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M-I-12-9

March 30, 2012

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Questions And Answers Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During Fiscal Years 2010 and 2011

Following are questions and answers received from the field; Regional Milk Seminars; and FDA training courses (Advanced Milk Processing, Special Problems in Milk Protection, Milk Plant Sanitation and Inspection, Milk Pasteurization Controls and Tests, and Dairy Farm Sanitation and Inspection) held during fiscal years 2010 and 2011.

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 Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State 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 robert.hennes@fda.hhs.gov.



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1. **PMO-Section 1, Definition X-Milk Products**

Is the minimum percentage by weight criteria determination contained in Definition X-Milk Products of the PMO, 2.0% milk protein and 65% milk, milk product or a combination of milk products, based on a “liquid/wet as is” or on a “dry matter” basis?

It is based on calculations obtained from the “liquid/wet as is” in final packaged and labeled form.

2. **PMO-Section 1, Definition X-Milk Products**

A milk plant is drying and packaging a dry milk powder product labeled as “Skimmed Milk Powder” and is intended for the export market. This “Skimmed Milk Powder” has a higher protein content than what is typically found in nonfat dry milk (NFDM) in the U.S. and is manufactured in accordance to the CODEX Standards for “Skimmed Milk Powder”. Since the “Skimmed Milk Powder” did not conform to the U.S. NFDM Standard of Identity (SOI) and was being manufactured for export only, the product would not fall under the IMS program. As such, the product was not labeled Grade "A" and was not sampled in accordance with Section 6 of the PMO.

Under what conditions would this “Skimmed Milk Powder” be considered a Grade "A" milk product?

The two (2) determining factors as cited in the Definition for Milk Products of the PMO for requiring Grade "A" labeling and requiring the milk plant to be IMS Listed would be:

- 1) If the “Skimmed Milk Powder” was used as an ingredient in a Grade "A" defined milk or milk product, or*
- 2) If the milk plant chooses to label the “Skimmed Milk Powder” as Grade "A".*

If this “Skimmed Milk Powder” would be IMS Listed, it would be identified with Product Code #22-Dry Milk and Milk Products.

NOTE: *A dry milk product labeled “Skimmed Milk Powder” may not meet the SOI for NFDM and might not be permitted for use in some SOI milk or milk products.*

3. **PMO-Section 1; and Appendix L**

a) When would retort packaged and processed evaporated milk, which adheres to the standard of identity in 21 CFR 131.130, be considered a Grade “A” milk product under the PMO?

Evaporated milk adhering to 21 CFR 131.130 would be considered under the Definition for Milk Products of the PMO if it is used as an ingredient to produce any Grade "A" milk or milk products or if the manufacturer chooses to label the product as Grade "A".

b) A food is labeled "Evaporated Milk"; may it be made from milk powder that is rehydrated by the addition of water?

The following answer was provided by CFSAN's Office of Nutrition, Labeling and Dietary Supplements (ONLDS):

No. To be labeled as "Evaporated Milk" it must adhere to 21 CFR 131.130.

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

Two separate (2) Grade "A" milk products are being labeled as "Fresh Skim Fat Free Milk with Probiotics" and "Fresh 2% Reduced Fat Milk with Probiotics" and in the ingredient statement for both of these Grade "A" milk products it identifies that *Bacillus coagulans* is being added to these Grade "A" milk products. Would this labeling, with the addition of the bacteria culture *Bacillus coagulans*, be considered appropriate?

The following answer was provided by CFSAN's ONLDS:

FDA does not have a regulatory definition for "probiotic". However, bacterial cultures such as the one that you mentioned above as being added are not permitted as an ingredient in milk (refer to 21 CFR 131.110). If these cultures are added, the name of the food must be called something else to distinguish it from the standardized food, "milk".

Also, the product labels indicate statements of identity, "2% reduced fat milk with probiotics" and "skim fat free milk with probiotics". The term "with" is an implied nutrient content claim and "probiotics" are not nutrients. 21 CFR 130.10 permits standardized foods to be modified in order to make a nutrient content claim, e.g., "reduced fat milk and fat free milk". The product using a nutrient content claim must not be nutritionally inferior to the standardized food and the product must not be inferior in performance characteristics to the standardized food. Thus, 21 CFR 130.10 permits the addition of ingredients not found in the standardized food. However, in this case because "probiotics" are not nutrients and are not ingredients used to make the modified food nutritionally equivalent or have the same performance characteristics, "probiotics" are not permitted in reduced-, low- or non-fat milks.

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

A Grade “A” milk product is being labeled as “Probiotic Lowfat 1% Milk - Vitamin A & D - PROBIOTICS - Live microorganisms which beneficially affect the immune system by improving its microbial balance, thus inhibiting pathogens and toxin-producing bacteria.” Would this labeling be considered appropriate?

The following answer was provided by CFSAN’s ONLDS:

“Probiotic Lowfat 1% Milk - Vitamin A&D” does not appear to be an appropriate statement of identity for this food product. “Low Fat Milk” is a food subject to the requirements of 21 CFR 130.10. There is no provision under 21 CFR 130.10 that provides for the addition of “Probiotics” to the food named by the nutrient content claim “low fat” and the standardized food name “milk” (21 CFR 131.110).

The claim “Live microorganisms which beneficially affect the immune system by improving its microbial balance, thus inhibiting pathogens and toxin-producing bacteria.” would be considered to be a disease claim. This therapeutic claim causes the product to be a drug, as defined in Section 201(g)(1)(B) of the Act, [21 U.S.C. 321(g)(1)(B)].

6. **PMO-Sections 1, 4 and 7, Item 12p; and Appendix L**

a) Is Lecithin, derived from soy, considered an allergen?

Yes.

The following answer was provided by CFSAN’s ONLDS:

FDA’s Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy under Section 403(w) of the Federal Food, Drug, and Cosmetic Act states that FDA would take 18 months from January 1, 2006 to finalize their enforcement position on the labeling of soy lecithin. When the guidance on soy lecithin expired, FDA did not issue any follow up documents, but began enforcing the law noted in the guidance.

b) How is the product to be labeled? Does it need to be in the ingredient statement?

The following answer was provided by CFSAN’s ONLDS.

If soy lecithin is used in a food, the food is misbranded under 403(w) of the act unless either:

- *The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients [section 403(w)(1)(A) of the Act, 21 U.S.C. § 343(w)(1)(A)]; or*
- *The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name).*

c) How would this affect the use of a dryer when changing from one (1) product to another, i.e. would the filter bags in the baghouse be required to be completely changed after drying a product containing soy lecithin?

Manufacturers should take steps necessary to eliminate cross contamination between milk and milk products that contain soy lecithin and other milk and milk products. A milk drying plant shall conduct a risk assessment to determine if their own individual cleaning management program eliminates any potential cross-contact issues or if allergen labeling is warranted.

NOTE: *Precautionary labeling such as "may contain soy" or "processed on equipment that also processed soy" should not be used in lieu of adherence to Good Manufacturing Practices (GMPs). Allergen advisory statements are voluntary and their use would be based on dairy manufacturers determining the potential risk of product contamination from an undeclared allergen.*

7. PMO-Section 1; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Section C

May an IMS listed milk plant request the State Rating Agency to exclude PMO defined product(s) from their IMS Listing on the basis that the Grade "A" defined product(s) is (are) not intended and will not be shipped in interstate commerce?

Yes.

8. PMO-Sections 3, 6 and 7

a) May a Grade "A" dairy farm skim some raw milk, using a separator located on the dairy farm, then put the resulting cream back into the farm bulk milk tank with the rest of the milking?

No.

b) May the milk then be picked up as Grade "A" raw milk off the farm?

No.

Background Information:

The PMO only provides for the milking, cooling, handling and storing of raw milk to be conducted under the definition of a "Dairy Farm". The separation and/or clarification of whole raw milk on a Grade "A" dairy farm would be considered processing operations; therefore, a room or facility completely separate from the milkhouse operation that meets Grade "A" milk plant requirements would be required in which these processing operations would be required to occur. These types of processing operations would also require the issuance of a milk plant permit by the Regulatory Agency for the separate room or facility. Neither the skim nor the cream can be added back to the farm bulk milk tank. If skim and/or cream are added back to the bulk milk tank the resulting raw product cannot be sold as Grade "A" raw milk from the permitted Grade "A" dairy farm.

The use of a separator or clarifier alters the bacterial count of the remaining product. Any official sample of the producer's Grade "A" whole raw milk, required under Section 6 of the PMO, shall be collected prior to the separation and/or clarification process.

M-a-31 (Supplement 1) states that the use of separators on producer dairies should not be permitted "unless it is so installed that it will not affect the bacterial and abnormal milk results of a sample of raw milk". M-a-31 makes the same statement for the use of clarifiers on the dairy farm.

9. PMO-Section 3; and Appendix E

Following a Grade "A" dairy farm permit suspension for three (3)-out-of-five (5) samples exceeding the standard for somatic cell count (SCC), the Regulatory Agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates that the milk supply is within acceptable limits. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This is considered "Accelerated Sampling" and would be required for the full reinstatement of the dairy farm's permit. Would the sample that was taken for the issuance of the temporary permit, as cited above, be considered one (1) of the samples required under Accelerated Sampling?

No. This sample is for the issuance of a temporary permit so that the producer may begin shipping Grade "A" milk again. After the temporary permit has been issued then "Accelerated Sampling" is to begin in accordance with the PMO.

10. PMO-Section 4

"Non-fat" is a synonym for "Fat Free" and may be used to identify a milk product ("Non-Fat Milk", "Fat Free Milk" or "Skim Milk") that has less than 0.5 grams of fat per Reference Amounts Customarily Consumed (RACC) Per Eating Occasion. May a nutrition content claim placed on the label and/or a nutrition declaration in the Nutrition Facts panel on the packaging cite "0 grams of fat" or must they make the claim of "less than 0.5 grams of fat"?

The following answer was provided by CFSAN's ONLDS:

For purposes of a nutrient content claim, the defined claims would be "non-fat", "fat free", etc. However, percentage and amount claims are also permitted if the milk meets the established definition. If in fact, the milk contains "0 grams of fat", that claim could appear on the package. Likewise, if the milk contained some fat, but still "less than 0.5 grams of fat", that claim could also be used. In the last case; however, we would caution the manufacture to ensure that the claims don't cause consumer confusion about a product that is otherwise labeled as "fat free", keeping in mind that most consumers are likely not aware of our definitions.

For purposes of nutrition labeling, the amount declared in the Nutrition Facts panel on the packaging for a "Fat Free", "Non-fat" or "Skim" milk product, i.e. one containing less than 0.5 g fat, would be "0 grams of fat".

11. PMO-Sections 4 and 7

During a routine Grade "A" milk plant regulatory inspection, milk product labels were reviewed and the ingredients listed on one (1) of the labels were not the actual ingredients contained in that milk product. Where on FORM FDA 2359-Milk Plant Inspection Report would this labeling violation be debited?

FORM FDA 2359 does not have any specific Item provided to debit this labeling observation/violation. However, this labeling observation/violation should be noted within the write-up report for this routine regulatory inspection.

12. **PMO-Section 4; Appendix B; and MMSR-Section B**

a) Does the PMO allow for the electronic collection and storage of information that is required to be included on the farm weight ticket that is left at the dairy farm for milk that is collected from individual dairy farms?

NOTE: This is in reference to Proposal 203 from the 2011 NCIMS Conference and FDA's commitment to the author of the Proposal to issue a Q/A addressing their issue.

Yes. However, the electronic collection and storage device shall have the capability of generating a written record containing all of the PMO required information with a copy of this written record to be left at the dairy farm in place of the traditional farm weight ticket. The information that would be required to be readily available to the State Regulatory/Rating personnel and FDA Regional Milk Specialist during every routine inspection, State rating and FDA check rating, respectively, would include the following:

- *Temperature of the milk per milk collection;*
- *Collection time (optionally, in military time (24 hour clock));*
- *Date of collection;*
- *Weight of milk for the individual bulk milk tank(s) and/or silo(s) collected per specific pickup(s) on the day of collection;*
- *IMS Bulk Tank Unit (BTU) identification number or the IMS Listed Milk Plant Number for farm groups listed with a milk plant; and*
- *Name and license or permit number of the bulk milk hauler/sampler per collection.*

NOTE: *At each producer dairy farm, during a State rating or FDA check rating of a BTU, the State Rating Officer (SRO) and FDA Regional Milk Specialist, respectively must determine the identification of the bulk milk hauler/samplers, from at least the previous thirty (30) days, to be used when computing the Enforcement Rating for the BTU. At a minimum, thirty (30) days of records must be available on the dairy farm at any given time.*

b) Does the PMO allow for the electronic collection and storage of information required on shipping manifest (bills of lading or pickup and transport of milk and milk products from milk plants, receiving stations and transfer stations?

Yes. However, the electronic collection and storage device must have the capability of generating a written record containing all of the PMO required information and a copy of this written record must be readily available at the milk plant, receiving stations or transfer station for State Regulatory/Rating personnel and FDA Regional Milk Specialist during routine inspections, State ratings and FDA check ratings, respectively.

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

If vitamins are added to cottage cheese, do they need to be claimed on the principle display panel; or do they need to be in the ingredient statement?

The following answer was provided by CFSAN's ONLDS:

As a minimum, the vitamins would need to be listed in the ingredient statement. Per 21 CFR 130.10(b), vitamins added to restore nutrient levels so that the product is not nutritionally inferior to the standardized food (in this case 21 CFR 133.128 "Cottage Cheese" and 133.129 "Dry Curd Cottage Cheese") shall be reflected in the ingredient statement. The addition of vitamins added in excess of levels provided for in the standard of that food is optional. If the manufacturer chooses to fortify and use a nutrient content claim such as "Vitamins A & D Added" or "Fortified with Vitamins A & D" on a standardized product as outline per 21 CFR 130.10(a), then the nutrient content claim would need to appear on either the principal display panel or the information panel per 21 CFR 101.2(b). The vitamin ingredients would also need to be declared in the ingredient statement as outlined in 21 CFR 130.10(f).

NOTE: *The standards of identity for cottage cheese and dry curd cottage cheese do not specifically address the optional addition of vitamins and fortification requirements. 21 CFR 184.1950(c)(1) for Vitamin D would limit fortification to 89 IU per 100 grams. 21 CFR 184.1930(c) for Vitamin A allows for no fortification limit other than good manufacturing practice.*

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

Is there a designation for the colors yellow #1, #2, or #3 in the CFR?

The following answer was provided by CFSAN's ONLDS:

By default, if a color additive for use in food is not listed in 21 CFR Part 73, Subpart A or 21 CFR Part 74, Subpart A, then it is not permitted for use as a food coloring. Yellow #1, #2 and #3 are not listed in these Sections of the CFR.

NOTE: *The Color Additive Amendment to the CFR was passed in 1960. Yellow #2 was dropped as an approved color additive during that process. Yellow #1 was provisionally listed until further studies could be completed. After further study, Yellow #1 was dropped in 1977. (Refer to 21 CFR 81.10 (i). The certificate for Yellow #3 was cancelled in 1968. (Refer to 21 CFR 81.30 (e)).*

15. **PMO-Section 5, and Appendix P**

If a State chooses the option to inspect their Grade "A" dairy farms under Appendix P-Performance-Based Dairy Farm Inspection System as cited in Section 5-Inspection of Dairy Farms and Milk Plants of the PMO, may they designate certain areas of the State; or specific Grade "A" dairy farms to be inspected under this Performance-Based Dairy Farm Inspection System; or must the State's Grade "A" dairy farms, as a whole, be inspected in accordance with Section 5 and Appendix P of the PMO?

*If a State chooses the Performance-Based Dairy Farm Inspection System as addressed in the PMO, then the State's Grade "A" dairy farms, as a whole, would be required to be inspected under this System. Section 5 of the PMO, under the inspection of dairy farms, cites footnote 6, which states that Regulatory Agencies desiring to inspect dairy farms under a performance-based inspection system should substitute the following language in 5. "5. Inspect **each** dairy farm as provided in Appendix P. Performance-Based Dairy Farm Inspection System."*

16. **PMO-Section 6**

The following questions relate to the sampling requirements of Section 6-The Examination of Milk and Milk Products of the PMO in relationship to yogurt and cottage cheese milk products.

a) Are plain yogurts considered to be separate and distinct products from flavored yogurts, i.e., "fruit on the bottom" or "blended", for sampling purposes so that both plain and flavored yogurt milk products would be sampled separately by % milkfat?

Yes.

b) Are cottage cheese products that are flavored with fruit or flavorings considered to be distinct from non-flavored cottage cheese milk products so that both would be required to be sampled by % fat?

Yes.

c) Are cottage cheese products defined by % milkfat in the dressing utilized for sampling purposes? For example; dry curd, 4%, 2%, Skim dressing cottage cheese = 4 samples or 2 samples?

Yes, four (4) separate samples as defined by % milkfat would be required under Section 6 of the PMO.

NOTE: Section 6 of the PMO regarding sampling frequency does not specify that each different flavored milk or milk products shall be sampled separately. It is recommended that each different flavor of milk and/or milk products at each fat level be sampled on a rotational basis.

17. PMO-Section 6

A milk plant is packaging plain yogurt in the lower portion of a dual container that is separated from the upper portion that contains honey. (A similar approach to granola in a separate container packaged with yogurt.) The portion containing honey is opened by the consumer and added to the yogurt and mixed together. How should this product be sampled for compliance with Section 6 of the PMO? Only the plain yogurt portion or the combined yogurt and honey mixture?

Only the plain yogurt would be required to be sampled and tested in accordance with Section 6 of the PMO.

18. PMO-Section 6

A milk plant is producing the following Grade "A" dry whey products: dry whey, delactose dry whey, whey protein concentrate (WPC) and whey protein isolate (WPI), which of these dry whey products are required to be sampled and tested under Section 6 of the PMO?

All four (4) of them are required to be individually sampled and tested at the frequency cited in Section 6 of the PMO. The four (4) dry whey products cited above are very distinct and different dry whey products and are specifically identified as dry whey, delactose dry whey, WPC and WPI.

19. PMO-Sections 6 and 7, Table 1

a) What are the Section 6-The Examination of Milk and Milk Products of the PMO sampling and testing requirements for "Ultra-filtered Whey Permeate" (Product Code #42) and "Ultra-filtered Milk Permeate" (Product Code #41)?

Temperature and coliform testing at the required frequency as cited within Section 6 of the PMO.

b) Where are these two (2) products referenced in Table 1 of the PMO?

These two (2) products are referenced under "Grade "A" Pasteurized Concentrated (Condensed) Milk and Milk Products" for Ultra-filtered Permeate from Milk-Product Code #41 and "Grade "A" Pasteurized Condensed Whey and Whey Products for Ultra-filtered Permeate from Whey-Product Code #42.

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

Is there an NCIMS approved method for testing vitamins in vitamin fortified nonfat dry milk (NFDM)?

No. This dry milk product has never been included in the NCIMS laboratory proficiency program.

21. **PMO-Sections 6 and 7, Items 8r and 18r; Appendix G; and MMSR-Sections B and D**

One (1) dairy farm is transferring from an existing twenty-five (25) farm BTU to become a single farm BTU. There is not a change of ownership or permit. Would this single dairy farm be considered a new dairy farm and be required to begin with a new sampling protocol for their water supply (Items 8r-Water Supply and 18r-Raw Milk Cooling) and Section 6-The Examination of Milk and Milk Products (four (4) out of six (6) month raw milk sampling) of the PMO?

No. Because there is not a change of ownership or permit they can use their existing water supply and raw milk samples that were obtained when they were included in the twenty-five (25) farm BTU.

22. **PMO-Section 7, Item 1r**

May clean abnormal milking equipment be stored in the milkhouse and/or milking area?

Yes, to both the milkhouse and milking area

23. **PMO-Section 7, Items 1r, 3r and 6r**

What Item(s) on FORM FDA 2359a-Dairy Farm Inspection Report would you debit if you observed violations concerning the use, handling, construction, cleanliness and storage of abnormal milking equipment?

Please refer to **M-I-00-8 (QUESTIONS AND ANSWERS FROM FY 2000 510-SPECIAL MILK PROBLEM COURSES) (QUESTION 6)-12/18/2000.**

The 1999 NCIMS Conference moved the evaluation of Abnormal Milk Handling Equipment (i.e., "The Fresh Cow Bucket") to Item 1r, which is a 5 point item. Many State and Industry people think that improper storage (of a reasonably clean fresh cow bucket) shouldn't be debited 5 points (use Professional Judgment) but instead choose to evaluate it under Item 12r(a)-Storage of Cleaned Equipment (2 points). I understand their intent, but I

believe the Conference put everything for fresh cow buckets under Item 1r. What is correct?

Evaluation of abnormal milk handling equipment was moved to Item 1r to deal with the issue of cow-to-cow transfer of infections. Therefore, cleaning, repair and drainage concerns regarding this equipment are evaluated under Item 1r. If storage of this equipment is contributing to a cleaning (housekeeping) concern in the milking area or milkhouse, this is evaluated under Item 3r or 6r, respectively.

24. PMO-Section 7, Item 9r

a) On a Grade "A" dairy farm, is an upright wash vat used only for the cleaning and sanitizing of milk pipelines and milk machines required to have a cover?

This upright wash vat, meets one (1) of the following PMO criteria:

- Is accepted by the Regulatory Agency as meeting one (1) part of the two (2) compartment wash vat; or
- Because of the CIP cleaning/recirculated system it eliminates the need for the handwashing of equipment; therefore, a second wash vat is optional, so the Regulatory Agency has determined this to be acceptable on an individual basis.

No.

b) If a cover is being utilized, does this cover have to meet the equipment construction criteria of the PMO?

Yes.

c) If the cover that is being utilized has a piano hinge for example, where would this equipment construction violation be debited on FORM FDA 2359a-Dairy Farm Inspection Report?

Item 9r(d)-Utensils and Equipment - Construction (proper design).

25. PMO-Section 7, Item 5r

When using stubbed lines for transferring milk from the bulk milk tank to the milk tank truck, are the stubbed lines required to be stubbed outside the milk house or may they be on the inside of the milkhouse?

Currently within Item 5r-Milkhouse - Construction and Facilities of the PMO it only refers to the stubbing of the milk transfer and associated CIP cleaned lines for the transfer of milk from a bulk milk tank to a bulk milk pickup tanker outside the milkhouse wall. Therefore, in the context of the PMO, the associated lines would have to be stubbed outside the milkhouse.

NOTE: Connections that are made within the milkhouse for the transferring of milk from the farm bulk milk tank to the bulk milk pickup tanker are permitted and are not considered stubbed lines within the content of Item 5r of the PMO.

26. **PMO-Section 7, Item 5r**

If the surface under a hoseport is dirty where would this be debited on FORM FDA 2359a-Dairy Farm Inspection Report?

Item 5-Miscellaneous Requirements (e)-Acceptable surface under hoseport.

27. **PMO-Section 7, Item 5r**

a) For direct loading of milk tank trucks without a shelter as provided for in Item 5r-Milkhouse - Construction and Facilities of the PMO and approved by the Regulatory Agency, is it required that the milk tank truck's manhole dome lid be sealed while the milk tank truck is being direct loaded?

Yes.

b) In the scenario as cited in a) above, must the milk tank truck's outlet valve be sealed between milkings if the milk tank truck is only partially loaded with milk?

No. The sealing of the outlet valve is not required by the PMO.

28. **PMO-Section 7, Items 8r and 7p; and Appendix D**

If the "State Water Control Authority" approves hydrogen peroxide (H₂O₂) as a ANSI/NSF Standards 60 (ANSI/NSF 60) additive for direct addition into wells or water systems to increase the yield, remove or treat contaminants (other than microbial contaminants), objectionable tastes or odors, or rehabilitate the well or boring would this be considered a violation of Items 8r or 7p-Water Supply of the PMO?

Not if the following criteria are met:

- *The State Dairy Regulatory Agency has a letter on file from the State Water Control Authority stating that the additive (H₂O₂) meets ANSI/*

NSF 60-Direct Water Treatment Chemicals-Health Effect and is approved for use within their State for specific uses such as being injected into wells; or injected into individual water systems; or other applications as the State Water Control Authority may specify in their letter of approval.

- *The State Dairy Regulatory Agency shall follow the interpretation from the State Water Control Authority when conducting inspections of wells or individual water systems on dairy farms and in milk plants that are utilizing an approved additive (H₂O₂).*
- *The following criteria for dairy producers and milk plants that are using a ANSI/NSF 60 additive (H₂O₂) need to be satisfied:*
 - *Pumping the water additive (H₂O₂) directly into the well casing:*
 - ✓ *A letter available at the dairy farm or milk plant from the manufacturer or the vendor (distributor) of the additive (H₂O₂). The letter shall contain the name of the additive (H₂O₂) and a statement indicating that the additive (H₂O₂) meets ANSI/NSF 60 requirements.*
 - *Injecting the water additive (H₂O₂) into the water line **AND** the size of the container of additive (H₂O₂) is one (1) gallon or **LESS**:*
 - ✓ *A letter available at the dairy farm or milk plant from the manufacturer or the vendor (distributor) of the additive (H₂O₂). The letter shall contain the name of the additive (H₂O₂) and a statement indicating that the additive (H₂O₂) meets ANSI/NSF 60 requirements.*
 - *Injecting the water additive (H₂O₂) into the water line **AND** the size of the container of additive (H₂O₂) is **GREATER** than one (1) gallon:*
 - ✓ *A letter available at the dairy farm or milk plant from the manufacturer or the vendor (distributor) of the additive (H₂O₂). The letter shall contain the name of the additive (H₂O₂) and a statement indicating that the additive (H₂O₂) meets ANSI/NSF 60 requirements.*
 - ✓ *An appropriate backflow prevention device installed in the potable water line prior to the point of injection of the additive (H₂O₂).*

In all cases cited above, the additive (H₂O₂) container or dedicated end-use container shall be properly labeled with the product name, the seal of the certifier (NSF, UL or WQA) and other applicable PMO requirements. The dairy producer will be debited five (5) points under Item 8r on FORM FDA 2359a-Dairy Farm Inspection Report and the milk plant will be debited four (4) points under Item 7p on FORM FDA 2359-Milk Plant Inspection Report on State ratings and check ratings if:

- *The manufacturer's letter is not available at the time of the State rating or check rating (Item 8a or 7a, respectively);*
- *The dairy producer or milk plant is using an additive other than the one (1) listed on the manufacturer's letter (Item 8a or 7a, respectively);*

- *The additive (H₂O₂) container or dedicated end-use container is not properly labeled (Item 8a or 7a, respectively); or*
- *The dairy producer or milk plant is dispensing the additive (H₂O₂) directly into the water line, from a container larger than one (1) gallon, without a proper backflow prevention device installed to protect the water supply or water system (Item 8c or 7b, respectively).*

NOTE: *H₂O₂ cannot be used alone as a disinfectant (sanitizer) for an individual farm's or milk plant's well or water supply. The CFR lists H₂O₂ when combined with peracetic acid as an approved sanitizer. NSF lists companies that are approved for the production of H₂O₂ for water treatment and cites the specific products (H₂O₂) that are approved. In all cases, the approval contains the following statement: "Use of this product shall be followed by chlorination to remove residual levels of H₂O₂. Chlorine residuals may not exceed 4 mg/l, the EPA's proposed maximum residual levels." Therefore, any disinfectant (sanitization) usage for an individual farm's or milk plant's well or water supply would require a chlorine follow-up to assure effective kill.*

29. PMO-Section 7, Item 9r

Is it acceptable to use a stainless steel clamp inside a sanitary/moisture trap that is located directly above the milk receiver and the sanitary/moisture trap is CIP cleaned with the receiver vessel?

No. Also, the sanitary/moisture trap is not permitted to be installed directly above the milk receiver in accordance with 3-A Sanitary Standards and the PMO. The sanitary/moisture trap shall be installed so that liquid collected in the sanitary/moisture trap cannot get back into the milk receiver.

30. PMO-Section 7, Items 10r and 11r

The CIP pipeline is disconnected during milking and the CIP pipeline is found to be dirty upon inspection, why is it not 10 points and only a 5 point violation.

Cleaning violations of milk contact surfaces will always include a sanitizing violation. CIP pipelines are not considered a milk contact surface; therefore, these pieces of equipment are not normally required to be sanitized.

31. PMO-Section 7, Items 10r and 12p

Are detergents, cleaners and other cleaning compounds used for the cleaning of dairy equipment on dairy farms and milk plants required to come from an approved source or listing similar to 21 CFR 178.1010 (40 CFR 180.940) for approved sanitizers?

No. There is not a CFR section or reference that lists approvals for cleaning compounds and the PMO is silent on chemicals that may or may not be used for cleaning dairy equipment. A detergent, cleaner or other cleaning compound is generally considered anything that can remove soils from the dairy equipment. It would be expected that a cleaning compound would be rinsed off prior to the required sanitization and would not come in direct contact with the milk and/or milk product that is conducted through the dairy equipment. Therefore, as long as the equipment is clean to sight and touch after the cleaning step and there is not any harmful residue remaining that could contaminate or adulterate the milk or milk products produced using this cleaned and sanitized equipment, the cleaning compound would be acceptable for use on dairy farms and milk plants under the PMO.

32. PMO-Section 7, Items 16r and 8p

a) Are electric hand driers allowed to be used on dairy farms for hand drying following handwashing, instead of individual sanitary towels?

No. Item 16r-Personnel - Handwashing Facilities of the PMO allows for only "individual sanitary towels".

b) Are electric hand driers allowed to be used in milk plants for hand drying following handwashing, instead of individual sanitary towels?

Yes. Item 8p-Handwashing Facilities of the PMO allows for "individual sanitary towels or other approved hand-drying devices".

c) Would cloth roller type towels in a dispenser be considered to meet the intent of "individual sanitary towels" for handwashing on dairy farms and in milk plants?

Yes to both dairy farms and milk plants.

NOTE: *Cloth roller type towels in a dispenser would be considered to be in violation of Item 16r or Item 8p, respectively when they get to the end of the roll and the cloth towel becomes a multi-use towel.*

33. PMO-Section 7, Item 1p

a) Are clean wooden pallets that are in good repair prohibited from use in a milk plant under the PMO?

No.

b) Are plastic pallets required to be used in a milk plant under the PMO?

No.

34. **PMO-Section 7, Items 2p, 3p and 15p; Appendix B**

a) May a CIP system (tanks, pumps, valves, etc.) be located outside without overhead protection in the form of a physical structure such as a roof or ceiling?

Yes, as long as all openings into the tanks, pumps, valves, etc. are properly protected with appropriately designed covers, lids, caps, fittings or connections and climatic and operating conditions can warrant such an installation. This provision must be acceptable to the Regulatory Agency.

b) May a milk tank truck be washed outside without overhead protection in the form of a physical structure such as a roof or ceiling?

No. Because of the required manual disassembly, cleaning and sanitizing of milk tank truck parts, overhead protection in the form of a physical structure such as a roof or ceiling would be required. If climatic and operating conditions can warrant such an installation without walls this provision must be acceptable to the Regulatory Agency.

c) May raw milk receiving equipment (pumps, piping connections, etc.) at a milk plant or receiving station be located outside without overhead protection in the form of a physical structure such as a roof or ceiling?

No.

d) What exactly does "Provided in every case, overhead protection shall be provided" mean as cited in Section 7 of the PMO in reference to transfer stations and facilities for the cleaning and sanitizing of milk tank trucks?

At transfer stations it has been acceptable to use a filter holder apparatus for the milk tank truck that is transferring the milk, This filter holder apparatus shall completely protect the filter material and the manhole opening of the milk tank truck to meet the criteria for overhead protection as cited in Section 7 of the PMO. Provided that there are not any other openings into the milk tank truck that were not properly protected, i.e., capped, etc. Please refer to M-I-95-3 (Question 16).

NOTE: *If climatic and operating conditions can warrant such an installation without a physical structure such as a roof (ceiling) and walls this provision must be acceptable to the Regulatory Agency.*

At facilities used for the cleaning and sanitizing of milk tank trucks, a physical structure such as a roof or ceiling would be required to meet the criteria for overhead protection as cited in Section 7 of the PMO.

NOTE: *If climatic and operating conditions can warrant such an installation without walls this provision must be acceptable to the Regulatory Agency.*

35. PMO-Section 7, Item 7p

May tower water be used in a jacketed vessel in a milk plant?

No. Water that complies with Item 7p-Water Supply of the PMO is required to be used in a jacketed vessel in a milk plant.

36. PMO-Section 7, Item 7p

Is there an allowance in a milk plant for the addition of chemicals from a container that is greater than one (1) gallon in capacity at a foot spray located at a door way through a venturi system without the requirement for backflow prevention?

No.

37. PMO-Section 7, Item 11p; and Appendix B

In a receiving milk plant's receiving bay, it is observed that a construction violation related to a milk tank truck that is being unloaded exists, i.e., an improperly installed and constructed dam around the manhole, would this be considered a violation of the PMO and be potentially debited against the receiving milk plant on a State rating or Federal check rating?

Yes. It would be considered a violation of Item 11p-Construction and Repair of Containers and Equipment of the PMO and could be debited against the receiving milk plant on a State rating or Federal check rating. The Rating Officer or Regional Milk Specialist shall use professional judgment to determine if this violation alone would constitute a debit against the receiving milk plant on a State rating or Federal check rating.

NOTE: *If the dam is collecting and holding water, which has the potential to contaminate the milk in the milk tank truck during unloading, and the milk plant receives the milk, then this practice would be considered a violation of Item 15p(A)-Protection from Contamination of the PMO and could be debited against the milk plant on a State rating or Federal check rating.*

38. PMO-Section 7, Item 12p

When reviewing the wash tags at the milk plant to verify that the milk tank trucks are being washed at a permitted and inspected facility for the cleaning and sanitizing of milk tank trucks, if such a facility is found not to be meeting the six (6) month inspection frequency, would the washing of the milk tank trucks at this facility be considered a violation of the PMO?

No.

39. PMO-Section 7, Items 12p and 15p(B)

What are the cleaning requirements for Double-Seat Mix-Proof Valves with the Vent Cavity Cleaning Option?

These mix-proof valves shall be cleaned as required in Item 12p.-Cleaning and Sanitizing of Containers and Equipment of the PMO, of once each day used unless they are within an evaporator system that is cleaned at the end of a continuous operation, which does not exceed forty-four (44) hours, or within a system that has been evaluated and accepted for "extended run".

Mix-proof valves that meet the criteria specified in Item 15p.(B)-Protection from Contamination, Administrative Procedures 1.b.(6) of the PMO may meet the required Item 12p. cleaning frequency, as cited above, without having to clean all parts of the mix-proof valve at the same time as long as all parts of the mix-proof valve are cleaned within the PMO required frequency

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

It has been accepted that a water line may be attached to a raw closed vessel, i.e., a constant-level tank, using a fail-safe block-and-bleed valve arrangement. Item 15p.(A)-Protection from Contamination, Administrative Procedures #19 of the PMO allows that water piping and raw milk and milk product lines and vessels may be separated by one (1) fail-safe valve. A sanitary check-valve is also required to be installed between the fail-safe valve and the vessel.

a) What is the purpose of the fail-safe valve?

The fail-safe valve or fail-safe block-and-bleed valve arrangement is to minimize the chance of adulteration of the raw milk or milk product with water.

b) Would this fail-safe valve or fail-safe block and bleed valve arrangement in this scenario be required if all water piping was constructed of stainless steel?

Yes.

c) Could the sanitary check-valve alone serve this function?

No. A correctly installed check-valve would not prevent water from leaking into the milk or milk product. It would only prevent milk and/or milk product from leaking through the check-valve into the water piping and contaminating the water supply.

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

If the active ingredients are on the label of the container of a boiler additive, used for the production of culinary steam, and the label does not state that it is USP, Food Grade or that the ingredients are GRAS, is the milk plant required to have on file a letter from the boiler additive manufacturer that states that the additive meets 21 CFR 173.1010 for milk and milk products?

The milk plant is required to provide documentation that the additives comply with 21 CFR 173.1010 for milk and milk products.

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

The dispensing tube for a bag-in-the-box container/case is enclosed in a plastic protective sleeve, which adequately protects the dispensing tube, and is sticking out of the container/case, is this considered a violation of Item 15p-Protection from Contamination of the PMO?

No.

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

May a milk plant chase raw milk or pasteurized milk with potable water if a study has been done that shows that the raw milk or pasteurized milk is not being adulterated?

Yes, for raw milk.

No for pasteurized milk, as it is required to be chased with pasteurized water or equivalent.

44. PMO-Section 7, Items 15p(A) and 17p

May “Bitrex” (a trade-named chemical (denatonium benzoate) used to produce a repulsive flavor) be added to boiler water used to produce culinary steam and/or recirculated cooling water in a milk plant?

“Bitrex” is being used by a variety of manufacturers to make products that should not be consumed, i.e., cleaners, detergents, garden chemicals, antifreeze, windshield washer, denatured alcohol, etc. It is designed to be added to products that you do not want ingested by providing a repulsive flavor to the specific product that it is being added to. The Jewish authorities for the use of the Kosher trademark are requiring “Bitrex” to be added to boiler water and recirculated cooling water in a milk plant.

When used in boiler and/or captive water applications in Grade "A" milk plants, “Bitrex” appears to be a chemical that would be considered an indirect food additive. If “Bitrex” treated water would accidentally enter a food product, then “Bitrex” produces a noticeably bitter taste in that food product. We are not aware that “Bitrex” holds GRAS status; or has been approved as an indirect food additive under 21 CFR Parts 174-178; or is approved as a boiler water additive under 21 CFR 173.310. Until such time as proper documentation of “Bitrex’s” acceptance by FDA for direct or indirect contact with food is provided it is not approved under the PMO for usage in boiler water and/or recirculated cooling water that could bring it into incidental contact with Grade "A" milk and milk products.

45. PMO-Section 7, Items 15p(A) and 18p

For pasteurized or ultra-pasteurized milk and milk products, what is the proper procedure for the intermittent fogging or spraying of sanitizing solutions on the outside of packaging machines during filling runs?

The filling operation shall be stopped and all containers isolated and/or properly protected before the fogging or spraying operation begins. Sufficient time shall be provided for the solution to drain from the packaging equipment before filling is resumed.

46. PMO-Section 7, Item 15p(B); and Appendix D

Does cow water that complies with Section V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants, Category I-Used for Portable Water Purposes of the PMO meet the criteria of Pasteurized Equivalent Water as cited in Item 15p.(B)-Protection from Contamination, Administrative Procedures #2?

No.

47. PMO-Section 7, Item 15p(B); and Appendix D

Proposal 114, as passed at the 2011 NCIMS Conference, provides protection and operational criteria for a raw milk or milk product-to-water-to-pasteurized milk or milk product plate or double/triple tube type heat exchanger when used only for heat-exchange purposes that is not included within a continuous flow pasteurization system. This Proposal provides new language in both Item 15p(B)-Protection from Contamination relating to a raw milk or milk product-to-water-to-pasteurized milk or milk product heat exchanger that is not considered a legal pasteurization system and Appendix D-Standards for Water Sources, Category II-Used for Limited Purposes (reclaimed water) of the PMO. What process or processes would Proposal 114 be applicable to?

This type of heat exchange system is typically found in condensing milk plants that want to use cow water exiting an evaporator to pre-heat raw milk or milk product in a plate or double/triple tube type heat exchanger and then subsequently use the same cow water to pre-cool pasteurized milk or milk product in a different plate or double/triple tube type heat exchanger.

These systems are specific to non-recirculating raw milk or milk product-to-water-pasteurized milk or milk product heat exchange systems. It was not the intent of the author of the Proposal or the NCIMS Technical Engineering Review Committee for it to be associated with any type of heat exchange systems utilizing recirculated glycol/cooling water identified in Item 17p-Cooling of Milk and Milk Products of the PMO.

48. PMO-Section 7, Item 16p

Does the PMO require a thermometer on a heat exchanger used to produce heat-treated cream?

No.

49. PMO-Section 7, Item 16p

May whey, which contains at least forty percent (40%) total solids and held at a minimum temperature of 140°F, be transported to another milk plant to be dried without being required to be re-pasteurized at the receiving milk plant prior to drying?

No.

Following are the re-pasteurization exemptions, specifically for whey, that are cited in the PMO:

- *Re-pasteurization at the receiving (drying) milk plant would not be required for acid whey (pH less than 4.7) as allowed for in Item 16p.-Pasteurization and Aseptic Processing, Administrative Procedures #3.*
- *The only exception for sweet whey (pH of 4.7 or greater) would be condensed whey containing at least forty percent (40%) total solids, which has been partially crystallized by cooling to 45°F or less, as allowed for in Item 16p.-Pasteurization and Aseptic Processing, Administrative Procedures #5.*

50. PMO-Section 7, Items 16p and 17p

May a milk plant mix and store different sources and different methods of treatment of fluid skim milk, as described below, prior to the final blending of the milk and/or milk product and pasteurization at this milk plant? The milk or milk products include an externally produced pasteurized or heat-treated skim milk and an internally manufactured heat-treated skim milk.

Yes. The storage and blending of milk or milk product(s) received from one (1) milk plant with milk or milk product(s) produced at another milk plant is an acceptable practice, provided the blending of the milk or milk product(s) occurs in the milk plant that will be pasteurizing the final blended milk or milk product. In the scenario presented, the "externally produced pasteurized or heat-treated skim milk" and the "internally manufactured heat-treated skim milk" should be handled and stored similar to raw milk or milk product(s) that is held prior to pasteurization. Unless there are additional circumstances that have not been presented, this scenario appears to be an acceptable practice as provided for within the PMO.

51. PMO-Section 7, Item 16p; and Appendix H

Where does the flow recording pen and event pen on a flow chart for a Magnetic Flow Meter Based Timing System receive their signal(s) from?

The flow pen, which records the flow on the flow chart, would be receiving it's signal from the magnetic flow meter and the event pen, which records the position of the FDD on the flow chart, would be receiving its signal through the FDD by means of the high flow and low flow/loss of signal alarms.

52. PMO-Section 7, Item 16p(A); and Appendix H

May an air supply that complies with Figure 46-Individual Blower-Type Air Supply contained within Section II-Air for Drying Equipment and Air Under Pressure – Direct Contact with Milk and Milk Products and Milk Product-Contact Surfaces, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO be used for the air space heating of batch (vat) pasteurizers?

No. Figure 46 represents equipment that is not designed for air space heating but indicates a means to move filtered air. It does not provide a means for heating the air to be used for airspace heating or how to assure that adequately heated air is continuously provided into the air space during the required holding time.

Figure 51-Culinary Steam Piping Assembly for Airspace Heating or Defoaming contained within Section III-Culinary Steam – Milk and Milk Products, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO is currently the only Figure in the PMO addressing a means to provide air for batch (vat) pasteurizer air space heating.

NOTE: The PMO does not prohibit the use of other heat sources other than steam but these would be required to be evaluated on an individual case-by-case basis.

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

Currently, the PMO states that the sanitary check-valve or normally closed control valve on a magnetic-flow meter based timing system shall be located upstream from the start of the holding tube. The reason given was to prevent fluids from flowing in reverse through the body of the mag-flow meter when forward flow through the system is stopped. With the sanitary check-valve located after the mag-flow meter, any fluid located between the mag-flow meter and the check-valve would still flow in reverse direction through the meter when forward flow is stopped. If the sanitary check-valve was located before the mag-flow meter, it would stop all flow of fluids in a reverse direction through the meter when forward flow is stopped. May the sanitary check-valve for a magnetic flow meter be located in line before the mag-flow meter?

Yes.

NOTE: Proposal 124 from the 2011 NCIMS Conference allows for a sanitary check-valve to be placed either before or after the magnetic flow meter. Refer to the wording from Proposal 124 below:

*“For HTST systems, when a sanitary check valve or normally closed automatically controlled sanitary valve,... is used with a variable or constant speed flow promoting device, it shall be located downstream of the last regenerator outlet and upstream of the holding tube. **NOTE:** This provision is not applicable to HHST systems.”*

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

With the G&H mechanically cleanable vacuum breaker, must the actual discharge port be located twelve (12) inches or higher above the highest raw milk in the pasteurization system or may it discharge through a solid pipe connection that reaches down and discharges at the floor level?

The Vent/CIP discharge port is required to open to the atmosphere twelve (12) inches above the highest raw milk in the pasteurization system. (Refer to M-b-322.)

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

a) For a HTST pasteurization system with a raw-to-pasteurized milk or milk product regenerator section, would it be acceptable for the raw milk or milk product line to enter **at the top** of the raw-to-pasteurized milk or milk product regenerator section?

*Yes. For any HTST pasteurization system in which the raw milk or milk product enters **at the top** of the raw-to-pasteurized milk or milk product regenerator section, the raw milk or milk product shall exit at the bottom of this regenerator section.*

The HTST pasteurization system shall be designed and operated so that all raw milk or milk product in the raw-to-pasteurized milk or milk product regenerator section will automatically drain freely into the constant-level tank or to the floor when the raw milk or milk product pump(s) is shut down and the raw milk or milk product connection(s) at the regenerator(s) is disconnected.

If a valve is used to facilitate the drainage of the raw-to-pasteurized milk or milk product regenerator section, it shall be an automatic fail-safe (fail-to-open) valve located and interwired to automatically allow drainage from the exit of this regenerator section, which is located at the bottom of the raw-to-pasteurized milk or milk product regenerator section, whenever the raw milk or milk product pump(s) is shut down.

b) For a HTST pasteurization system, which has a pre-heater located between the constant-level tank and a raw-to-pasteurized milk or milk product regenerator section, would it be acceptable for the raw milk or milk product line to enter **at the top** of the pre-heater and the raw milk or milk product exiting the pre-heater to internally enter the raw-to-pasteurized milk or milk product regenerator section

Yes. The HTST pasteurization system shall be designed and operated so that the raw-to-pasteurized milk or milk product regenerator section complies with the criteria cited in a) above.

c) For a HTST pasteurization system, which has an auxiliary piece of equipment, such as a clarifier or separator that splits the raw milk regenerator section of the HTST pasteurization system into two (2) sections, would it be acceptable for the raw milk or milk product line to enter **at the top** of either, or both, of the raw-to-pasteurized milk or milk product regenerator sections?

Yes. The HTST pasteurization system shall be designed and operated so that each of the raw regenerator sections individually comply with the criteria cited in a) above.

56. PMO-Section 7, Item 16p(E); and Appendix I

Are milk plants mandated to participate in the Industry Temporary Sealing Program for pasteurization equipment addressed in Item 16p. (E)- Pasteurization and Aseptic Processing Records, Equipment and Examinations of the PMO if the State offers the program?

Under the PMO, this Industry Temporary Sealing Program is not mandatory. However, if the Regulatory Agency requires milk plants within the State to have an Industry Temporary Sealing Program then it would become mandatory and FDA would look at each individual milk plant to confirm that they are complying with this option for the handling of broken pasteurization system seals.

Without the "On an emergency basis ..." Industry Temporary Sealing Program in place, it falls back on the Regulatory Agency to immediately follow up on every reported broken seal and retest the pasteurization system as warranted.

57. PMO-Section 7, Item 17p

a) If a balance or surge tank(s) is located prior to the entrance of a spray dryer and is determined to be continuous flow and is sized for a maximum retention time of twenty (20) minutes, may this balance or surge tank(s) be used continuously for up to twenty-four (24) hours if the milk or milk product temperature is being maintained at any temperature?

Yes. All raw milk and milk products, pasteurized milk and milk products and whey and whey products in continuous flow balance or surge tanks with a retention time not to exceed one (1) hour may be at any temperature for up to twenty-four (24) hours.

b) When would a balance or surge tank(s), located prior to the entrance of a spray drier, be required to be emptied, switched and properly cleaned/sanitized?

If the milk and milk products are being held for more than one (1) hour and are not in continuous flow, then the balance or surge tank(s) would be considered a storage tank and the balance and surge tank exemption cited in a) above would not apply. Milk and milk products held in these tanks that would be considered storage tanks would be required to be maintained at 45°F or below at all times.

There are two (2) specific cited exemptions in the Administrative Procedures of Item 17p-Cooling of Milk and Milk Products of the PMO. One applies to the storage of whey and whey products at temperatures above 7°C (45°F) and below 57°C (135°F). This would require the storage tank(s) to be emptied, cleaned and sanitized after each four (4) hours or less of use. The other applies to pasteurized milk or milk products being stored in a tank(s) between a condenser and dryer above 10°C (50°F) and below 57°C (135°), which shall be emptied and cleaned after each six (6) hours or less of operation.

c) Does the exemption for a balance or surge tank(s) cited in Administrative Procedure #1 of Item 17p-Cooling of Milk and Milk Products of the PMO only apply to applications that are not for condensing and/or drying?

No. This exemption applies to all balance and surge tank applications including condensing, drying, filtration, pasteurizing and similar processes.

NOTE: *Documentation shall be available to assure less than one (1) hour retention time in the balance or surge tank.*

58. PMO-Section 7, Item 19p

A Grade "A" milk plant would like to use a hand-held pneumatic cap tightening device to tighten (snug-up) caps/closures on milk containers that have had the caps/closures previously applied on approved mechanical capping, closing and/or sealing equipment. This tightening is to ensure a liquid-tight seal for the milk containers. Would this be considered a violation of the PMO?

No, not as long as the caps/closures have already been properly mechanically placed on the milk containers as required under Item 19p-Capping, Container Closure and Sealing and Dry Milk Product Storage of the PMO.

Since the pouring lip of the milk containers will already be covered by a cap/closure that has been mechanically applied in accordance to the PMO and the hand-held pneumatic cap tightening device is used in a sanitary manner to only "snug-up" the cap/closure to ensure a liquid-tight seal this would not be considered a violation of the PMO.

NOTE: *The statements cited above as provided in the answer do not apply to when this hand-held pneumatic cap tightening device would actually be used to place the individual caps/closures on the milk containers and/or the "correcting" of any milk containers that are imperfectly capped as this then would be considered to be hand capping of milk containers and considered a violation(s) of Item 19p of the PMO.*

59. PMO-Appendix B

A producer/processor wished to utilize a farm bulk milk tank installed on an open trailer as their bulk milk pickup tanker. What would be required to meet the construction and protection from contamination requirements addressed in Appendix B-Milk Sampling, Hauling and Transportation, IV-Milk Tank Truck Permitting and Inspection of the PMO?

All openings, including valves and piping, into the farm bulk milk tank must be adequately capped/covered and protected at all times. For the manhole, which does not have a dust cover, this may be accomplished with a tight sealing gasketed lid. If an agitator is installed, this opening must also be properly protected at all times.

For a Regulatory Agency to accept the use of a farm bulk milk tank, with a gasketed manhole without a dust cover, installed on an open trailer for use as a bulk milk pickup tanker as described above, it will be necessary for those wanting to use the farm bulk milk tank to be able to clearly demonstrate to the Regulatory Agency that all of the farm bulk milk tank's openings are adequately capped/covered to protect the milk stored within the farm bulk milk tank from potential contamination.

NOTE: *While being unloaded at the milk plant, all requirements cited in Item 15p-Protection from Contamination, Administrative Procedures #3 of the PMO shall be complied with.*

60. PMO-Section 11; and Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (PROCEDURES)-Sections II, V and VI

a) Are State regulatory personnel that conduct routine regulatory inspections of IMS listed Grade "A" milk plants required to obtain the source(s) of raw milk and/or milk products utilized in the production of Grade "A" milk and/or milk products during each regulatory inspection?

Yes.

b) What action would be required of the State regulatory personnel if they determine that an IMS listed Grade "A" milk plant is receiving and utilizing raw milk and/or milk product for the production of Grade "A" milk and/or milk products from an unlisted source(s) or a source(s) having a Sanitation Compliance Rating of less than 90%?

They shall immediately notify the State Rating Agency and the State Rating Agency shall immediately initiate a rating and withdraw the Grade "A" milk plant's IMS listing.

61. PMO-Appendix B, Sections I and II

a) For direct loads on a dairy farm that are using an in-line sampler, how are they obtaining the temperature for the temperature control (TC) and universal samples that are being collected with each tanker load of milk?

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) cites that the temperature of the universal sample is using the temperature obtained from the TC sample.

NOTE: *In-line samplers take a composite sample as the milk is being loaded into the milk tank truck. Once collected the composite sample is mixed and the TC and universal sample are poured into separate vials. The TC vial shall be checked for temperature.*

b) May they use the in-line temperature recording chart located downstream from the cooling device, or the indicating thermometer located as close as possible to the temperature recording device, or use the temperature indicated on the thermometer located in the refrigerator?

No.

62. PMO-Appendix B, Section II

With an approved in-line sampler, may the Regulatory Agency utilize the trained permitted bulk milk hauler/sampler to monitor the sampler device temperature and milk sample temperatures, and the milk temperature?

Refer to M-I-06-6 for each individual approved in-line sampler's Standard Operating Procedures (SOP).

ISO-LOK, QMI and Anderson In-Line Samplers:

- *No, as the SOP requires that the thermometer(s) used to monitor the refrigerator and TC temperatures shall be checked for accuracy and tagged annually by an NCIMS accredited plant or laboratory facility.*
- *Yes, for the daily (AM-PM) refrigerator temperature checks and recordings, if acceptable to the Regulatory Agency.*

63. PMO-Appendix C, Section V

What is the minimum distance from a farm bulk milk tank outlet valve to a floor drain?

The PMO does not specify a minimum distance; however, Appendix C-Dairy Farm Construction Standards and Milk Production, V. Dairy - Construction and Operation, Milkhouse of the PMO states that floor drains should not be located directly under the outlet of the bulk milk tank. It also states that floor drains should not be located under bulk milk tanks unless there is sufficient room for servicing.

64. PMO-Appendix D, Section V

Does the required reclaimed water samples cited in Section V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants, Category I-Used for Potable Water Purposes, Appendix D-Standards for Water Sources of the PMO have to be collected from the storage vessel, or may they be collected in-line prior to the storage vessel?

These required reclaimed water samples may be collected from any location downstream from the turbidity or electrical conductivity (EC) meter and the divert valve.

65. PMO-Appendix D, Section V

May reclaimed water from an evaporator or condenser be used in a raw milk heat exchanger, and then used for boiler make up water which is not

producing culinary steam (Category III-Use of Reclaimed Water Not Meeting the Requirements of this Section)?

Yes.

66. PMO-Appendix H, Section I

OPTION 1 for pressure relief valves located between the timing pump and the beginning of the holding tube within HTST systems, as cited in Appendix H-Pasteurization Equipment and Procedures and Other Equipment, I. HTST Pasteurization, Pressure Relief Valves Located Within HTST Systems of the PMO, requires that leakage may be determined by observation at the pressure relief valve vent opening to the floor or at the opening of the return piping from the pressure relief valve vent to the constant-level tank. Does this require that a sight-glass be installed on the pressure relief valve vent line returning product to the constant-level tank?

No.

NOTE: OPTION II under this Item does require such a sight-glass to be properly located and installed on the pressure relief valve vent line returning product to the constant-level tank.

67. PMO-Appendix H, Section I

Appendix H-Pasteurization Equipment and Procedures and Other Equipment, Section I-HTST Pasteurization, The Use of Liquid Ingredient Injection Within HTST Systems of the PMO cites the requirement for the use of a slurry pump within an acceptable slurry injection system. May this required slurry pump be of the positive displacement type?

Yes.

68. PMO-Appendix I, Test 11

What is the recommended “can fill” method for completing an accurate drop time on product?

The “can fill” test is a comparison of the time that it takes to pump equal volumes of water and milk or milk product under the same pasteurization system flow settings and operating conditions that were used to conduct the “salt” testing. The volume of liquid is not important as long as the same volume is used for both the water and milk or milk product. Any means that can accurately compare the time that it takes to pump equal volumes of water and milk or milk product under the same pasteurization system flow settings and operating conditions that were used to conduct the “salt” testing

may be evaluated and accepted by the Regulatory Agency for use with Test 11.

Test 11 describes how to use a calibrated tank of considerable size for this purpose when the pasteurization system flow rates make it difficult to use a 38 liter (10 gallon) milk can.

State regulators have evaluated and accepted the use of a calibrated “dip stick” designed to hang inside the pasteurization system’s constant-level tank, which is used to measure the liquid level drop on both water and milk or milk product in pasteurization systems where the constant-level tank foam does not interfere with the reading the “dip stick”.

69. PMO-Appendix J, Section A

The following question relates to yogurt containers that have an additional separate container used to store “crunch” type products, i.e., Oreo or granola, on top of the yogurt container, that are used for the yogurt “crunch” type products. The “crunch” container is not designed to be a lid for storage as this is a mix and eat product. This question is specifically addressing the container used to hold the "crunch" product. Is this container and lid required to be from an IMS Listed source?

No. This plastic "crunch" container and lid are not considered to be a milk product-contact surface, or a component part of the actual milk product container closure or the actual milk product-contact container closure itself.

70. PMO-Appendix J, Section C

A single service closure manufacturing plant is receiving component parts from IMS Listed plants and assembling the final container closures. This assembly plant is then providing their closures to another IMS Listed plant that is attaching the closures to the containers, boxing the assembled containers and shipping the boxes of assembled containers to a contractor for irradiation treatment. **NOTE:** The boxes are not opened for irradiation treatment. From this irradiation plant the boxes of assembled containers are shipped to milk plants to be filled. Which plant is required to comply with the sampling requirements of Section C-Bacterial Standards and Examination of Single-Service Containers and Closures, Appendix J-Standards for the Fabrication of Single-Service Containers and Closures of Milk and Milk Products of the PMO?

With this scenario, the plant that is assembling the final containers with the closures, prior to irradiation treatment, would be required to comply with the sampling and examination requirements of Section C, Appendix J of the PMO.

NOTE: *If the plant that assembles the final container closures also provides assembled closures to another plant that does not attach the closures to the containers prior to being shipped to a milk plant for filling; or directly to a contractor for irradiation treatment without any other assembly with a container; or ships assembled closures directly to a milk plant, which are attached to a container after filling at the milk plant, then the plant that assembles the final container closures would also be required to comply with the sampling and examination requirements of Section C, Appendix J of the PMO*

71. PMO-Appendix N

a) What tests have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family other than for Beta lactams?

The following tests have been evaluated and accepted by the NCIMS for raw, commingled bovine milk:

- *Charm II Sulfa (Competitive Assay)-Sulfamethazine, Sulfadiazine, Sulfadimethoxine and Sulfathiazole (IMS-a-33);*
- *Charm II Tetracycline (Competitive Assay)-Tetracycline, Chlortetracycline and Oxytetracycline (IMS-a-36);*
- *Charm II Chloramphenicol (M-I-92-11); and*
- *Charm Beta-lactam and Flunixin (M-I-12-3).*

b) Are industry and the Regulatory Agency required to follow the testing protocol, reporting, trace back, etc. as cited in Appendix N when these tests cited above are being utilized?

Yes.

72. PMO-Appendix N, Section I

a) Is each compartment of a multi-compartment bulk milk tank truck required to be tested individually for drug residues in accordance with Appendix N of the PMO?

Yes.

b) If one (1) or more of the compartments is (are) confirmed positive for drug residues is that adulterated milk to be handled and regulated in accordance with Appendix N of the PMO, i.e., not being unloaded by the milk plant and producer trace back to identify the producer(s) responsible?

Yes.

c) If one (1) or more of the compartments is (are) confirmed negative for drug residues is that milk allowed to be unloaded and used by the milk plant, even if the bulk milk tank truck was loaded using the same pump?

Yes, as long as none of the negative compartments contain any milk from any identified confirmed positive dairy producer from a confirmed positive compartment on that milk tank truck.

With the specific situation as cited above, if the positive compartment(s) has to be unloaded and the adulterated milk properly disposed of before the negative compartment(s) can be unloaded, the common loading pump, which is also used for unloading; or a separate common unloading pump; or common outlet shall be properly cleaned and sanitized before unloading the negative compartment. Also, the milk tank truck shall be properly cleaned and sanitized prior to picking up any more milk.

73. PMO-Appendix N, Section I

What positive antibiotic test results from analysis conducted by industry are required to be reported to the Regulatory Agency?

All positive test results for drug residues, using either approved or unapproved test kits or methods, from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale), and finished milk or milk product samples shall be reported to the Regulatory Agency and appropriate Regulatory Agency action and follow up in accordance with Appendix N is required.

74. PMO-Appendix N, Sections I and III

What action is required if a load of milk is found negative or non-violative at a milk plant and subsequent testing either by the milk plant or other laboratory identified a positive producer was on that load of milk?

The load of milk, which tested negative or non-violative, and in most situations would have already been received by the milk plant, would be acceptable to be processed. However, with the identified positive producer on the load, the Regulatory Agency shall be advised and the producer's permit suspended until such time as subsequent testing reveals a non-violative result. The permit reinstatement shall be in accordance with Appendix N and shall count on the producer's record of first, second or third occurrences which may lead to the permanent revocation of permit.

75. PMO-Appendix N, Section III

A single producer's direct load milk tank truck is confirmed positive for antibiotics. Does an approved lab have to go thru the producer trace back procedure since there is only one (1) producer on the milk tank truck?

Yes.

76. PMO-Appendix Q, Item 13r

Item 13r-Milking, Flanks, Udders and Teats within Appendix Q-Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization of the PMO requires that Automatic Milking Installation (AMI) manufacturers shall submit data to FDA to show that the teat preparation system employed in their system is equivalent to Item 13r, Administrative Procedures #4 of the PMO. FDA has issued M-I's citing which AMI manufacturer's teat preparation systems have been determined to be equivalent. Do these issued M-I's also approve the construction issues related to the applicable AMI system cited in the M-I's?

No. These M-I's only address the AMI manufacturer's teat preparation system as being determined by FDA to be equivalent with Item 13r, ADMINISTRATIVE PROCEDURES #4 of the PMO.

77. PROCEDURES-Section IV

a) A milk plant and their single source of raw milk (BTU) are separately rated and IMS Listed. If the BTU is delisted, would the milk plant be automatically delisted because this is their only source of raw milk as listed on page 2 of FORM FDA 2359i-Interstate Milk Shipper's Report?

No. The milk plant or company shall be immediately notified by the State Rating Agency of this official delisting. The milk plant following this official notification, shall then obtain raw milk from a source(s) that has a current valid IMS Listing with a Sanitation Compliance Rating of ninety (90) or greater to maintain their current IMS Listing. The Regulatory Agency shall be monitoring this situation to make sure that the milk plant is not receiving raw milk from this unlisted source. If the milk plant chooses to obtain their raw milk from this unlisted raw milk source then the Regulatory Agency shall immediately notify the State Rating Agency and the State Rating Agency shall immediately removed the milk plant from the IMS List.

b) A milk plant and their single source of raw milk (BTU) are listed under the same State rating. If either the BTU or milk plant is delisted, would the milk plant or BTU, respectively, be automatically delisted?

Yes.

78. PROCEDURES-Section IV

a) A milk plant has Grade "A" milk and/or milk product inventory in their cooler when they are delisted by a State rating. Once the milk plant or company receives the official letter of notification of delisting, may they still ship this Grade "A" milk and/or milk product inventory, which was produced before the rating?

No.

b) Must the milk plant cease shipping any Grade "A" milk or milk product in interstate commerce once the official letter of notification is received?

Yes. They cannot ship any Grade "A" milk or milk product in interstate commerce based on the date of the delisting cited in the official letter of notification from the State Rating Agency. This would include any Grade "A" milk or milk product produced prior to the official delisting date and still in the possession of the milk plant.

c) Once the milk plant is delisted, the milk plant may be allowed by the State Regulatory Agency to produce Grade "A" milk and/or milk products for intrastate sale only. However, once re-rated, with an acceptable rating and a signed permission-to-publish, the milk plant may have Grade "A" milk and/or milk product inventory in their cooler that was produced while they were removed from the IMS List, may these Grade "A" milk and/or milk products be shipped in interstate commerce?

No. These Grade "A" milk and milk products were produced when the milk plant did not have an acceptable IMS rating and listing. They would be authorized to begin shipping in interstate commerce product produced after they receive an acceptable IMS rating, signed permission-to-publish, the submitted rating is signed off by the RMS, and the milk plant is again listed on the IMS List.