculated cooling water samples; and
- A milk plant's reclaimed water samples?

No. An Officially Designated (Industry) Laboratory is a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging; and 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.

The samples cited above can only be tested by an Official Laboratory, which is a biological, chemical or physical laboratory that is under the direct supervision of the Regulatory Agency (Central or local department laboratory) or an Officially Designated (Commercial) Laboratory that is authorized to do official work by the Regulatory Agency or Milk Laboratory Control Agency. (Please refer to Section 1 of the PMO and the EML.)

(Please refer to IMS-a-51, Proposal 231, which will incorporate the uniform definition for Officially Designated Laboratory into Section 1 of the 2017 PMO and EML.)

b) May an Official Laboratory or an Officially Designated (Commercial or Industry) Laboratory be IMS accredited to conduct coliform testing of a dairy producer's raw milk?

No. The PMO does not address or require the testing for coliforms of a dairy producer's raw milk.

NOTE: *The only coliform testing required in the PMO is for finished milk and/or milk products and then only if the milk and/or milk product is so identified in the latest revision of M-a-98. Any IMS listing for coliform, i.e., Laboratory Procedure Codes 18, 19, 20 or 21, would only be for testing finished milk and/or milk products. Also, the FDA/NCIMS 2400 Forms do not address coliform testing of raw milk.*

9. **PMO-Sections 2 and 7, Item 16p(A)**

Is it acceptable to inject culinary steam into the air space of a batch (vat) pasteurizer for the sole purpose of pre-heating the milk or milk product prior to beginning legal pasteurization and without any culinary steam injected during the recorded pasteurization time?

Yes. Provided the steam meets Appendix H-Pasteurization Equipment and Procedures and Other Equipment, Section III-Culinary Steam – Milk and Milk Products of the PMO. The culinary steam is injected through a piping assembly that will assure a clean, dry saturated steam and will not provide a means for the adulteration of the milk or milk product with added water.

10. **PMO-Section 3**

Are there any PMO restrictions on a dairy producer being issued a permit as a bulk milk hauler/sampler for the collection of their own PMO, Section 6 "Universal" milk samples?

A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such products.

The authorization for a dairy producer to collect their own "Universal" milk samples through the issuance of a bulk milk hauler/sampler's permit is at the discretion of the Regulatory Agency that issues the bulk milk hauler/sampler permits.

11. **PMO-Section 3; Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipment (PROCEDURES)-Section IV; and Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)-Section B**

The PMO would allow for the issuance of two (2) separate permits on a single dairy farm, at the discretion of the Regulatory Agency, where there are two (2) owners; two (2) separate herds, which are milked separately; and two (2) separate farm bulk milk tanks/silos with both sharing the same milking area, milkhouse and equipment. It must be recognized that if they operate with the same equipment and facilities, all debits on inspections would be the same for both dairy producers and would require two (2) inspection reports with separate and complete official Regulatory Agency records for each dairy producer. Under no circumstances shall milk from one (1) permittee's farm bulk milk tank/silo be interchanged or commingled with the milk from the other permittee's farm bulk milk tank/silo. With this scenario, would it be acceptable for one (1) permit holder to ship milk to one (1) bulk tank unit (BTU) and the other permit holder to ship milk to a different BTU?

Yes.

12. **PMO-Section 4**

During transition phases, a milk plant is flushing milk with water and sending this "reclaimed" mixture to a dedicated refrigerated storage tank/silo, and then shipping this "reclaimed" mixture to another IMS listed milk plant for use as an ingredient in Grade "A" milk products where the SOI permits such use or in non-Grade "A" milk products. How should this "reclaimed" mixture be labeled on shipping manifests/bills of lading?

Grade "A" raw milk-water mixture.

13. **PMO-Section 4; and Appendix L**

The following questions concern the terms genetically modified organism (GMO) or genetically engineered (GE) when used in the labeling of milk and milk products.

The following answers were provided by CFSAN's ONFL:

a) May the term "GMO-Free" be used on a label of a milk or milk product?

FDA discusses the use of the labeling term "GMO-free" in our final Guidance, "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants". Available online at:

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm059098.htm

In the Guidance, we said: "The term "free" conveys zero or total absence unless a regulatory definition has been put in place in a specific situation (Refs. 14, 15). The potential challenges of substantiating a "free" claim are described in Section III., D. of this Guidance, and in light of these challenges FDA recommends that manufacturers not use food labeling claims that indicate that a food is "free" of ingredients derived through the use of biotechnology. Instead, FDA recommends that manufacturers consider the use of other types of statements to indicate that a plant-derived food has not been produced using bioengineering, as described above and below."

b) If "non-GE" claims are used, what are the requirements for location and font size?

All "non-GE" claims are voluntary, so there are not any requirements for the location and font size. However, manufacturers should keep in mind that certain mandatory label requirements are based on the largest print on the label, e.g., statement of identity and Nutrition Facts labeling.

c) Is there any qualifying statement required to accompany a "non-GE" statement?

Qualifying statements are not required with voluntary "non-GE" claims. However, as with all other information on the label, FDA expects the claims to be truthful and not misleading. FDA encourages manufacturers who are considering including "non-GE" claims to consult the guidance to understand our current thinking on the topic.

d) What is required of the milk plant to prove their milk or milk product is "non-GE"?

Please refer to the above answer regarding the use of the term "GMO-free". As we discuss in the Guidance, claims apply to the food itself, in this case the milk or milk product. An ingredient such as cow's milk would not be considered as being produced using genetic engineering. This is the case because feed from bioengineered plants is not a direct component of the milk and there are not any approved bioengineered cows. However, FDA would

object to a "non-GE" claim on a milk-based product that contained other ingredients produced using genetic engineering.

14. **PMO-Section 4; and Appendix L**

A business makes application for a small business nutrient label exemption because their unflavored yogurt product only contains the ingredients milk and cultures and is labeled as "gluten-free". Would this be considered a nutrient content claim?

The following answer was provided by CFSAN's ONFL:

No. The term "gluten-free" is not a nutrient content claim, but is an avoidance claim. An avoidance claim is not part of the evaluation of an application for a small business nutrient label exemption.

15. **PMO-Section 4; and Appendix L**

On August 11, 2017, FDA announced in the Federal Register (FR) the availability of a guidance for industry entitled "Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry". The guidance advises manufacturers who wish to use ultrafiltered milk (UF milk) or ultrafiltered nonfat milk (UF nonfat milk) in the production of standardized cheeses and related cheese products that, pending completion of rulemaking regarding the use of UF milk in the production of these products, we intend to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products. We also intend to exercise enforcement discretion regarding the declaration of ingredients in the labeling of standardized cheeses and related cheese products when fluid UF milk and fluid UF nonfat milk are used as ingredients.

The following questions have been raised as it relates to Grade "A" cottage cheese:

The following answers were provided by CFSAN's ONFL:

a) Does this guidance apply to Grade "A" dry curd cottage cheese and thus creamed cottage cheese as defined in 21 CFR 133.129?

The Guidance applies to both dry curd cottage cheese defined in 21 CFR 133.129 and cottage cheese (commonly referred to as creamed cottage cheese) defined in 21 CFR 133.128, as both products are ***standardized cheeses****. The Guidance applies to all cheeses or related cheese products*

with SOI in 21 CFR Part 133. The fact that a dairy product may or may not be Grade "A" does not have any bearing on the issue.

b) FDA intends to exercise enforcement discretion regarding the declaration of ingredients in the labeling of standardized cheeses. Does this mean that a standardized cheese utilizing UF milk or UF nonfat milk does not need to state "ultrafiltered milk" in the ingredient statement, and could merely say "milk" or "nonfat milk"?

The third paragraph of page 6 of the Guidance states: "FDA is … announcing its intent to exercise enforcement discretion with respect to the labeling of standardized cheeses and related cheese products, when, ***in addition to milk or nonfat milk,*** *fluid UF milk or fluid UF nonfat milk is used as an ingredient, but is not declared in the ingredient statement, provided that milk or nonfat milk is declared in the ingredient statement.*

c) Will enforcement discretion also be used for other milk products where we have ONFL's responses published in M-Is that state if UF milk is used it must be declared as UF milk or if used as an ingredient, the term 'ultrafiltered milk' shall be used?

The Guidance and enforcement discretion only applies to standardized cheeses and related cheese products; or stated differently, the Guidance and enforcement discretion applies only to those cheeses or related cheese products with SOI in 21 CFR Part 133. The Guidance and enforcement discretion does not apply to any other dairy products, including non-standardized cheeses. For dairy products not covered by the Guidance, if fluid UF milk or fluid UF nonfat milk is used, the terms "ultrafiltered milk" or "ultrafiltered nonfat milk," as appropriate, shall be used.

16. **PMO-Section 5; and MMSR-Section E**

Section 5-Inspection of Dairy Farms and Milk Plants of the PMO requires that one (1) copy of the inspection/audit report shall be electronically generated or hand written to be provided to the operator, or other responsible person; or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.

A State Regulatory Agency is planning on going paperless and will be issuing licenses and inspection reports electronically. They will no longer be posting inspection reports on dairy farms and in milk plants, which may mean that the

last inspection report may or may not be available on the individual dairy farm or at a milk plant. They state that they will make the inspection reports available to all concerned via the State Regulatory Agency's computer system. If a dairy producer does not have access to the internet, their proposal is for the inspector to go to their regional office, print the inspection report, and deliver a copy of the inspection report by U.S. mail. Would this be acceptable?

The issuance of inspection/audit reports electronically is authorized under the PMO; however, the inspection/audit report shall be posted or made available to the Regulatory Agency at the dairy farm or milk plant upon their request and the inspection/audit report shall be filed with the official records of the Regulatory Agency. If a dairy farm or milk plant does not have the last inspection/audit report posted or the dairy farm or milk plant operator cannot provide a hard or electronic copy of the last inspection/audit report upon the request of a Sanitation Rating Officer (SRO) or FDA Milk Specialist (MS) during a rating or check rating, respectively, then the BTU's or milk plant's Enforcement Rating (ER) will be debited for the following Item:

Dairy Farm(s) (BTU):

- *Item 3-Inspection sheet posted or available*

Receiving Station, Transfer Station or Milk Plant:

- *Item 3-Inspection sheet posted or available*

NOTE: *Just having the inspection/audit reports available to a SRO or FDA MS on the Regulatory Agency's computer system does not meet the PMO requirement that the last inspection report/audit shall be either posted or available for review at the dairy farm, receiving station, transfer station or milk plant.*

If the Regulatory Agency cannot provide a hard or electronic copy of the previous inspection/audit reports upon the request of a SRO or FDA MS during the records review following a rating or check rating, respectively, then the BTU's or milk plant's ER will be debited for the following Item:

Dairy Farms (BTUs):

- *Item 11-Records systematically maintained and current*

Receiving Station, Transfer Station or Milk Plant:

- *Item 10-Records systematically maintained and current*

NOTE: *If this is an ongoing issue that the Regulatory Agency cannot provide a hard or electronic copy of required official regulatory records, this Grade "A" Milk Safety Program requirement will be identified in the next triennial State Program Evaluation. If significant enough, it could trigger a Strategic Action Plan (SAP) to be developed jointly by the State and FDA's Office of State Cooperative Programs, Division of Milk Safety.*

17. **PMO-Section 6; and Appendix B, Section I**

On dairy farms that ship milk from multiple tanks/silos on a given day, how are the PMO, Section 6 "Universal" samples to be collected? Is it required that a "Universal" sample be collected from each tank/silo; or can a composite sample of milk be taken from milk that has been collected from each tank/silo; or can the sample be collected from the individual milk tank trucks shipped that day?

A "Universal" sample shall be collected from each tank/silo shipped that is representative of the milk in the individual tank/silo. The "Universal" sample collected from each tank/silo shall accompany the individual milk tank truck to the receiving facility. A "Universal" sample cannot be a composite sample of milk collected from individual tanks/silos or collected from milk tank trucks that are shipped on a given day.

18. **PMO-Section 6; and Appendix B, Section I**

Would it be acceptable for a bulk milk hauler/sampler to officially measure the volume of milk in a dairy producer's bulk tank(s)/silo(s) using a flow meter installed either on the milk transfer hose or mounted in the rear or side compartment of a bulk milk pickup tanker? The official PMO, Section 6 "Universal" sample will be collected using established sampling methods (dipper, drip or septum sampling device) before the milk is pumped from the bulk tank(s)/silo(s) and measured through the flow meter.

Yes. The flow meter shall be of sanitary design and properly installed.

19. **PMO-Section 6; and Appendices B and J; and the EML**

Are the laboratory submission form(s) used to identify the milk and/or milk products, single-service containers and/or closures, and/or water samples, if applicable, required to remain with the samples on or within the shipping case when being shipped or may the form(s) be electronically transmitted separately to the assigned official IMS listed testing laboratory?

An electronically submitted laboratory form(s) may be used, provided that it is acceptable to the Regulatory Agency and the Milk Laboratory Control Agency. All the required and pertinent information shall be on the form(s) so that the assigned official IMS listed testing laboratory can properly identify the milk and/or milk products, single-service containers and/or closures, and/or water samples, if applicable, being received for testing.

NOTE: *The information provided on the electronically submitted laboratory form(s) shall be readily available to the Laboratory Evaluation Officer (LEO) and FDA's Laboratory Proficiency and Evaluation Team (LPET) when they are visiting the laboratories.*

20. **PMO-Section 6; and Appendix O; and MMSR-Appendix A**

Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO states that vitamin metering pumps **should** be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows. Would the lack of this interwiring be considered a violation of the PMO?

No.

21. **PMO-Section 6; and Appendix N**

In some parts of the U.S., bulk milk pickup tankers with exceptionally large capacities (100,000-120,000 lbs.), referred to as "super-tankers", are being used to collect milk from dairy farms. Due to varying vehicle weight restrictions in some states, these super-tankers need to be split into two (2) or more smaller bulk milk tank trucks (which have been previously washed and sanitized) at a transfer station prior to being dispatched over state lines.

1. Would the super-tanker of milk be required to be sampled and tested for compliance with Appendix N-Drug Residue Testing and Farm Surveillance of the PMO prior to being transferred into two (2) or more smaller bulk milk tank trucks (assuming no other commingling is done)?

   No, the only time the super-tanker would need to be sampled for Appendix N compliance is prior to further comingling of raw milk within the smaller tank trucks or just prior to processing if the super-tanker was to be received in a milk plant or receiving station.

2. When super-tankers are being split into two (2) or more smaller bulk milk tank trucks to travel out of state, would the Section 6 "Universal" dairy producer sample(s) be required to travel with the smaller bulk milk tankers going to their respective destination(s)?

No, the universal sample(s) and TC could either be retained for further laboratory testing at the transfer station were the super-tanker was split or at another location acceptable to Regulatory Agency provided the sample chain of custody is maintained for the purpose of producer trace-back.

3. What type of documentation would be required to be maintained with the two (2) or more smaller bulk milk tankers that have received milk from the super-tanker?

   The smaller tankers receiving the milk would be required to have all the applicable information as cited in Section 4-Labeling of the PMO on the shipping statement or bill of lading to include the identity of the dairy producer(s) and the IMS BTU Identification Number(s) for the farm groups represented on the super-tanker.

22. **PMO-Section 6; MMSR-Sections B, C, D and E; and EML**

How should IMS listed laboratories be reporting water (individual supply (source), pasteurized equivalent, recirculated and reclaimed) testing results?

Reporting (FDA/NCIMS 2400m Rev. 2/16):

- *Multiple Tube Fermentation (MTF) by Most Probable Number (MPN)- (Item 23)*

  - *Recirculated and Reclaimed Water (Except Category I)*
    - *Total Coliforms: **Not Found (NF)** is <1.1/100 mL*
    - *Total Coliforms: **Positive** is ≥1.1/100 mL*
    - *Total Coliforms: **Invalid** (Turbid with no gas production)*
      ***Note:** Requires same recirculated or reclaimed water system/location to be resampled, if not tested for Heterotrophic Plate Count (HPC) from the same sample.*

  - *Source, Pasteurized Equivalent Water and Category I Reclaimed Water*
    - *Total Coliforms: **Not Found (NF)** is <1.1/100 mL*
      ***Note:** E. coli is not tested; therefore. E. coli cannot be reported.*
    - *Total Coliforms: **Positive** is ≥1.1/100 mL*
      ***Note:** Requires testing for E. coli; therefore, E. coli is also reported.*
      - ✓ *E. coli: **Not Found (NF)** is <1.1/100 mL*
      - ✓ *E. coli: **Positive** is ≥1.1/100 mL*
    - *Total Coliforms: **Invalid** (Turbid with no gas production)*

Note: *Requires same source or pasteurized equivalent water system/location to be resampled, if not tested for HPC from the same sample.*

- *MTF by Presence/Absence (P/A)-(Item 23)*

  - *Recirculated and Reclaimed Water (Except Category I)*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1/100 mL*
    - *Total Coliforms:* ***Positive*** *is ≥1/100 mL*
    - *Total Coliforms:* ***Invalid*** *(Turbid with no gas production)*
      Note: *Requires same recirculated or reclaimed water system/location to be resampled, if not tested for HPC from the same sample.*

  - *Source, Pasteurized Equivalent Water and Category I Reclaimed Water*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1/100 mL*
      Note: *E. coli is not tested; therefore, E. coli cannot be reported.*
    - *Total Coliforms:* ***Positive*** *is ≥1/100 mL*
      Note: *Requires testing for E. coli; therefore, E. coli is also reported.*
      - ✓ *E. coli:* ***Not Found (NF)*** *is <1/100 mL*
      - ✓ *E. coli:* ***Positive*** *is ≥1/100 mL*
    - *Total Coliforms:* ***Invalid*** *(Turbid with no gas production)*
      Note: *Requires same source or pasteurized equivalent water system/location to be resampled, if not tested for HPC from the same sample.*

- *Membrane Filter (MF)-(Item 29)*

  - *Recirculated and Reclaimed Water (Except Category I)*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1/100 mL*
    - *Total Coliforms:* ***Positive*** *is ≥1/100 mL*
    - *Total Coliforms:* ***Invalid*** *(Too Numerous to Count (TNTC) or Confluent Growth (CG))*
      Note: *Requires same recirculated or reclaimed water system/location to be resampled, if not tested for HPC from the same sample.*

  - *Source, Pasteurized Equivalent Water and Category I Reclaimed Water*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1/100 mL*
      Note: *E. coli is not tested; therefore, E. coli cannot be reported.*
    - *Total Coliforms:* ***Positive*** *is ≥1/100 mL*
      Note: *Requires testing for E. coli; therefore, E. coli is also reported.*

- ✓ *E. coli:* ***Not Found (NF)*** *is <1/100 mL*
- ✓ *E. coli:* ***Positive*** *is ≥1/100 mL*

▪ *Total Coliforms:* ***Invalid*** *(TNTC or CG)*
Note: *Requires same source or pasteurized equivalent water system/location to be resampled, if not tested for HPC from the same sample.*

- *Heterotrophic Plate Count (HPC)-(Item 30f)*
  - ***Not Found (NF****) if < 500 CFU/mL*
  - ***Positive*** *if ≥ 500 CFU/mL*
    Note: *Equivalent to a Total Coliform positive result.*

- *Enzyme Substrate (Colilert, Colisure, and E*Colite) by P/A-(Items 33 and 40)*

  - *Source, Pasteurized Equivalent Water and Category I Reclaimed Water Only*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1/100 mL*
      Note: *Fluorescence check for presence of E. coli is not performed; therefore, E. coli cannot be reported.*
    - *Total Coliforms:* ***Positive*** *is ≥1/100 mL*
      Note: *Fluorescence check for presence of E. coli is performed; therefore, E. coli is also reported.*
      - ✓ *E. coli:* ***Not Found*** *is <1/100 mL*
      - ✓ *E. coli****: Positive*** *is ≥1/100 mL*

- *Enzyme Substrate (Colilert, Colisure, and E*Colite) by MPN-(Items 37 and 40)*

  - *Source, Pasteurized Equivalent Water and Category I Reclaimed Water Only*
    - *Total Coliforms:* ***Not Found (NF)*** *is <1.1/100 mL*
      Note: *Fluorescence check for presence of E. coli is not performed; therefore, E. coli cannot be reported.*
    - *Total Coliforms:* ***Positive*** *is ≥1.1/100 mL*
      Note: *Fluorescence check for presence of E. coli is performed; therefore, E. coli is also reported.*
      - ✓ *E. coli:* ***Not Found*** *is <1.1/100 mL*
      - ✓ *E. coli****: Positive*** *is ≥1.1/100 mL*

23. **PMO-Section 6; and MMSR-Sections C and E**

Is Grade “A” raw commingled cream that is being shipped out of a milk plant required to be sampled/tested in accordance with Section 6 of the PMO?

No.

24. **PMO-Section 6; and MMSR-Sections C and E**

a) If two (2) different flavors of milk of the same fat level, i.e., whole chocolate and whole strawberry, are sampled from the same milk plant in the same month (on different days) are the laboratory results required to be averaged and that averaged result recorded on the official regulatory ledger?

No. Samples collected on different days during any month will stand on their own and the laboratory results shall be recorded separately for the different days on the official regulatory ledger.

NOTE: *When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency or by personnel 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.*

b) If two (2) different flavors of milk of the same fat level, i.e., whole chocolate and whole strawberry, are sampled from the same milk plant on the same day are the laboratory results required to be averaged and that average recorded on the official regulatory ledger?

No. The samples of whole chocolate milk and whole strawberry milk are of the same fat level; however, they are not of the same flavored milk and/or milk product. These samples collected on the same day will stand on their own and the laboratory results shall be recorded separately on the official regulatory ledger for whole flavored milk.

25. **PMO-Section 6; and MMSR-Sections C and E**

In the latest revision of M-a-98, the only flavored milk, flavored reduced fat or low fat milk, and flavored nonfat (skim) milk that is identified as having a test method available for inhibitors that has been validated by FDA and accepted by the NCIMS is chocolate. Is chocolate required to be sampled and tested separately or can it be included in a rotational flavored milk sampling scheme

per various fat levels as recommended in previously issued M-Is addressing questions and answers?

It may be sampled and tested using a rotational flavored milk sampling scheme per various fat levels. The Regulatory Agency should be aware that for rating and check rating purposes when calculating the Sanitation Compliance Rating (SCR) and Enforcement Rating (ER), the PMO requirement is that samples of each milk plant's milk and milk products (for this scenario flavored milk at various fat levels) are collected at the require frequency and ***all necessary examination are made****. With chocolate being the only flavored milk, flavored reduced fat or low fat milk, and flavored nonfat (skim) milk with a test method available for inhibitors, whenever chocolate is sampled it shall be tested for inhibitors to be given credit.*

26. **PMO-Sections 6 and 7, Item 11p; and Appendix B**

On direct load dairy farms that use an approved in-line sampler to collect milk that is being loaded onto each milk tank truck load of milk shipped, is the bottle or container that collects the milk directly from the approved in-line sampler from which a portion of the sample contents, using aseptic techniques, are transferred to a sterile sample vial for the "Universal" sample, required to be from an IMS listed source?

M-I-06-6 (Application and Standard Operating Procedures (SOPs) for the Installation and use of Approved In-Line Samplers (ISO-LOK, Anderson Instruments and QMI) for the Collection of Dairy Farm Samples from Direct Load Tankers as Required in Section 6 of the Grade "A" PMO) states: "The sample collection container, if not single use, shall be hand washed and sanitized after each use, meet the PMO requirements, and have the State Milk Regulatory Agency approval."

If the sample collection bottle or container is single use, then it shall come from an IMS listed source. If the sample collection container is multi-use it shall meet the requirements cited under Item 11p-Construction and Repair of Containers and Equipment of the PMO and the requirements cited in M-I-06-6.

27. **PMO-Sections 6 and 7, Item 12p**

A milk plant has extended run approvals from their Regulatory Agency in consultation with FDA for three (3) of their filling/packaging lines. The PMO requires that finished milk and/or milk product produced during an extended run shall meet all applicable requirements of Section 7-Standards for Grade "A" Milk and/or Milk Products of the PMO. The current extended run approvals

have the milk plant testing finished milk and/or milk product for coliform once an hour once the milk plant hits the twenty-four (24) hour mark on the individual filler/packaging line. The milk plant wishes to switch to Enterobacteria testing, which according to the milk plant picks up all coliforms plus certain pathogens, from the PMO required coliform testing. Will this testing for Enterobacteria meet Section 7 requirements of the PMO for coliform testing?

No. There currently are not any provisions in the Grade "A" Milk Safety Program for the recognition to test for Enterobacteria in place of the PMO required testing for coliforms. Both are indicators of sanitation and some would say testing for Enterobacteria would give a better possible indication of the presence of gram negative pathogens.

If the milk plant chooses to test for Enterobacteria in addition to the PMO required testing for coliforms that would be acceptable; however, to outright substitute to test for Enterobacteria for the required PMO coliform testing would not be acceptable.

28. **PMO-Section 7, Items 3r and 4r**

a) If the holding area for dairy animals directly off the milking area (barn, stable or parlor) is completely separated from the milking area during non-milking times and the holding area is observed to be dirty with excessive manure, would this holding area be debited under Item 3r-Milking Barn, Stable or Parlor – Cleanliness or Item 4r-Cowyard?

Item 4r-Cowyard.

b) If the holding area for dairy animals directly off the milking area (barn, stable or parlor), as cited in a) above, is open to the milking area during milking times and the holding area is observed to be dirty with excessive manure, would this holding area be debited under Item 3r-Milking Barn, Stable or Parlor - Cleanliness or Item 4r-Cowyard?

Item 4r-Cowyard.

c) If the holding area for dairy animals opens directly into the milking area (barn, stable or parlor) without any means to completely separate the two, i.e., a milking area without four (4) walls extending from the floor to the ceiling, and the holding area during non-milking and/or milking times is observed to be dirty with excessive manure, would this holding area be debited under Item 3r-Milking Barn, Stable or Parlor - Cleanliness or Item 4r-Cowyard?

Item 3r-Milking Barn, Stable or Parlor – Cleanliness.

29. **PMO-Section 7, Item 8r**

A large dairy farm wants to add technical grade potassium permanganate to reduce iron in their water prior to a reverse osmosis (RO) water treatment system. Would technical grade potassium permanganate be allowed for this use on a Grade "A" dairy farm?

Yes. EPA regulates the use of chemicals such as potassium permanganate when used in water treatment systems. EPA does not prohibit or limit the use of potassium permanganate including technical grade in water treatment systems (including those used to treat water prior to reverse osmosis). EPA did note that oxidants including potassium permanganate when used in water treatment may form byproducts that may be regulated under the National Primary Drinking Water Regulations and that use of an oxidant in water prior to Reverse Osmosis, or any membrane treatment, could have a negative impact on the membranes.

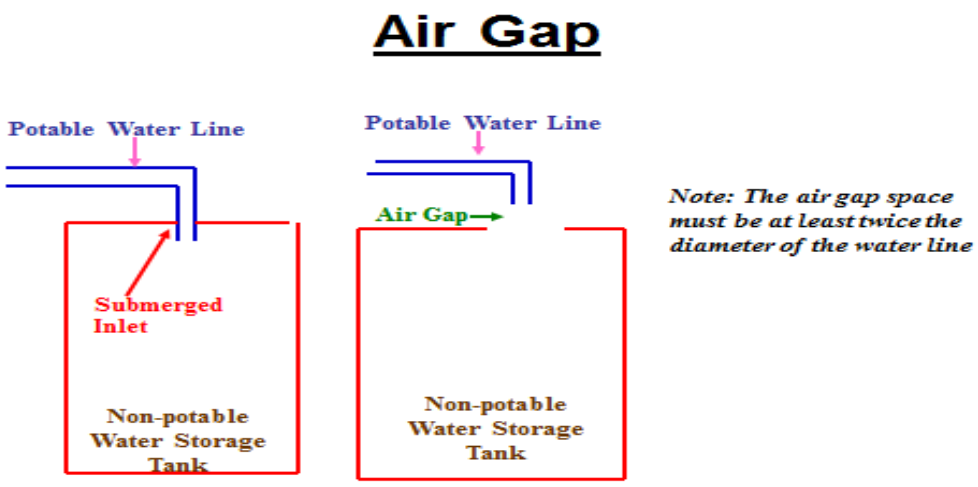
30. **PMO-Section 7, Items 8r and 7p**

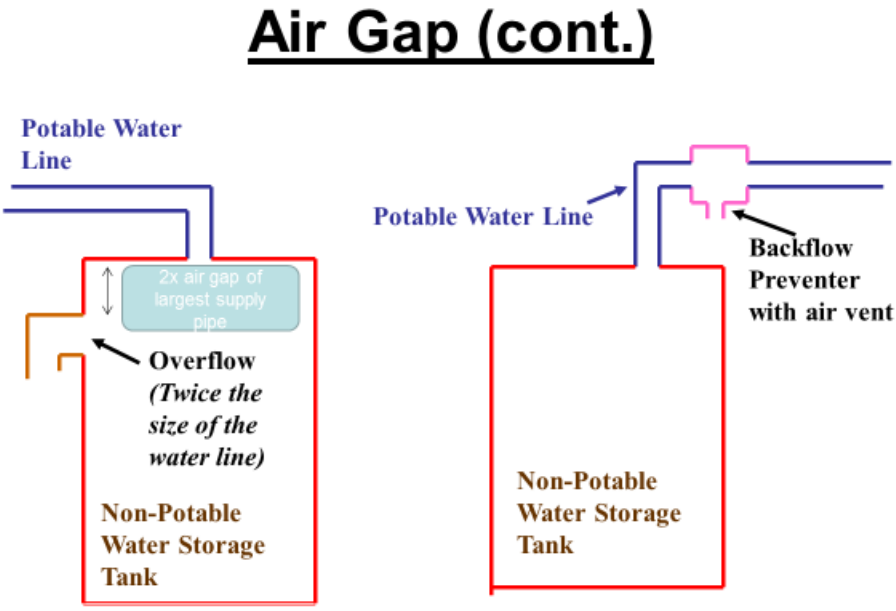
Please explain an approved air gap and the size of an effective overflow when required.

An approved air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle. The distance of the air gap is to be measured from the bottom of the potable inlet supply pipe or faucet to the top of the effective overflow, i.e. flood rim or internal overflow, of the vessel. In no case, may the effective air gap be less than 1 inch (2.54 centimeters).

An overflow would not be required, provided the air gap is located above the flood level of the vessel. However, if the water supply pipe or faucet were to extend below the flood level of the vessel, an effective overflow or an approved mechanical backflow prevention device would be required. An effective overflow would be considered an opening/pipe that is at least twice the diameter of the largest incoming water supply pipe or faucet (or multiple openings/pipes having the equivalent surface area) with the top of the overflow pipe located at least twice the diameter of the largest incoming water supply pipe or faucet below the water supply pipe or faucet.

An approved air gap is shown in the following illustrations:





31. **PMO-Section 7, Item 11r**

A dairy farm would like to use potable water which has been chilled through a plate heat exchanger to cool product contact surfaces of a raw milk silo, bulk milk tank or bulk milk pickup tanker following sanitization and prior to filling. Would this process be permitted?

No. Item 11r-Utensils and Equipment – Sanitization of the PMO requires that all product-contact surfaces of multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized

before each usage. Sanitization of multi-use containers, equipment and utensils used in the handling, storage or transportation of milk as required does not allow for the rinsing of multi-use containers, equipment and utensils following sanitization. Therefore, this potable water which has been chilled through a plate heat exchanger would have to contain an EPA registered sanitizer at the appropriate concentration for the sanitizer that is being used, for an appropriate contact time, for the required sanitization of the silo, bulk milk tank or bulk milk pickup tanker before each usage as required by the PMO.

32. **PMO-Section 7, Item 14r; and Appendix B**

Are tobacco products permitted to be used in the milkhouse on a dairy farm?

The use of tobacco products by dairy farm personnel within the milkhouse is not specifically addressed in the PMO. If it is observed that direct contamination of the milk or milk product-contact surfaces is occurring, then this would be considered a violation of Item 14r-Protection from Contamination of the PMO.

NOTE: *The use of any tobacco products by dairy farm personnel within the milkhouse or milking area should be discouraged.*

Appendix B-Milk Sampling, Hauling and Transportation of the PMO states that bulk milk hauler/samplers shall not use tobacco in the milkhouse. If a bulk milk hauler/sampler is observed using tobacco in the milkhouse this would be debited under 3-Clean outer clothing, no use of tobacco of FORM FDA 2399a-Bulk Milk Hauler/Sampler Evaluation Report.

33. **PMO-Section 7, Item 15r**

May silver sulfadiazine cream, an approved human prescription (Rx) drug, which is labeled for topical use only, be used on dairy animals and/or be stored on a Grade "A" dairy farm?

Silver sulfadiazine cream, is a sulfonamide drug that is prohibited from extra-label use on lactating or dry dairy cattle. If properly extra-labeled by a licensed veterinarian for dairy animals less than twenty (20) months of age it can be stored on a Grade "A" dairy farm and would be required to be stored with the "Non-lactating Drugs". If found on the dairy farm and it is not properly extra-labeled by a licensed veterinarian for use as cited above, it would be considered a violation of Item 15r-Drug and Chemical Control of the PMO and would be debited under Item 15(e) on FORM FDA 2359a-Dairy Farm Inspection Report (five (5) point debit). If properly extra-labeled for dairy

animals less than twenty (20) months of age and is stored with the "Lactating Drugs", it would be considered a violation of Item 15r of the PMO and would be debited under Item 15(c) on FORM FDA 2359a (two (2) point debit).

34. **PMO-Section 7, Item 15r**

a) May "Keto-Treat" (propylene glycol) be used on dairy cattle for the prevention and treatment of bovine ketosis (acetonemia) if the label indicates for "Veterinary use Only"?

Yes. FDA's Center for Veterinarian Medicine (CVM) has determined that Keto-Treat (propylene glycol) is intended for use in the mitigation, treatment, or prevention of diseases in animals, which makes it a drug under section 201(g)(1)(B) of the FFD&C Act [21 U.S.C. § 321(g)(1)(B)]. Furthermore, this product is an unapproved new animal drug; however, there are currently no new animal drugs approved to treat bovine ketosis. Due to the seriousness of the condition in dairy cattle and the low risk of drug residues from the use of this product, CVM has historically not taken action regarding the marketing and sale of propylene glycol for this intended use. Therefore, it would not be considered a violation of Item 15r of the PMO and would not be debited on ratings or check ratings as long as it meets the labeling requirements of Item 15r of the PMO and the following are met.

b) Would the propylene glycol used in the "Keto-Treat" be required to be "USP" or "Food Grade"?

Yes.

c) Would the label on the "Keto-Treat" be required to state that the propylene glycol is "USP" or "Food Grade"?

No.

d) If the label on the "Keto-Treat" does not state that the propylene glycol is "USP" or "Food Grade", is the dairy producer required to have a letter from the manufacturing company of the "Keto-Treat" stating such?

Yes.

e) May the letter with the letterhead of the manufacturing company that states that the propylene glycol is "USP" or "Food Grade" be signed by a sales person who only distributes the product?

No. The letter should be signed by a representative of the manufacturing company that has the knowledge and the authority to make such a claim for the manufacturing company. Examples of manufacturing company's representatives that have signed such letters include directors/supervisors of quality assurance or quality control; directors/supervisors of research and development; vice president of operations; a sales person who is directly employed by the manufacturing company and has the authority to make such claim; or the president/CEO of the manufacturing company.

35. **PMO-Section 7, Item 18r**

A dairy farm is considering injecting ozone into their recirculated glycol cooling water system. Does the PMO allow for this practice?

Yes.

36. **PMO-Section 7, Items 18r and 17p**

a) May "Keto-Treat" (propylene glycol) that has "USP" and "For Veterinary Use Only" on the label of the container be used in recirculated cooling water systems on a dairy farm or in a milk plant?

Yes. The labeling on the container of the propylene glycol identifies the product as "USP" or "Food Grade" or contains a statement that all ingredients (components) are "GRAS"; therefore, this product would be acceptable without an additional letter stating that fact. However, if the label on the container does not contain that information, then either the Safety Data Sheet (SDS) or a letter on the letterhead of the manufacturing company shall contain one (1) of the above appropriate statements to be acceptable for use on a dairy farm or in a milk plant.

b) May a letter with the letterhead of the manufacturing company that states that the propylene glycol is "USP", "Food Grade" or that all ingredients (components) are "GRAS" be signed by a sales person who only distributes the product?

No. The letter should be signed by a representative of the manufacturing company that has the knowledge and the authority to make such a claim for the manufacturing company. Examples of manufacturing company's representatives that have signed such letters include directors/supervisors of quality assurance or quality control; directors/supervisors of research and development; vice president of operations; a sales person who is directly employed by the manufacturing company and has the authority to make such claim; or the president/CEO of the manufacturing company.

37. **PMO-Section 7, Items 5p and 15p(A)**

Are packaged non-Grade “A” dried milk and/or milk products and/or non-Grade “A” dried whey and/or whey products that are stored in the same warehouse as packaged Grade “A” dried milk and/or milk products and/or Grade “A” dried whey and/or whey products required to be located in an area that is specifically designated and labeled as non-Grade “A”?

No.

38. **PMO-Section 7, Items 11p and 12p; and Appendix J**

A milk plant informs the routine regulatory inspector that they consider the glass containers that they are using to package Grade “A” milk and/or milk products to be multi-use containers. However, upon inspection, the milk plant treats these glass containers like single-service glass container as they do not have any means to receive the used glass containers back into the milk plant, clean and sanitize the used glass containers, nor do they have plans to receive or re-use the glass containers. Would these glass containers be considered multi-use or single-service?

These glass containers would be considered single-service and shall comply with Item 11p-Construction and Repair of Containers and Equipment, Item 12p-Cleaning and Sanitizing of Containers and Equipment, and Appendix J and shall come from an IMS listed source.

39. **PMO-Section 7, Items 11p and 18p**

Is it acceptable to use a ball valve on a Grade “A” bottling/packaging machine as a fill valve?

Yes. The ball valve shall be of a sanitary design and construction, installed so that it is readily accessible and removable for inspection, and the valve is manually cleaned after each usage.

40. **PMO-Section 7, Item 15p(A)**

Does the wash/cleaning solution connection or the hose attached to a tank/silo agitator used to specifically clean the agitator shaft that are designed to be cleaned-in-place (CIP) required to be capped or protected after the completion of the cleaning of the tank or silo?

No.

41. **PMO-Section 7-Item 15p(A)**

Item15p-Protection from Contamination (A) of the PMO states, “15. In the case of, a water rinse after processing non-Grade “A” and prior to Grade “A” is adequate separation, provided both are processed as Grade “A”, and raw and pasteurized milk or milk products are kept physically separated”.

Does the reference to non-grade “A” apply to juice, tea and similar non-dairy beverages?

Yes.

42. **PMO-Section 7, Item 15p(A)**

What Item on FORM FDA 2359-Milk Plant Inspection Report would be debited when there is milk or milk product residue observed in an air blow device between the final air filter and the required sanitary check valve?

Only Item 12-Cleaning and Sanitizing of Containers and Equipment (a)-Containers, utensils and equipment clean.

43. **PMO-Section 7-Item 15p(A); and Appendix H-Section III**

a) Appendix H, III-Culinary Steam-Milk and Milk Products of the PMO states: “Only compounds complying with 21 CFR 173.310 may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal.” It also states: “Boiler compounds containing cyclohexylamine, morpholine, octadecylamine, diethylaminoethanol, trisodium nitrilotriacetate, and hydrazine shall not be permitted for use in steam in contact with milk and milk products.” What are the conditions and limitations cited in 21 CFR 173.310 for the six (6) boiler compounds addressed above for use in a milk plant?

The following answer was provided by FDA’s Office of Food Additive Safety (OFAS):

In 21 CFR 173.310 (d) it states the following:

Substances	***Limitations***
Cyclohexylamine	*Not to exceed 10 parts per million in steam and excluding use of such steam in contact with milk and milk products.*
Diethylaminoethanol	*Not to exceed 15 parts per million in steam and excluding use of such steam in contact with milk and milk products.*
Hydrazine	*Zero in steam.*

Morpholine	*Not to exceed 10 parts per million in steam and excluding use of such steam in contact with milk and milk products.*
Octadecylamine	*Not to exceed 3 parts per million in steam and excluding use of such steam in contact with milk and milk products.*
Trisodium nitrilotriacetate	*Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with milk and milk products.*

FDA/OFAS interprets this regulation to prohibit the use of these six boiler water additive compounds (cyclohexylamine, diethylaminoethanol, hydrazine, morpholine, octadecylamine, and trisodium nitrilotriacetate) from use in the production of milk and milk products. The above table explicitly states that these compounds are excluded from use in steam that contacts milk and milk products. FDA/OFAS believes the safety of these six compounds have not been evaluated for the population of milk and milk product consumers, and as such if anyone would like to use these compounds in milk or milk products, they are required to receive premarket authorization and should submit a food contact notification (FCN) submission to FDA. More information on how to submit a FCN may be found at:

https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm

b) Are the conditions and limitations for use of these six (6) boiler compounds in steam that will be in contact with milk and milk product ***contact surfaces*** the same as for steam that will contact milk or milk products?

FDA shares jurisdiction with EPA on food processing equipment/migrants from food processing equipment. However, if the six boiler water additive compounds stated above were used on food contact surfaces during production and migrated to the food, this would be considered adulteration under 402(a) of the Federal Food, Drug, and Cosmetic Act. Therefore, FDA/OFAS recommends that these six boiler water additive compounds not be used on any surface that contacts milk or milk products.

c) Do these conditions and limitations apply to steam used to indirectly heat milk or milk products through a plate or tubular cooler in which the steam would only be in contact with the milk or milk product if the plate or tubular heat exchanger leaks?

Because these plate or tubular heat exchangers have the potential to leak, FDA/OFAS recommends that you do not use these six boiler water additives in these plate or tubular heat exchangers as when they leak they will

adulterate (as defined in the Federal Food Drug and Cosmetic Act Section 402) the milk or milk products with which they come into contact.

FDA's review of this inquiry was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

44. **PMO-Section 7, Item 15p(B); and Appendix H-Section IX**

a) A milk plant plans to treat their water supply utilizing only a UV light system to produce pasteurized equivalent water. Would this UV light system have to comply with the criteria cited in Appendix H, Section IX-Accepted Process for the Creation of Pasteurized Equivalent Water, UV Light Disinfection of Water of the PMO?

Yes.

b) A milk plant plans to treat their water supply utilizing a combination of processes, which includes a UV light system that is used to mitigate or control potential hazards to produce pasteurized equivalent water. Would this UV light system have to comply with the criteria cited in Appendix H, Section IX-Accepted Process for the Creation of Pasteurized Equivalent Water, UV Light Disinfection of Water of the PMO?

No.

NOTE: *The milk plant would be required to conduct a hazard evaluation and safety assessment of the specific water supply and treatment involved to destroy or remove bacteria, which would be acceptable to the Regulatory Agency in consultation with FDA to ensure that the water will not compromise the safety of the milk or milk products in accordance with Item 15p-Protection from Contamination (B) of the PMO.*

45. **PMO-Section 7, Item 15p(B) and Appendix L**

May a cheese plant that receives Grade "A" milk and is IMS listed to sell Grade "A" cream perform a water flush in order to flush raw milk from the bulk milk tankers to the raw milk silos?

Yes. Provided the cheese plant takes appropriate actions to prevent the dilution or adulteration of milk with added water. Please refer to M-I-04-6 (Question 46) in relationship to Grade "A" milk plants.

46. **PMO-Section 7, Item 16p(B); and Appendix H**

Variable frequency drives (VFDs) are used to control the speed of various pumps within continuous flow HTST or higher-heat-shorter-time (HHST) pasteurization systems, including ones that utilize a magnetic flow meter based timing system (MFMBTS). May the VFDs have communication ports that are interconnected to a telecommunication data network?

Yes. Proposal 130 passed at the 2017 NCIMS Conference added requirements for a "data network" to Appendix H, Section VI-Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of the PMO. A data network is a telecommunication network that allows networked computing devices to exchange data with each other. Multiple devices, including solenoids, motor controls and VFDs, may be connected through a data network dedicated to the HTST or HHST pasteurization system.

a) When a data network is used, any electronic switching equipment (switches, routers, hubs, etc.) associated with the data network shall be placed in an enclosure sealed by the Regulatory Agency.
b) Non-public health computers and/or devices that are not associated with the public health control functions of the individual pasteurization system shall not be connected to the data network.
c) In the case of devices that have the capability to be electronically reprogrammed to disable or modify regulatory limits, this functionality shall be disabled by a hardware switch that has been sealed by the Regulatory Agency.
d) All data network cables or ports enabling connectivity to the public health computer shall be sealed by the Regulatory Agency to prevent any other device connection.

47. **PMO-Section 7, Item 16p(B); and Appendices H and I**

A milk plant is building a pilot plant and wants to install a pasteurization system that is designed and operated to process typical HTST pasteurized, extended shelf-life (ESL) and aseptic milk and milk products. For flexibility purposes, the pasteurization system's holding tube can be manually adjusted (lengthen or shortened) depending upon the type of milk and/or milk product being processed. Is this type of pasteurization system acceptable?

The Grade "A" Milk Safety Program requirements would not be associated with a pilot plant that is using a pasteurization system to process and package milk and/or milk products for research and development (R&D) purposes only, such as analytical testing, shelf-life studies, employee taste testing, processing parameter experimentation, batch formulation testing, etc. However, if the milk and/or milk products that were processed on this

pasteurization system and packaged in the pilot plant are used for general consumer consumption, such as consumer taste panels, in-store demos, trial runs for limited distribution, etc., the Grade "A" pasteurized (HTST, HHST or Ultra-pasteurized (UP)) milk and/or milk products shall comply with all of the applicable requirements of the PMO and the Grade "A" aseptic milk and/or milk products shall comply with all of the applicable requirements of the NCIMS Aseptic Program (AP) (21 CFR Part 113). When the pasteurization system is modified to process Grade "A" pasteurized (HTST, HHST or UP) milk and/or milk products it shall be properly configured and operated in accordance with Item 16p-Pasteurization, Aseptic Processing and Packaging, and Retort Processed after Packaging, Appendix H, and Appendix I-Pasteurization Equipment and Controls – Tests of the PMO.

48. **PMO-Section 7, Item 16p(B); and Appendices H and I**

When programming the Honeywell DR4500A Truline Series HTST, Safety Thermal Limit Recorder (STLR) and Pasteurization Flow Circular Chart Recorder/Controller, is the "header" required to be turned off during the Chart Configuration process?

M-b-346 (Honeywell DR4500A Truline Series HTST, STLR and Pasteurization Flow Circular Chart Recorder/Controller), issued March 30, 2004, does not specifically state that the "header" shall be turned off. However, 7.9-Locking and Sealing the Recorder, Step 6 of the Chart Configuration Table noted on page 9 of M-b-346 states: "You can ignore this, since no header is to be used." Step 7 states: "The upper display should read NO." These statements would imply that the "header" needs to be turned off during the Chart Configuration process.

49. **PMO-Section 7, Item 16p(B); and Appendix I**

Do the minimum required legal pasteurization temperatures for milk and milk products as cited in the PMO need to be adjusted due to an elevation change below or above sea level?

No.

50. **PMO-Section 7, Item 16p(D); and MMSR-Section E**

Does the PMO or MMSR require that the signature of the Regulatory Agency personnel that is conducting the quarterly pasteurization equipment testing be on FORM FDA 2359b-Milk Plant Equipment Test Report or an equivalent Form utilized by the Regulatory Agency?

No. However, the name of the Regulatory Agency personnel that is conducting the quarterly pasteurization equipment testing is required to be on the form utilized by the Regulatory Agency. In lieu of the required name, a signature or electronic signature would be acceptable, but is not required.

51. **PMO-Section 7, Item 17p**

Within Item 17p-Cooling of Milk and/or Milk Products of the PMO, under the section for cooled immediately prior to filling or packaging, a distinction is made for milk to be cultured and cultured buttermilk ("at all milkfat levels with a pH of 4.60 or below*"). However, under the section for the required storage temperature following filling, it states cultured buttermilk at all milkfat levels with a pH of 4.60 or below needs to be cooled to 7^0C (45^0F) within twenty-four (24) hours of filling.

a) Is this limited only to cultured buttermilk that has been cultured in a tank (vat) that upon reaching a pH of 4.60 or below, needs to be cooled to 7^0C (45^0F) within twenty-four (24) hours of filling? The cultured buttermilk is usually filled at 22^0-30^0C (72^0-86^0F). Does the clock start when the pH reaches 4.60 or when it is filled?

Cultured buttermilk cultured in a tank (vat) with a pH higher than 4.60 at the time of filling/packaging is required to be immediately cooled to 7 ^{0}C (45 ^{0}F) or less <u>prior</u> to filling or packaging and maintained thereat following filling. By not meeting the initial pH level of 4.60 at filling/packaging, the cultured buttermilk would not meet the initial criteria to fill/package the cultured buttermilk above 7 ^{0}C (45 ^{0}F).

<u>NOTE:</u> *For tank (vat) set cultured buttermilk, a pH of 4.60 or below shall be obtained prior to filling/packaging to not have the cultured buttermilk be immediately cooled to 7 ^{0}C (45 ^{0}F) or less prior to filling/packaging. By obtaining this initial pH of 4.60 or below at filling/packaging the cultured buttermilk can be filled/packaged above 7 ^{0}C (45 ^{0}F) and shall reach a temperature of 7 ^{0}C (45 ^{0}F) or less within twenty-four (24) hours of filling/packaging to meet the cooling temperature exception for cultured buttermilk cited within Item 17p of the PMO.*

b) What about cultured buttermilk that has been filled/packaged prior to reaching a pH of 4.60 and then cultured in the package/container (cup set)? Would the twenty-four (24) hour clock start when the cultured buttermilk in the package/container (cup set) reaches a pH of 4.60?

Yes. Cultured buttermilk cultured in a package/container (cup set) at a pH higher than 4.60 at the time of filling or packaging for culturing in the

package/container (cup set) is not required to be immediately cooled to 7°C (45°F) or less prior to filling or packaging. However, when the cultured buttermilk in the package/container (cup set) reaches a pH of 4.60, the cultured buttermilk shall reach a temperature of 7°C (45°F) or less within twenty-four (24) hours to meet the cooling temperature exception for cultured buttermilk cited within Item 17p of the PMO.

52. **PMO-Section 7, Item 17p**

Please clarify the following statement in M-I-15-3 (Questions and Answers Received from the Field: Regional Milk Seminars; and FDA Training Courses Held During Fiscal Year 2013) (Question 57):

b) Do the remaining exemptions cited in Item 17p of the PMO (2-Cultured Sour Cream; 3-Acidified Sour Cream; 4-All Yogurt Products; 5-Cultured Buttermilk; and 6-Cultured Cottage Cheese) only include pasteurized milk and/or milk products that are cultured and set in a processing vat, tank or vessel, "vat set", prior to filling and; therefore, are required to meet the specific pH and/or temperature and/or container size criteria when the products are filled at temperatures above 7ºC (45ºF)?

No. This would also apply to "cup set" cultured milk and/or milk products and would require that these cultured milk and/or milk products meet the specified exemption requirements cited in Item 17p of the PMO for the applicable cultured milk and/or milk product.

Does this indicate that only compliance with the specified pH and remaining cooling timelines apply?

Yes. b) above is asking if the specified pH and cooling requirements apply only to "vat set" cultured products. That answer is "No. However, for "cup set" cultured milk and/or milk products following the completion of incubation in the cup and placement of the "cup-set" cultured milk and/or milk product into storage for cooling, the "cup-set" cultured milk and/or milk product shall meet the specified pH and cooling timeline requirements for that applicable "cup-set" cultured milk and/or milk product. For "cup set" cultured milk and/or milk products, when the pH meets the level for the specific cultured milk and/or milk product cited in Item 17p of the PMO then the specific cooling timeline determination begins.

53. **PMO-Section 7, Item 18p**

A milk plant is looking into injecting ozone into their plastic bottles prior to filling as a means to extend the shelf-life of their milk and/or milk products. Does the PMO allow for this practice?

Yes.

54. **PMO-Appendix D**

a) Is it permissible to treat "cow water" with an EPA registered sanitizer that contains peroxyacetic acid such that water reclaimed from milk and milk products can be used for Category I potable water purposes?

Yes.

b) Which other chemicals may be used to treat “cow water” to produce Category I reclaimed water?

EPA registered sanitizers are permitted to be used as a part of a “cow water” treatment program provided the treatment program “shall produce a safe supply as determined by bacteriological testing”. In addition, Appendix D-Standards for Water Sources, Section IV-Continuous Water Disinfection of the PMO describes a process of Ultraviolet Light Disinfection of Water that can be used to provide Category I “cow water”.

55. **PMO-Appendix H, Section II**

What micron size is equivalent to a final filter efficiency of at least 99% as measured by the Dicotylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns) as cited in Appendix H, Section II-Air for Drying Equipment and Air Under Pressure – Direct Contact with Milk and Milk Products and Milk-Product Contact Surfaces, Air Under Pressure – Milk Product-Contact Surfaces, Filter Performance of the PMO?

There is not an appropriate correlation between micron size and a final filter efficiency of at least 99% as measured by the DOP test with a mean particle diameter of 0.3 microns. The DOP test is a standard test developed by the military to challenge filter media with the most difficult particle to capture. Dioctylphthalate is oil that is aerosolized into 0.2 to 0.3 micron sized particles. By measuring the particle concentration both upstream and downstream of the filter media, the filter media retention efficiency can be determined. Retention efficiency is generally represented by percent (%) removal of the DOP aerosol.

56. **PMO-Appendix J, Sections C and D-Items 18 and 19**

A single-service container manufacturer is producing polyethylene terephthalate (PET) pre-forms. They will dump these pre-forms into a tote and

the pre-forms will be fed into a molding unit to make either pint or ½ pint plastic bottles in their final form. These formed plastic bottles will then be placed into another tote. Subsequently, these formed plastic bottles will be hand stacked and placed in a plastic overwrap (bag).

May these single-service formed plastic bottles be stacked and bagged by hand or are they required to be handled and bagged by mechanical means?

The PMO states: "...handling container and/or closure surfaces shall be kept to a minimum". As long as this form of handling operation/practice as described above will keep the handling of milk product-contact surfaces of the formed plastic bottles at a minimum it will be acceptable. Handlers shall sanitize their hands frequently or wear clean, single-use gloves.

57. **PMO-Appendix J, Section D-Item 15**

Appendix J-Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products, Item 15-Fabrication Equipment of the PMO requires that storage tanks, silos, gaylords or bins used for plastic resins shall be so constructed to protect the resin from contamination. All air vents shall be filtered to prevent the entrance of dust, dirt or insects. This Item also applies to all raw material handled in a like manner.

a) Are screens instead of filters acceptable for openings and air vents on resin storage tanks/silos/bins located either inside or outside the fabrication plant?

No.

b) Are screens instead of filters acceptable for openings and air vents on train cars if the openings and air vents are protected from rain?

No.

c) Are screens instead of filters acceptable for openings and air vents in a regrind room?

No.

58. **PMO-Appendix N**

When can a bulk milk pick up tanker be re-sampled and retested for drug residue testing results?

Please refer to Appendix N, III-Testing Program for Drug Residues Established, Bulk Milk Pickup Tanker and/or Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Test, 3-Re-Sampling of the PMO for circumstances, where the Regulatory Agency may allow the industry to re-sample and retest the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. Specific circumstances may include an error in sampling, or a suspicious test result is discovered, or the Regulatory Agency has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices. The reasons that made the re-sampling and retesting necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

59. **PMO-Appendix P**

Under the Inspection Interval and Criteria, Minimum One (1) Year Inspection Interval; Minimum Six (6) Month Inspection Interval; and Minimum for Four (4) Month Inspection Interval within Appendix P-Performance Based Dairy Farm Inspection System of the PMO it states the following:

No "Critical control point" violations observed during farm inspections. Critical violations are identified on FORM FDA 2359a as:

a. 10-Cleaning and 11-Sanitization;
b. 15(d)-Drugs properly labeled and 15(e)-Drugs properly used and stored; and
c. 18-Cooling (Significant Violations);

The text suggests that a, b, and c (all three (3) combined) are required for it to be considered a “critical control point” violation. I don’t think that was intended. It makes sense that it might require 10 and 11, however requiring both 15d and 15e seems incorrect as each of those individually can be considered “critical control point” violations.

Would you please clarify the intent of the word “and” in each of the cases above (a., b., and c.)?

“Critical control points” violations would be considered as any violations of the following sanitation Items from FORM FDA 2359a:

- *Items 10 and 11; or*
- *Item 15(d); or*
- *Item 15(e); or*

- *Item 18 (a-b).*

60. **PROCEDURES-Section III; and MMSR-Section A**

A FDA certified SRO is also certified by USDA to conduct USDA surveys in milk plants that have elected to participate in the USDA Agriculture Marketing Service (AMS) voluntary plant survey program.

a) If this person conducts a USDA survey in an IMS listed milk plant, will he/she be required to wait two (2) years before performing an IMS rating of the same milk plant as is customarily required for a SRO to perform an IMS rating of a Grade "A" milk plant where they conducted routine Grade "A" regulatory inspections?

No. These are two (2) separate inspections operating within two (2) very distinct and separate programs overseen by USDA and FDA, respectively.

b) Can a USDA survey and an IMS rating be performed simultaneously at the same milk plant?

No. These are two (2) very distinct and separate programs overseen by USDA and FDA, respectively.

61. **PROCEDURES-Section VI**

Does the *Procedures* require that the re-certification of a SRO be conducted during check ratings? Or can the re-certification be conducted during mock dairy farm or milk plant inspections? Or both?

While it is preferable to be conducted during check ratings to save money for both the Regulatory Agency and FDA, it is not mandatory. The re-certification of a SRO can be either conducted during check ratings, mock inspections or utilizing both.

NOTE: *The initial certification of a new SRO cannot be conducted during check ratings.*

62. **PROCEDURES-Section VI**

If a FDA certified Sampling Surveillance Officer (SSO) fails to work with a FDA MS to be recertified by the expiration date cited on their most current SSO certificate, what procedure, is required to be conducted for the re-certification of the SSO? Is the requirement that of a new SSO or would it be that of the re-certification of an SSO?

- *If it was the fault of the FDA MS because he/she could not complete the re-certification prior to the expiration date of the SSO's current certification, then the FDA MS would follow the procedures for the re-certification of a SSO as cited in the Procedures.*
- *If the issue for not being able to be re-certified in the time frame required was based on health issues of the SSO, then the FDA MS would follow the procedures for the re-certification of a SSO as cited in the Procedures.*
- *If it was the fault of the SSO or Regulatory Agency for not making the time to be re-certified in the time frame required, then the FDA MS would follow the procedures for the initial certification of a SSO as cited in the Procedures.*

63. **PROCEDURES-Section IV**

One of PHS/FDA's responsibilities within the *Procedures* is to conduct a triennial written program evaluation of the IMS Program administered by each member State and TPC, respectively. FDA worked with the NCIMS Liaison Committee to develop and identify Minimum State Program Evaluation Requirements and Criteria as cited on page 14 of M-I-03-12 (Updated State Program Evaluation Report General Guidelines and Format and the Addition of Minimum State Program Evaluation Requirements and Criteria and State Program Evaluation Resolution Process (Supplement 1), issued March 6, 2007. Within the Minimum State Program Evaluation Requirements and Criteria, the following are identified with an asterisk (*), which triggers a Strategic Action Plan (SAP) to be jointly developed by the FDA Region and the State if the percent Compliance falls below the identified level:

1. **Regulatory Authority**
   a. State regulations equivalent to Pasteurized Milk Ordinance (Must have the PMO adopted or equivalent regulations for not more than six (6) years prior to the most recent Conference)*

3. **Dairy Plant Program** (All must be 90% Compliance or greater) (b. and e.)*
   a. Licenses/permits issued
   b. Inspection frequency maintained
   c. Product sample frequency maintained
   d. Water sample frequency maintained
   e. HTST equipment testing frequency maintained
4. **Appendix N Program**
   a. Bulk milk pickup tankers sampled and tested as required (Must be 100% Compliance)*
   b. 10% sampling program or equivalent maintained (Must be 90% Compliance or greater) *

9. **Compliance and Enforcement Actions Appropriate** (Use Enforcement Ratings from Check Ratings for farms and plants – 90% Compliance or greater.)*

a. State has established compliance and enforcement procedures for the above listed state program requirements and is following them.

The Minimum State Program Evaluation Requirements and Criteria also states: "Other program requirements not meeting the minimum criteria should lead to a discussion of corrective action between the FDA Region and the State, which may include the development and implementation of a Strategic Action Plan."

If one (1) or more of the Minimum State Program Evaluation Requirements and Criteria identified with an asterisk (*) or other program requirements not meeting the minimum criteria which includes the development and implementation of a SAP is identified on a triennial State Program Evaluation would the State be classified as "Not in Compliance" with the IMS Program?

Yes.

64. **PROCEDURES-Section IV**

a) What is the time frame for a rating of a milk shipper that is currently on the IMS List to be completed?

The Procedures requires that the Rating Agency shall keep current the ratings of all IMS listed milk shippers within its State or a Third Party Certifier's (TPC's) jurisdiction. A new rating needs to be completed and submitted for publication on the IMS List prior to the expiration date of the current IMS listing on the IMS List.

b) If a rating is started before their IMS listing expiration date, is it allowed for the SRO to continue with the rating after the IMS listing expiration date?

It is not recommended but yes. The milk plant, receiving station, transfer station or dairy farm inspection(s) shall continue without any interruption for the consecutive days required to complete the milk plant, receiving station, transfer station or required number of dairy farm inspections for the rating. Please note that for an IMS listing, if a new rating is not completed and submitted for publication it will expire on the expiration date cited on the IMS List.

Scenario: A rating was started before their IMS listing expiration date. A month after the expiration date the rating is still not completed.

a) Would the rating be allowed to continue following a month of inactivity or shall a new rating be conducted and for a BTU a new random selection of dairy farms be made?

A new rating shall be conducted and for a BTU a new random selection of dairy farms shall be made.

b) What Regulatory Agency action would be required to be taken with this scenario?

The Regulatory Agency shall immediately notify the milk shipper and any receiving IMS listed milk plant, receiving station and/or transfer station within the State or a TPC's jurisdiction, all known receiving States and FDA that this milk shipper is no longer on the IMS List because the State failed to complete a rating prior to the current IMS listed BTU's expiration date as cited on the IMS List.

c) What FDA action would be required to be taken with this scenario?

FDA will immediately remove the milk shipper from the IMS List.

65. **PROCEDURES-Section IV; and MMSR-Sections B, C and D**

For a SRO to conduct a rating of a BTU; or a rating or NCIMS HACCP audit of a receiving station, transfer station or milk plant; or certification of a single-service containers and/or closures manufacturing facility that they previously had direct responsibility for the routine inspection, and/or equipment testing for pasteurization systems and enforcement or regulatory auditing of the milk shipper to be rated, audited or certified for IMS listing, what are the restrictions on the SRO, if any?

During the time period of the required official Regulatory Agency's records review for the rating, listing or certification, none of the routine inspections, and/or equipment testing for pasteurization systems and routine enforcement or regulatory auditing of the milk shipper to be rated, audited or certified for IMS listing can be performed by the SRO that will be conducting the rating, audit or certification.

For BTUs, receiving stations, transfer stations, milk plants and single-service containers and/or closures manufacturing facilities that are IMS listed, the required official Regulatory Agency's records review period is from the

earliest rating, auditing or certification date, respectively, back to the last rating, auditing or certification date. If this period of time is less than six (6) months, then six (6) months of records shall be reviewed.

For BTUs, receiving stations, transfer stations, milk plants and single-service containers and/or closures manufacturing facilities that have requested and are seeking their initial IMS listing, the required official Regulatory Agency's records review period is from the earliest rating, auditing or certification date, respectively, and back six (6) months.

66. **PROCEDURES-Section IV; and MMSR-Section C**

A SRO conducts the routine inspections of a Grade "A" permitted milk tank truck cleaning facility. May the SRO conduct a rating if the milk tank truck cleaning facility requests to be IMS listed as a receiving station?

No. A SRO cannot have direct responsibility for the routine inspection and enforcement or regulatory auditing of the milk shipper to be rated or listed. (Please refer to Question 65 above for when an SRO may conduct a rating of this receiving station.)

67. **PROCEDURES-Section VI; and MMSR-Sections E and H**

If a milk plant has both an aseptic and pasteurized IMS listing and the aseptic IMS listing has a Sanitation Compliance Rating (SCR) and Enforcement Rating (ER) of ninety (90) or higher and the pasteurized IMS listing has a SCR of ninety (90) or higher; however, the ER is less than ninety (90) on the rating, may both IMS listings be submitted by the SRO and approved by an FDA MS for IMS listing?

Yes. There could be separate issues related to pasteurized product sampling and testing, pasteurization equipment testing, etc. The pasteurized IMS listing would have to have an expiration date of six (6) months from the earliest rating date for this rating.

NOTE: *The only exception to this would be if this was the initial IMS listing for the pasteurized milk plant.*

- Both the SCR and the ER must be ≥90 to be IMS listed.
- With an ER <90, the milk shipper would be denied an IMS listing.

68. **PROCEDURES-Section IV; and MMSR-Section F**

What should be done when there is a change of ownership (handler) for a BTU that does not include a change (addition or deletion) of any dairy producers from their current IMS listing?

If the existing BTU IMS listing is to expire within six (6) months, it is recommended that a new rating be conducted, and FORM FDA 2359i-Interstate Milk Shipper's Report be submitted indicating the new ownership (handler) or name of the BTU.

At a minimum, a newly signed FORM FDA 2359o-Permission for Publication shall be signed by the new owner (handler) and an updated FORM FDA 2359i from the current IMS listing that indicates the new ownership (handler) or name of the BTU should be immediately submitted to FDA. All the other information on FORM FDA 2359i from the current IMS listing shall remain the same with the possible exception that a new laboratory may be utilized by the new owner (handler). When submitting the updated FORM FDA 2359i to FDA, in the comment section it should be noted that this is only a change in ownership (handler) or the name of the BTU.

69. **PROCEDURES-Section IV; and MMSR-Section H**

a) An initial IMS rating is conducted with the following results:

- SCR = 90
- ER = 85

  - *Both the SCR and the ER must be ≥90 to be IMS listed.*
  - *With an ER <90, the milk shipper would be denied an IMS listing.*

b) A rating is conducted of an IMS listed milk shipper with the following results:

- SCR = 90
- ER = 85

  - *With an ER <90, the milk shipper would be IMS listed for six (6) months.*

c) A re-rating is conducted within the six (6) months after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the IMS listed milk shipper is in substantial compliance with the following results:

- SCR = 90

- ER = 85

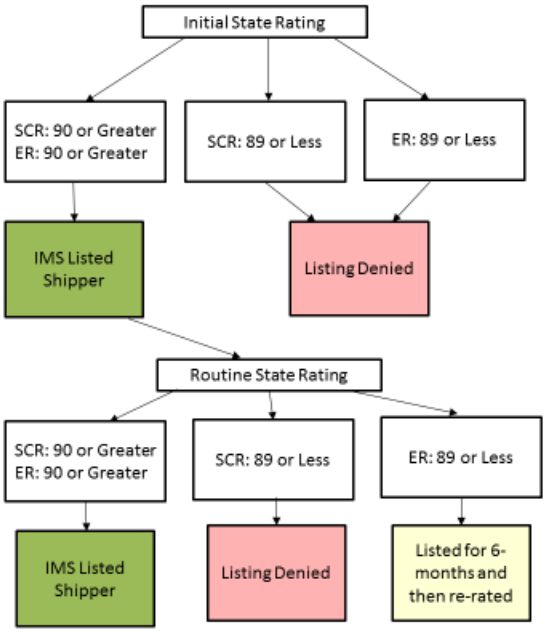
  - *Both the SCR and the ER must be ≥90 to be IMS listed.*
  - *With an ER <90, the milk shipper's IMS listing would be immediately withdrawn.*

d) A new rating is conducted after the Rating Agency receives written notification from an authorized representative of the Regulatory Agency indicating that the milk shipper is in substantial compliance with the following results:

- SCR = 90
- ER = 85

  - *Both the SCR and the ER must be ≥90 to be IMS listed.*
  - *With an ER <90, the milk shipper would be denied an IMS listing.*

The above scenarios are also shown in the following flow diagram.



70. **MMSR-Section B**

On page 9 of the 2015 MMSR, under B-Random Selection of Dairy Farms to be Rated it states: "Whenever possible, random selection or announcements of such selection for only one (1) day's work at a time should be made." When is the proper time for the random selection of dairy farms to be inspected on

a rating or check rating to take place? Is it the day that the rating or check rating dairy farm inspections start or can it take place one (1) to three (3) weeks ahead and the list furnished to the Regulatory Agency? What are the guidelines of when the random selection of dairy farms for a rating or check rating can to be done?

With the random selection of dairy farms, it shall be representative to reflect conditions throughout the BTU or attached supply. It is important that the selection method excludes elements of pre-selection and provides a truly random sample. The selection of dairy farms for a rating should be made from a current listing of dairy farms making up the BTU or attached supply and may be compared to a list for the previous sixty (60) days to determine if an appreciable shifting of dairy farms has taken place. Random selections, once made, should be deviated from only in cases of emergencies. Replacements, where necessary, should also be selected at random.

It is preferable and strongly recommended that the random selection of dairy farms be made on the day that the rating or check rating is to begin to eliminate the possibility of the pre-notification of the individual dairy producers/farms selected. While this is the best method, we understand that sometimes that may not be possible. Any method or time frame used shall assure that the individual dairy producers/farms and/or the dairy industry personnel (field person, procurement manager, etc.) are not pre-notified of the selection for the rating or check rating. The appropriate time frame for this random selection comes down to the comfort level that the SRO or FDA MS has with the Regulatory Agency involved. This comfort level is knowing that individual dairy producers/farms and/or the dairy industry (field person, procurement manager, etc.) are not going to be pre-notified of the selection or that the official regulatory records are not going to be scrutinized prior to the rating or check rating.

Some States utilize dairy industry personnel (field person, procurement manager, etc.) to accompany them on ratings and check ratings. If this approach is being utilized, then every effort shall be made to eliminate the possibility of the pre-notification of the individual dairy producers/farms selected. Prior to the day that a rating or check rating is to start, dairy industry personnel (field person, procurement manager, etc.) shall not be informed of the specific BTU or attached supply or the individual dairy producers/farms selected that will be rated or check rated.

NOTE: *If prior to, or when conducting the field work for a rating or check rating, the SRO or FDA MS determines that the dairy farm(s) has/have been pre-notified, i.e., specifically prepared for this rating or check rating, the SRO or FDA MS, respectively, shall immediately terminate all rating or check rating*

activities. Please refer to M-I-04-6 (Question 83) for additional information related to pre-notification.

71. **MMSR-Sections B, C and E**

A BTU, receiving station, transfer station or milk plant scores below ninety (90) on either the SCR or ER on a rating with one (1) of the areas debited being the required PMO sampling/testing frequency for water supplies and/or re-circulated cooling water systems. Would two (2) water samples of the applicable water supply and/or re-circulated cooling water system(s) be taken in one (1) week on separate days take care of this missed sampling/testing frequency issue?

No. Accelerated sampling that is addressed in the PMO for the reinstatement of milk and or milk products following three (3) out of five (5) samples exceeding the limits of the PMO would not be applicable to this situation. The collection and testing of a single water sample from the water supply and/or re-circulated cooling water system(s) that was not in compliance, which obtains a result from the testing laboratory of Not Found (NF), will clear this water supply and/or re-circulated cooling water system(s) SCR PMO violation. Compliance with the bacterial standards of the PMO for the water supply and/or re-circulated cooling water system(s) is based on whether, at the time of the new rating, the water supply and/or re-circulated cooling water system(s) meets the standards of Section 7 of the PMO.

When conducting a new rating because of either the SCR or ER being below ninety (90), the new rating will be conducted within six (6) months of the previous rating. Therefore, when conducting the records review for this new rating, a period of six (6) months preceding the new rating will be evaluated. Any PMO required sampling/testing frequency for a water supply and/or re-circulated cooling water system(s) that is missed during this six (6) month period will still be debited against the ER for the BTU, receiving station, transfer station or milk plant.

NOTE: *The PMO required testing frequency restarts with the collection and testing of any water sample from a water supply and/or re-circulated cooling water system(s).*

72. **MMSR-Section E**

If it is determined that a Regulatory Agency does not have an adequate valid training program for their bulk milk hauler/samplers, when calculating Item 4-All samplers hold a valid permit, Dairy Farm Sampling Procedures on FORM FDA 2359j-Section C-Evaluation of Sampling Procedures (Page 3) will the

bulk milk hauler/samplers that have been permitted be given credit for having a valid permit or not?

If their permit has not expired they will be granted credit for having a valid permit.

73. **MMSR-Section H**

A milk plant receives pasteurized condensed skim and pasteurized cream from other IMS listed milk plants. The condensed skim and cream is used in varying proportions to create three (3) milk products: concentrated skim milk, concentrated whole milk, and concentrated sweetened condensed milk (added fructose). All milk products are enzyme treated to break down lactose and then go through an aseptic process and are aseptically packaged. The resulting milk products are:

- Aseptically processed and packaged lactose reduced concentrated milk products; and
- Aseptically processed and packaged lactose reduced sweetened condensed milk.

What Product Code(s) should be used on FORM FDA 2359i for these aseptically processed and packaged milk products?

Product Code 6-Aseptic Milk and Milk Products (Including Flavored) and Sub-Product Code 19-Lactose Reduced Milk and Milk Products (6-19).

74. **EML-Section 2**

How often are State Central Laboratories (Official), Official (State and local Regulatory Agency) Laboratories, Officially Designated (Commercial and Industry) Laboratories and Certified Industry Supervisors (CISs) required to be evaluated for IMS accreditation or approval and by whom?

State Central Laboratories (Official)*: Once every three (3) years by a LEO from FDA's LPET.*

Official (State and local Regulatory Agency) Laboratories, Officially Designated (Commercial and Industry) Laboratories and CISs*: Once every two (2) years by a FDA certified LEO.*