

5001 Campus Drive  
College Park, MD 20740-3835

M-I-18-3

January 19, 2018

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 2016

Following are answers to questions received from the field; Regional 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 2016.

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 FDA Milk Specialists, Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your area. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties. It will also 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](mailto:robert.hennes@fda.hhs.gov).



Robert F. Hennes, RS, MPH  
CAPT, U.S. Public Health Service  
Milk and Milk Products Branch

1. **PMO; 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); and Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (PROCEDURES)**

IMS-a-50 (Supplement 1)-Effective Date Stayed for Joint Council (JC) Proposals 3, 4, 5 and 7 from the 2015 NCIMS Conference was issued May 9, 2016. It provided for Milk Sanitation Rating Officers (SROs) and FDA Milk Specialists (MSs) to exercise discretion on ratings and check ratings, respectively, by not debiting milk plants on the provisions of JC Proposals 3, 4, 5 and 7 until the extended compliance date of September 17, 2018 as established by FDA in Federal Register (FR) Notices published on September 17, 2015 and November 18, 2015.

a) Is this a stay on the NCIMS request to **NOT** debit during ratings and check ratings **OR** that all the referenced actions will be stayed for both Enforcement Ratings (ERs) and Sanitation Compliance Ratings (SCRs) until September 17, 2018?

*Both.*

b) Also, the 2015 PMO incorporated the new language into the new Item 15p(C) and the existing Appendix K-HACCP Program; will compliance with these actions also be stayed where States officially adopt the 2015 PMO by reference?

*Yes.*

c) What are FDA's recommendations related to this stay for SROs and FDA MSs when they are conducting ratings and check ratings, respectively, prior to September 17, 2018?

*FDA is recommending that SROs during ratings and FDA MSs during check ratings only ask milk plant management how they are addressing JC Proposals 3, 4, 5 and 7 and **DO NOT** debit the milk plant for non-compliance until the FDA extended compliance date of September 17, 2018.*

**NOTE:** *The answers provided above also apply to Proposals JC-2 and JC-4 passed at the 2017 NCIMS Conference, which addressed aligning the PMO with the requirements of the Food Safety Modernization Act's (FSMA) Final Rule for Preventive Controls for Human Food (PCHF). Proposals JC-2 and JC-4 made changes to the 2015 NCIMS Conference JC Proposals that were passed and established an effective date of September 17, 2018.*

## 2. **PMO; MMSR; and PROCEDURES**

JC Proposal 1 from the 2015 NCIMS Conference added the following to Section 7-Standards for Grade "A" Pasteurized, Aseptically Processed and Packaged Low-Acid Milk and/or Milk Products, and Retort Processed after Packaging Low-Acid Milk and/or Milk Products: "The Grade "A" PMO, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed." IMS-a-50 (Supplement 1) provides for SROs and FDA MSs to exercise discretion on ratings and check ratings, respectively, by not debiting milk plants on the provisions of JC Proposals 3, 4, 5 and 7 until the extended compliance date of September 17, 2018 as established by FDA in Federal Register (FR) Notices published on September 17, 2015 and November 18, 2015. Does this approach and stay addressed in Question 1 above also apply to JC Proposal 1?

Yes.

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

If rennet is being added to sour cream as part of the culturing process, is it required that rennet be declared in the ingredient statement on the sour cream label?

*Yes. The Standard of Identity (SOI) for sour cream provides for the addition of rennet. If rennet is added, it shall be declared in the ingredient statement on the principal display or information panel of the sour cream label.*

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

a) A milk plant that utilizes batch (vat) pasteurization wishes to add the term "Low Heat" or "Low Heat Pasteurization" on the labels of their Grade "A" milk and milk products. Wouldn't the use of these terms "Low Heat" or "Low Heat Pasteurization" without an explanation of what either of those terms means be considered to be misleading to the consumer?

*The following answers were provided by CFSAN's Office of Nutrition and Food Labeling (ONFL):*

*Yes. "Low Heat" or "Low Heat Pasteurization" are not defined in the CFR, so they are an undefined labeling term. Unless their labels are going to asterisk*

*those terms and then explain someplace on the label what "Low Heat" or "Low Heat Pasteurization" means, it would be misleading to the consumer.*

b) Would "Vat Pasteurized at 145°F" be acceptable labeling?

Yes.

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

A milk plant wishes to process a whole milk product with 3.8% butterfat, instead of the standard 3.25% and label the whole milk product as "Whole Milk Plus". Would there be any issues with doing this and labeling the product as such?

*The following answer was provided by CFSAN's ONFL:*

*The use of the standardized term "milk" on the Principle Display Panel (PDP) of the labeled container is subject to the SOI found in 21 CFR 131.110 "Milk". This SOI requires that the "milk" contain not less than 3.25% milkfat, but does not set a maximum milkfat percent. It would be acceptable for the PDP to declare the amount of milkfat present, e.g. 3.8%, in order to distinguish it from other "milk" that may contain various milkfat levels meeting this SOI. The nutritional information on the nutritional panel of the container label would also need to reflect the correct amount of milkfat in the product.*

*The use of the term "Plus" to describe this standardized food, "milk", is not acceptable, since it may mislead consumers to conclude that this milk or milk product is different or superior to other standardized milk or milk products that comply with 21 CFR 131.110. The only exception under Section 4-Labeling of the PMO addressing the label of a Grade "A" milk or milk product is if "Whole Milk Plus™" was the trade marked name of the milk or milk product.*

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

A milk product is being labeled with added ingredients: "with Acidophilus, Bifidus, & Vitamin E, Fat Free Milk Vitamins A & D".

a) Could this milk product be labeled as a multi-food product (Fat Free Milk with Acidophilus, Bifidus, and Vitamin E) if the milk product does not meet the SOI for milk or cultured milk?

*The following answers were provided by CFSAN's ONFL:*

*No. The addition of bacterial cultures cannot be considered a 2-food concept for a food. The milk company needs to explain why this is not a cultured milk under the standard of identity. If the milk product is not a cultured milk, they*

*cannot use this term. The milk product also does not meet the standard of identity for milk, or a fat-reduced milk, because the culture addition takes it out of the standard of identity as previously discussed.*

b) Is the citing of "Vitamin E" on the label considered a fortification claim as it does not state fortified or enriched?

*The vitamin E addition, even though it does not say "contains", would still be considered a fortification claim. However, since they are adding 100% of the Daily Value (DV), we do not object to the way it is presented on the label.*

**7. PMO-Sections 1 and 4; and MMSR-Section H**

A milk plant is ultra-pasteurizing (UP) and packaging; and/or aseptically processing and packaging a milk product that meets the definition of Milk Products contained within Section 1-Definitions of the PMO. They are labeling the Grade "A" milk product as a "Dairy Dessert". Utilizing the current Product Codes from the *IMS List*, what Product Codes should the Rating Agency use in listing this Grade "A" milk product for this milk plant?

*Product Code 5-Ultra-Pasteurized Milk and Milk Products or 6-Aseptic Milk and Milk Products (including Flavored), respectively, and Sub-Product Code (2)-Pasteurized Milk, Reduced Fat, Lowfat, Skim (for the skim milk, cream and added ingredients) depending on the means of pasteurization and packaging.*

**8. PMO-Sections 1, 4 and 11; and MMSR-Section E**

If a milk plant chooses to use butter flakes or granules as an optional ingredient in the production of Grade "A" cultured buttermilk and/or Grade "A" acidified buttermilk what would be the requirements for the source of the butter flakes or granules?

Please refer to M-a-61 revised 8/17/1979.

Use of Butter Flakes or Granules as Optional Ingredients in Grade A Cultured Buttermilk and/or Grade A Acidified Buttermilk.

Section 1-Definition ~~N~~ GG (2015 PMO) includes cultured buttermilk and acidified milk products. Definition ~~N~~ GG (2015 PMO) further exempts butter from the PMO requirements except when combined with other substances to produce any pasteurized milk product defined in the PMO. These defined products shall be labeled Grade "A" and all milk-derived components are products which have been produced under the provisions of the PMO.

We are of the opinion that whenever butter flakes or granules are added to Grade "A" cultured buttermilk or Grade "A" acidified buttermilk that they must be obtained from Grade "A" milk or cream and handled and processed in compliance with all applicable provisions of the PMO.

When conducting a milk sanitation rating or check-rating, if a Grade "A" dairy plant is using butter flakes or granules which do not comply with these criteria, the milk plant would be subject to immediate withdrawal from the *IMS List* as they are receiving milk products from an unlisted source.

Also, please refer to M-a-61 (Supplement 1), revised 8/17/1979, which outlines the criteria that we would expect a State to follow to certify sources of butter flakes and/or granules as "Acceptable" for use in the processing of Grade "A" Cultured Buttermilk and/or Grade "A" Acidified Buttermilk.

At the current time, there are not any "Acceptable" sources of butter flakes or granules as the last information available came from 1998 when the State of PA certified that butter flakes manufactured at Consumer Packaging Company, D/B/A Hanover Foods Lancaster Division, Lancaster, Pennsylvania were in compliance with M-a-61 (Supplement I) and the PMO. This certification was submitted on FORM FDA 2359i-Interstate Milk Shipper's Report to the MST and the MST issued an M-I stating:

- The addition of flakes or granules to Grade "A" cultured buttermilk or Grade "A" acidified buttermilk requires that the dairy ingredients be obtained from Grade "A" sources and handled and processed in compliance with all applicable provisions of the PMO.
- In addition, M-a-61, Supplement 1, outlines the necessary criteria for certification of sources of flakes or granules for cultured buttermilk or acidified buttermilk, since the present guidelines do not provide for inclusion of these sources on the *IMS List*. (**NOTE:** This still holds true today.)
- The State of PA certifies that butter flakes manufactured by Consumer Packaging Company, D/B/A Hanover Foods Lancaster Division, Lancaster, Pennsylvania are in compliance with these established guidelines for use in cultured buttermilk or acidified buttermilk.

*If a milk plant wishes to utilize butter flakes or granules in the processing of Grade "A" cultured buttermilk and/or Grade "A" acidified buttermilk from an outside source, the plant that is manufacturing the butter flakes and/or granules would be required to comply with M-a-61 (Supplement 1) and the State would have to conduct a rating and submit FORM FDA 2359i to MST so that MST can issue an M-I stating that the manufacturing plant is certified by the State and the butter flakes and/or granules are approved for use in the processing of Grade "A" buttermilk and/or Grade "A acidified buttermilk.*

*Another source of Grade “A” butter flakes could be for a milk plant to use pasteurized Grade “A” cream and whip it until it becomes butter and add food coloring.*

*If this is to be conducted in a Grade “A” IMS Listed milk plant and they are utilizing the butter flakes for their own in-milk plant processing of Grade “A” buttermilk and/or Grade “A” acidified buttermilk and are not selling the butter flakes or granules to other Grade “A” IMS Listed milk plants then as long as they comply with the following they would be approved to use the Grade “A” butter flakes in that milk plant for the production of Grade “A” buttermilk and/or Grade “A” acidified buttermilk.*

- *They shall use Grade “A” milk and/or cream from an IMS Listed source;*
- *The process shall use equipment that complies with the PMO; and*
- *They shall be handled and processed in facilities and under conditions that comply with the PMO.*

**9. PMO-Sections 3 and 5; and Appendix J; and MMSR-Section I**

a) For single-service containers and/or closures manufacturing facilities that do not ship single-service containers and/or closures, are not IMS listed and operate in conjunction with and under the same permit as an IMS listed milk plant, is it required that the Regulatory Agency complete both FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) and FORM FDA 2359-Milk Plant Inspection Report and issue them to the milk plant following the required quarterly Regulatory Agency milk plant inspection?

*No. Because this single-service containers and/or closures manufacturing facility is included under the milk plant’s permit and all of the single-service containers and/or closures are used within the milk plant, the required quarterly Regulatory Agency milk plant inspection would include the single-service containers and/or closures manufacturing facility and any violation(s) associated with the single-service containers and/or closures manufacturing facility would be debited on FORM FDA 2359.*

**NOTE:** *The same would be true when conducting the milk plant rating or check rating. Because the single-service containers and/or closures manufacturing facility is included under the milk plant’s permit and all the single-service containers and/or closures are used within the milk plant, the milk plant rating and check rating would include the single-service containers and/or closures manufacturing facility and any violation(s) associated with the single-service containers and/or closures manufacturing facility would be debited on FORM FDA 2359.*

b) For single-service containers and/or closures manufacturing facilities that are issued and operate under a separate permit and are located in conjunction with an IMS listed milk plant, are they required to be IMS listed and inspected, rated and check rated utilizing Appendix J-Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the PMO and FORM FDA 2359c even though they do not ship single-service containers and/or closures and all of the single-service containers and/or closures are utilized within the milk plant?

*Yes. Because the Regulatory Agency has chosen to issue a separate permit for the single-service containers and/or closures manufacturing facility then any violation(s) of Appendix J of the PMO associated with the single-service containers and/or closures manufacturing facility would be debited on FORM FDA 2359c. Also, because this single-service containers and/or closures manufacturing facility is operating under a separate permit and would not be included under the milk plant's permit it is not rated or check rated with the milk plant. The milk plant is required to only utilize single-service containers and/or closures from an IMS listed source; therefore, this single-service container and/or closures manufacturing facility would require their own IMS certification/listing.*

**NOTE:** *Section 3-Permits of the PMO does not require single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant or single-service containers and/or closures manufacturers that operate as a separate entity to be permitted by the Regulatory Agency. Where the Regulatory Agency is permitting single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant or single-service containers and/or closures manufacturers that operate as a separate entity applies is when these single-service containers and/or closures manufacturing facilities wish to be certified for an IMS listing and the period of time (12 or 24 months) that they may be listed for. Refer to Section I-Publication of the "Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) of the MMSR for additional information related to the certification and IMS listing of single-service containers and/or closures manufacturers.*

**10. PMO-Sections 3 and 5; and PROCEDURES-Section IV**

a) A Grade "A" milk plant has their permit suspended because of repeat sanitation item violations and they cannot process because they do not have a permit to do so. At the time of the permit suspension, what should happen to the Grade "A" milk and/or milk products that are located at the milk plant or under the control of the milk plant?

*The Regulatory Agency should embargo or stop the shipment of Grade “A” milk and/or milk products as they cannot distribute the Grade “A” milk and/or milk products as they do not have a Grade “A” permit.*

b) What other actions should the Regulatory/Rating Agency take?

*Section IV-Oversight and Responsibilities, B-State, TPC, and SSC Responsibilities of the Procedures would require the shipping State or TPC to immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs of this milk plant’s permit suspension.*

c) Once the permit is reinstated, can the milk and/or milk product that was placed on embargo or stoppage of shipment be allowed to be distributed either in intrastate or interstate commerce, must it be destroyed, or can the State use its own discretion?

*Based upon an individual State’s laws and statutes, the Regulatory Agency shall determine whether the milk plant would be able to ship the Grade “A” milk and/or milk products produced or received prior to the permit suspension in intrastate commerce. Also, based on an individual State’s laws and statutes and provided the milk and/or milk products have been maintained properly, i.e. temperature, package integrity, etc., the State shall determine whether reconditioning and reprocessing of these milk and/or milk products for intrastate shipment may be conducted. If the State determines that reconditioning and reprocessing may be conducted, the interstate shipment of these reconditioned and reprocessed milk and/or milk products would only be acceptable if the reconditioning and reprocessing occurs after the milk plant’s permit has been reinstated.*

**11. PMO-Sections 3, 5, 6 and 7, Items 11p and 12p; and Appendix J, Section C; and MMSR-Section D; and Appendix A**

The following questions relate to **BOTH** IMS listed single-service containers and/or closures manufacturing facilities and single-service containers and/or closures manufacturing facilities that operate in conjunction with a milk plant that are not IMS listed for single-service containers and/or closures and the single-service containers and/or closures are only used for in-milk plant use.

a) What criteria is utilized to determine if a sample set of single-service containers and/or closures exceeds the microbial (bacterial) count or coliform standards cited in Item 12p-Cleaning and Sanitizing Containers and Equipment of the PMO and which are referenced to Section C-Bacterial Standard and Examinations of Single-Service Containers and/or Closures, Appendix J of the PMO?

*A sample set from each manufacturing line, as defined in Appendix J of the PMO, shall consist of a minimum of four (4) containers and/or closures, when the rinse test is used, or a minimum of four (4) 250 cm<sup>2</sup> areas of surface, when the swab test is used.*

*To determine compliance of the individual sample sets, where a rinse test can be used, the residual microbial (bacterial) count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the microbial (bacterial) count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per fifty (50) cm<sup>2</sup> (1 per square centimeter) of product-contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.*

*Therefore, the single-service containers and/or closures sample set would not be considered to be in violation for residual microbial (bacterial) count when only one (1) or two (2) of the four (4) containers and/or closures of the sample set exceeded the residual microbial (bacterial) standards. The single-service containers and/or closures sample set would be considered to be in violation of the residual microbial (bacterial) limit if the sample results indicated that three (3) or more of the single-service containers and/or closures of the required sample set of four (4) taken on a given day exceeded the residual microbial (bacterial) standard as cited above for the rinse test or swab test. Also, if any single-service container and/or closure within the sample set of four (4) has one (1) or more coliform organisms detected, the sample set would be considered to be in violation of the coliform standard.*

b) If a single-service containers and/or closures manufacturer has two (2) out of the last four (4) consecutive microbial (bacterial) counts and/or coliform determinations for the individual sampling sets exceeding the standard(s) is the Regulatory Agency required to issue a written notice/warning letter and collect an additional sample set within twenty-one (21) days of the sending of the written notice/warning letter, but not before the lapse of three (3) days similar to what is required for milk and milk product samples addressed in Section 6-The Examination of Milk and Milk Products of the PMO?

*No. There currently is not a specific enforcement procedure, based on sample set results, for single-service containers and/or closures addressed in the PMO, as there is for milk and/or milk products as cited in Section 6-The Examination of Milk and/or Milk Products of the PMO. However, Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 1.b.2) of the MMSR states: "Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service manufacturer's containers and/or closures meet the standards of Appendix J. of the Grade "A" PMO. Each manufacturing line of containers and/or closures for each of the above*

*applicable requirements, shall be debited if two (2) of the last four (4) sample sets results exceed the limit(s), and the last sample set result is in violation...”.*

c) If a single-service container and/or closure manufacturer has three (3) out of the last five (5) consecutive microbial (bacterial) counts and/or coliform determinations for the individual sampling sets exceeding the standard(s) is the Regulatory Agency required to suspend the permit or stop the sale of single-service containers and/or closures similar to what is required for milk and milk product samples addressed in Section 6 of the PMO?

*No. There currently is not a specific enforcement procedure, based on sample set results, for single-service containers and/or closures addressed in the PMO, as there is for milk and/or milk products as cited in Section 6 of the PMO.*

The following questions relate **ONLY** to single-service containers and/or closures manufacturing facilities that operate in conjunction with a milk plant that are not IMS listed for single-service containers and/or closures and the single-service containers and/or closures are only used for in-milk plant use.

d) Where in the PMO is it required that enforcement action be taken on single-service containers and/or closures not meeting microbial (bacteria) and/or coliform standards for an IMS listed milk plant that only makes single-service containers and/or closures for in-milk plant use and the single-service container and/or closures manufacturing facility is not IMS listed?

*With the in-milk plant single-service containers and/or closures manufacturing facility not being IMS listed for single-service containers and/or closures, the routine inspection of the in-milk plant single-service containers and/or closures manufacturing facility would be under the milk plant’s permit and included in the routine three (3) month regulatory inspection of the IMS listed milk plant. Any violations identified within the single-service container and/or closures manufacturing facility would be debited against the milk plant and would be debited on FORM FDA 2359. For single-service containers and/or closures not complying with the microbial (bacteria) and/or coliform standards they would be debited on FORM FDA 2359 under Item 11-Construction and Repair of Containers and Equipment (c)-Approved single-service articles; not reused. This would also apply for ratings and check ratings conducted of this IMS listed milk plant.*

*Continued violations of the single-service containers and/or closures microbial (bacteria) and/or coliform standard would warrant the repeat consecutive debiting of Item 11(c) on FORM FDA 2359, which would trigger the required PMO enforcement action to suspend the IMS listed milk plant’s permit in accordance with Section 3 of the PMO.*

*It is recommended that the Regulatory Agency address all single-service containers and/or closures violations of microbial (bacteria) and coliform standards by promptly following up with an inspection to determine and correct the cause. It is also recommended that the Regulatory Agency resample and test the single-service containers and/or closures for compliance with the microbial (bacteria) and coliform standards cited in Item 12p and referenced to Section C within Appendix J of the PMO.*

e) While conducting a rating or check rating where in the MMSR does it require that the IMS listed milk plant be debited under the ER for single-service containers in violation of the microbial (bacteria) and coliform standards and the required PMO enforcement action not being taken?

*Appendix A-Guidelines for Computing Enforcement Ratings (FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods (Page 2)), PART II-Milk Plants, Item 9-Permit issuance, suspension, revocation, reinstatement, hearing and/or court action taken as required, Sanitation Requirements, Category II-Permit Suspension of the MMSR would be utilized. Item 2-Category II-Permit Suspension under Milk Plant Enforcement Procedures on FORM FDA 2359j, Section E-Milk Plant Enforcement Action and Record Evaluations (Page 5) would not be given Credit if the repeat consecutive debiting of Item 11(c) on FORM FDA 2359 for violations of the single-service containers and/or closures microbial (bacteria) and/or coliform standards, which would trigger the required PMO enforcement action to suspend the IMS listed milk plant's permit in accordance with Section 3 of the PMO was not taken.*

The following question relates **ONLY** to IMS listed single-service containers and/or closures manufacturing facilities.

f) While conducting a rating or check rating where in the MMSR does it require that the IMS listed single-service containers and/or closures manufacturing facility be debited under the ER for single-service containers in violation of the microbial (bacteria) and coliform standards and enforcement action not being taken?

*The MMSR does not address or require Enforcement Ratings to be conducted and calculated for the IMS certification/listing of single-service containers and/or closures for milk and/or milk products manufacturers.*

**NOTE:** *Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 1-Collection of Data, b-Recording of Laboratory and Other Test Data of the MMSR does address points that would be debited against the SCR of a single-service containers and/or closures for milk and/or milk products manufacturers during*

ratings and check ratings. Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service manufacturer's containers and/or closures meet the standards of Section C within Appendix J of the PMO. Each manufacturing line of containers and/or closures for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample set results exceed the limit(s), and the last sample set result is in violation. A debit shall be given when less than the required number of sample sets has been examined during the preceding six (6) months. For certification purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the certification is made and the preceding six (6) months. Single-service containers and/or closures manufacturers which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year-round basis and for which the Regulatory Agency, single-service consultants (SSCs) and/or single-service containers and/or closures manufacturer, as applicable, has not yet examined the required number of sample sets shall not be debited, provided that the last sample set result is within the limit(s).

12. **PMO-Sections 3 and 6; and Appendix E; and PROCEDURES-Section IV**

A milk plant's raw commingled milk supply had official Regulatory Agency samples collected following receipt by the milk plant and prior to pasteurization in accordance with Section 6 of the PMO. The sample results indicated three (3) out of the last five (5) consecutive samples exceeded the bacteriological standard of 300,000/ml. What regulatory actions are required by the Regulatory Agency under the National Conference on Interstate Milk Shipment's (NCIMS') Grade "A" Milk Safety Program?

- *Section 3, Suspension of Permit, and Section 6 of the PMO would require the immediate suspension of the milk plant's permit.*

**NOTE:** *Section 3 of the PMO provides that the Regulatory Agency ~~for~~ may forego the suspension of the permit provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product applies to specific pasteurized milk and/or milk products that are not in compliance and three (3) out of last five (5) consecutive samples exceed their respective standard(s). This does not apply to a milk plant's raw commingled milk supply.*

- *Section IV-Oversight and Responsibilities, B-State, TPC, and SSC Responsibilities of the Procedures would require the shipping State or TPC to immediately notify all known receiving States and/or TPCs and the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs of this milk plant's permit suspension.*

- *Section 3, Reinstatement of Permit, of the PMO also states that the process for the reinstatement of the permit for this situation of three (3) out of the last five (5) consecutive samples exceeding the bacteriological standard of 300,000/ml for raw commingled milk collected after receipt by the milk plant and prior to pasteurization may be conducted following written application for the reinstatement of their permit by the milk plant. Within one (1) week after the receipt of notification for reinstatement of their permit, the Regulatory Agency shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. 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. The Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of the PMO.*

**NOTE:** *Please refer to M-I-05-4 (QUESTIONS AND ANSWERS FROM FY'04 AND FY'05 FD3105-DAIRY FARM SANITATION AND INSPECTION COURSES AND FROM FY'05 REGIONAL MILK SEMINARS AND CHECK RATINGS) (QUESTION #1)-8/1/2005 for an example of when the raw commingled milk would be considered in compliance with the standard during the required accelerated sampling period cited above.*

**13. PMO-Sections 3 and 6; and MMSR-Appendix A**

Is eggnog, a seasonal milk product that may only be produced in October, November and December of each year, or cultured buttermilk that is produced two (2) or three (3) months per year, required to be sampled during each month of production for official regulatory purposes to be in compliance with Section 6 of the PMO?

*Yes. With the passage of Proposal 228 from the 2017 NCIMS Conference it states that if the production of Grade "A" raw milk or any Grade "A" milk or milk product, as defined in this Ordinance, is not on a continuous monthly basis and; therefore, cannot meet Section 6 sampling frequency requirement that during any consecutive six (6) months, at least four (4) samples of the Grade "A" raw milk milk or Grade "A" milk or product shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, then a sample of the Grade "A" raw milk or Grade "A" milk or milk product shall be collected during each month of production.*

**NOTE:** *The Regulatory Agency carries the sample history forward through the months where eggnog and/or eggnog products or cultured buttermilk, as*

*described above, were not produced and; therefore, were not available to be sampled. In accordance with Section 6 of the PMO the Regulatory Agency shall send a written notice whenever two (2) of the last four (4) consecutive coliform determinations or cooling temperatures exceed the standard for the eggnog and/or eggnog products or cultured buttermilk described above. This written notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such written notice, but not before the lapse of three (3) days. Immediate suspension of the permit or the stoppage of the production of the eggnog and/or eggnog products or cultured buttermilk, in accordance with Section 3 of the PMO, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) coliform determinations or cooling temperatures for the eggnog and/or eggnog products or cultured buttermilk. For both required regulatory enforcement activities, the records and additional sampling within twenty-one (21) days of the sending of a written notice, as cited above, may expand over two (2) calendar years.*

**14. PMO-Sections 1, 4 and 7, Item 16p**

If a milk or milk product is pasteurized at or above 280°F (138°C) for at least two (2) seconds is the milk or milk product required to be labeled “Ultra-pasteurized”?

Yes.

*21 CFR 131.110(e) cites the name of the food is “milk”.*

*21 CFR 131.110(e)(1). states: “The following terms shall accompany the name of the food whenever it appears on the principal display panel or panels on the label in letters not less than one-half the height of the letters used in such name:*

*(ii) The words “ultra-pasteurized” if the food has been ultra-pasteurized.”*

*By definition (21 CFR 131.3(c) and Section I-Definitions (BBB) of the PMO), “Ultra-Pasteurization”, when used to describe a milk and/or milk product is shall have been thermally processed at or above 280°F (138°C) for at least two (2) seconds, either before or after packaging, so as to produce a milk or milk product which has an extended shelf-life under refrigerated conditions.*

*(Please refer to M-I-06-15 (Question #14) and M-I-15-3 (Question #12) for additional information.)*

15. **PMO-Sections 5 and 7**

If a milk plant stores Grade “A” ingredients, single-service articles, and/or finished product in a leased or self-owned off-site storage facility, would this facility or facilities be included in a routine milk plant inspection, rating or check rating of an IMS listed milk plant?

*Yes. Refer to M-I-16-10 (FY 2014 Qs/As) (Question #10) for additional information related to this subject.*

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

Utilizing FORM FDA 2359j-Milk Sanitation Rating Report, Section C-Evaluation of Sampling Procedures (Page 3), Item #5-Samplers evaluated every two (2) years and reports properly filed, for either the dairy farm or milk plant sampling procedures, how is this to be properly evaluated? Is it to be evaluated to determine if the bulk milk hauler/sampler’s, or industry plant sampler’s, or dairy plant sampler’s last sampling procedures evaluation is current, within two (2) years of the rating or check rating date, **OR** is it to be properly evaluated back to the previous sampling procedures evaluation date?

*Both. Evaluate to determine that the last sampling procedures evaluation is current, within two (2) years of the rating or check rating date **AND** that it has been conducted within the two (2) years plus the remaining days of the month in which due since the previous sampling procedures evaluation.*

***For Example:*** A rating or check rating is conducted June 15, 2016. The bulk milk hauler/sampler’s, or industry plant sampler’s, or dairy plant sampler’s last sampling procedures evaluation was conducted April 1, 2016. This bulk milk hauler/sampler’s, or industry plant sampler’s, or dairy plant sampler’s sampling procedures evaluation would be considered current, within two (2) years of the rating or check rating date. However, when evaluating if this bulk milk hauler/sampler’s, or industry plant sampler’s, or dairy plant sampler’s sampling procedures evaluation, conducted April 1, 2016, was conducted within the two (2) years plus the remaining days of the month in which due since the previous sampling procedures evaluation, the previous sampling procedures evaluation date shall be determined. For this example, the previous sampling procedures evaluation date was determined to be February 12, 2014. Therefore, this bulk milk hauler/sampler, or industry plant sampler, or dairy plant sampler would not be in compliance and would be debited under Item #5-Samplers evaluated every two (2) years and reports properly filed because the sampling procedures evaluation was required to have been completed by Feb 29, 2016, two (2) years plus the remaining days of the month in which due.

17. **PMO-Section 5; and MMSR-Section E; and Appendix A**

Section 5-Inspection of Dairy Farms and Milk Plants of the PMO requires that milk plants be inspected at least once every three (3) months with the provision that for milk plants or portions of milk plants that are IMS listed to produce aseptically processed and packaged or retort processed after packaging low-acid milk and/or milk products shall be inspected at least once every six (6) months. For purposes of determining the inspection frequency for milk plants, the interval shall include the designated three (3) month period or six (6) month period, respectively, plus the remaining days of the month in which the inspection is due.

Appendix N-Drug Residue Testing and Farm Surveillance, II-Regulatory Agency Responsibilities, Monitoring and Surveillance of the PMO requires that Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program.

During a rating or check rating, when conducting the records review and calculating the Credit for Item #2-Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plants and transfer stations once every six (6) months under Milk Plant, Part II on FORM FDA 2359j, Section B (Page 2) for the Enforcement Rating for a milk plant, receiving station or transfer stations, as applicable, is the required on-site quarterly inspections to review industry records of their Appendix N sampling program to be considered in this calculation?

*No. The requirement for the Regulatory Agency to monitor Appendix N industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program is included within Appendix N and not Section 5 of the PMO. Documentation of these inspections to review industry's records of their sampling program for Appendix N shall be in the official Regulatory Agency's individual milk plant files.*

**NOTE:** *For FDA MSs, when conducting the required triennial State Program Evaluation (SPE) and it has been determined that the required Appendix N on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program are not*

*being conducted or are not being properly documented, this issue should be cited under the Appendix N section of the written SPE report.*

**18. PMO-Section 5; and MMSR-Section E; and Appendix A**

Section 5 of the PMO requires that milk plants be inspected at least once every three (3) months with the provision that for milk plants or portions of milk plants that are IMS listed to produce aseptically processed and packaged or retort processed after packaging low-acid milk and/or milk products shall be inspected at least once every six (6) months. For purposes of determining the inspection frequency for milk plants, the interval shall include the designated three (3) month period or six (6) month period, respectively, plus the remaining days of the month in which the inspection is due.

If a Regulatory Agency conducts complete routine inspections on a monthly or two (2) month frequency how should Milk Plant, Part II, Item 2-Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plants and transfer station(s) once every six (6) months on FORM FDA 2359j-Section B (Page 2) be calculated on ratings and check ratings?

*The PMO required inspection frequency for milk plants is once every three (3) months or six (6) months for aseptic and retort milk plants, with credit being given for the remaining days of the month in which the inspection is due during this required three (3) or six (6) month, respectively, inspection frequency. Therefore, we would not include every complete routine inspection that was conducted during the time period of the record review, either back to the last rating date or six (6) months if the previous rating was conducting within six (6) months of the new rating.*

*When conducting this required inspection calculation, the number of three (3) or six (6) month, respectively, inspection frequencies shall be determined during the required time period of the record review and this number will be the "Number Inspected" under Milk Plant, Part II, Item 2 on FORM FDA 2359j-Section B (Page 2).*

**For Example:** *A new rating is conducted 11/6/2016 and the previous rating was conducted 1/15/2015. The first complete routine inspection in the records review period back to the last rating (11/5/2016-1/1/2015) was 2/4/2015. Therefore, the projected required three (3) month complete routine inspection frequencies for this milk plant would be:*

*2/4/2015 (Conducted within the three (3) month frequency back to 1/1/2015.)  
5/2015  
8/2015  
11/2015*

2/2016  
5/2016  
8/2016  
11/2016

*With this example, the “Number Inspected” would be eight (8) if there was a complete routine inspection conducted between 8/1/2016 and 11/5/2016. If not, then the “Number Inspected” would be seven (7) as they have the remaining days of the month in which the inspection is due (11/30/2016) to receive Credit.*

*Because the Regulatory Agency conducts complete routine inspections on a monthly or two (2) month frequency, to determine the “Number Inspected” and the “Number Complying” for this calculation, determine that there is at least one (1) complete routine inspection conducted during each of the eight (8) or seven (7), as cited above, three (3) month frequencies. From the records review, complete routine inspections were conducted:*

2/4/2015  
4/18/2015  
5/15/2015  
7/20/2015  
9/10/2015  
11/29/2015  
1/15/2016  
2/29/2016  
4/10/2016  
6/15/2016  
8/22/2016  
10/25/2016

*With this example, the “Number Inspected” and “Number Complying” would both be eight (8) and not the total number of complete routine inspections conducted during the records review period of twelve (12) for both.*

**NOTE:** *This same approach and method would be utilized when a Regulatory Agency conducts complete pasteurization equipment testing on a monthly or two (2) month frequency when calculating Milk Plant, Part II, Item 5-Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.) on FORM FDA 2359j-Section B (Page 2).*

*Also, this same approach and method would be utilized for single farm BTU listings when a Regulatory Agency conducts complete routine inspections on dairy farms on a three (3) or four (4) month frequency, for example, when calculating Dairy Farms, Part I, Item 2-All dairy farms inspected once every*

*six (6) months or as required in Appendix P on FORM FDA 2359j-Section B (Page 2).*

**19. PMO-Section 6**

A dairy producer's raw milk is sampled and tested in accordance with Section 6 of the PMO, including when sampled and tested within twenty-one (21) days of the sending of written notice, but not before the lapse of three (3) days, whenever two (2) of the last four (4) consecutive samples exceed the PMO standard for Standard Plate Count (SPC). Is the drug (inhibitor) test result required to be recorded on the official laboratory report form that is provided to the Regulatory Agency and the results which are subsequently recorded on the dairy producer's official Regulatory Agency sampling ledger/record, or is it enough to be able to verify that the laboratory runs inhibitor testing with all SPC testing as part of their Standard Operating Procedures (SOP), and be able to produce records to verify if requested by FDA?

*The drug/inhibitor test result, along with the SPC result, are required to be recorded on the official laboratory report form that is provided to the Regulatory Agency and which is subsequently recorded on the dairy producer's official Regulatory Agency sampling ledger/record.*

**20. PMO-Section 6**

When a milk plant receives raw commingled milk and bulk pasteurized Grade "A" milk and/or milk products for further processing and pasteurization, is the Regulatory Agency required to sample the bulk pasteurized Grade "A" milk and/or milk products in accordance with Section 6 of the PMO, four (4) times, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, during any consecutive six (6) month period as is required for raw commingled milk?

No.

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

a) If a dairy farm holds a Grade "A" permit/license and is included in an IMS listed BTU or may be included as an attached supply with an IMS listed milk plant (producer/processor) and milk is piped from the farm bulk milk tank(s)/silo(s) to the milk plant for the processing and packaging of Grade "A" milk and/or milk products is the raw milk supply(ies) that has (have) not been transported in bulk milk tankers required to be sampled and tested before the milk is processed in accordance with Appendix N of the PMO?

Yes.

b) If there is milk remaining in the farm bulk milk tank(s)/silo(s) after a portion of the milk has been removed for Grade “A” milk and/or milk products processing and packaging is this milk remaining in the farm bulk milk tank(s)/silo(s) still considered Grade “A” and may be picked up by a milk handler’s bulk milk hauler/sampler?

*Yes. The milk remaining in the farm bulk milk tank(s)/silo(s) would be considered Grade “A” and a “Universal” sample shall be collected as required within Section 6 of the PMO before the milk is pumped onto the milk tank truck. Upon delivery to a milk plant, receiving station and/or transfer station, the individual receiving the Grade “A” milk, as appropriate, will collect an Appendix N sample for testing prior to receiving the Grade “A” milk in the milk plant, receiving station and/or transfer station.*

c) If a dairy farm holds a Grade “A” permit/license and is included in an IMS listed BTU and milk is piped from the farm bulk milk tank(s)/silo(s) to the milk plant (producer/processor) for the processing and packaging of non-Grade “A” milk and/or milk products is the raw milk supply(ies) that has (have) not been transported in bulk milk tankers required to be sampled and tested before the milk is processed in accordance with Appendix N of the PMO?

Yes.

d) If there is milk remaining in the farm bulk milk tank(s)/silo(s) after a portion of the milk has been removed for processing and packaging of non-Grade “A” milk and/or milk products is this milk remaining in the farm bulk milk tank(s)/silo(s) still considered Grade “A” and may be picked up by a milk handler’s bulk milk hauler/sampler?

*Yes. The milk remaining in the farm bulk milk tank(s)/silo(s) would be considered Grade “A” and a “Universal” sample shall be collected as required within Section 6 of the PMO before the milk is pumped onto the milk tank truck. Upon delivery to a milk plant, receiving station and/or transfer station, the individual receiving the Grade “A” milk, as appropriate, will collect an Appendix N sample for testing prior to receiving the Grade “A” milk in the milk plant, receiving station and/or transfer station.*

e) With the scenario addressed in a) and c) above what are the Appendix N sampling and testing requirements?

*What is required is that before any Grade “A” raw milk from a Grade “A” dairy farm(s) that is included in an IMS listed BTU or may be included as an attached supply with an IMS listed milk plant (producer/processor) is removed*

*from a farm bulk milk tank(s)/silo(s) for on-farm processing as either Grade “A” and/or non-Grade “A” milk and/or milk products the milk in the farm bulk milk tank(s)/silo(s) shall be sampled and tested in accordance with Appendix N of the PMO. If any milk is left in the farm bulk milk tank (s)/silo(s) it would still be considered Grade “A and may be collected by a milk handler’s bulk milk hauler/sampler following the normal procedures for Section 6 “Universal” sample collection.*

f) What would be the ramifications if any IMS listed BTU or attached supply was determined not to be in substantial compliance with Appendix N during a rating or check rating?

*During an IMS rating or check rating, it is necessary to determine compliance of the BTU or attached supply included with an IMS listed milk plant with the requirements of Appendix N of the PMO. If the BTU or attached supply is not in substantial compliance, a rating or check rating is not to be completed and the Rating Agency shall immediately withdraw the IMS listing.*

*Following are Items that will be evaluated by a SRO or FDA MS to determine if a BTU is in substantial compliance with Appendix N or not:*

*Determine from records that are stored in a manner acceptable to the Rating Agency that all raw milk shipped in bulk milk tankers and/or raw milk supplies that have not been transported in bulk milk tankers, regardless of final use, have been screened for Beta lactam residues in accordance with Appendix N of the PMO prior to processing with an approved test method. Determine that the testing was conducted in accordance with the established drug residue testing program cited in Appendix N of the PMO.*

*Compliance with the above Item would be satisfied in the following manner:*

- 1.) Records indicating that milk was always shipped to an IMS listed shipper shall suffice for actual test results.*
- 2.) If Grade “A” milk is being utilized by or shipped to a non-IMS listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs and FDA MSs may at their discretion request records on the testing of loads of milk that are sent to non-listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO or FDA MS should choose and request to review records for no more than fifteen (15) days, unless these selected records show a problem. If these records are not provided during a rating or check rating (upon request by the SRO or FDA MS, respectively),*

*the rating or check rating cannot be completed and the IMS listing shall be immediately withdrawn.*

*3.) If a load sample or individual dairy farm sample is positive for a drug residue, determine if the Regulatory Agency was immediately notified, the dairy producer's permit was suspended and what was the method of proper disposition to keep the contaminated milk out of the food chain.*

*4.) Determine if the violative dairy farm was not allowed to ship milk until the milk no longer tested positive for drug residues.*

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

a) If a milk plant processes low-fat white milk and low-fat chocolate milk, which are both vitamin A and D fortified, are both milk products required to be sampled on an annual basis by the Regulatory Agency or under the direction of the Regulatory Agency specifically for the collection of official regulatory milk and/or milk product samples to be submitted to an accredited laboratory authorized to conduct vitamin assay testing?

*Yes. Refer to M-a-98.*

b) When a milk plant is specifically authorized to collect and ship official regulatory milk and/or milk product samples to an accredited laboratory authorized to conduct vitamin(s) A and/or D assay testing under the direction of the Regulatory Agency for annual vitamin assays, is the Regulatory Agency required to instruct the milk plant what official regulatory milk and/or milk products are to be sampled and when the specified official regulatory milk and/or milk product samples are to be collected and shipped to an accredited laboratory?

*Yes. These milk and/or milk product samples are official regulatory samples that are authorized to be collected under the direction of the Regulatory Agency and tested annually for vitamin(s) A and/or D fortification.*

c) When a milk plant is specifically authorized to collect and ship official regulatory milk and/or milk product samples to an accredited laboratory for vitamin(s) A and/or D assay testing under the direction of the Regulatory Agency for annual vitamin assays, is the milk plant required to provide the vitamin assay testing results/reports that they receive for those submitted official regulatory milk and/or milk product samples from the accredited laboratory to the Regulatory Agency?

*Yes. These milk and/or milk product samples are official regulatory samples that are required to be collected and tested annually as cited within Section 6 of the PMO.*

**NOTE:** *If the accredited laboratory also provides a copy of the vitamin assay testing results/reports to the Regulatory Agency then the milk plant would not be required to provide the Regulatory Agency with a copy of the vitamin assay testing results/reports that they receive.*

d) Where are these official regulatory vitamin assay testing results/reports to be kept and reviewed when conducting a rating or check rating?

*They are official regulatory samples and the vitamin assay test results/reports are required to be kept at the Regulatory Agency in the official Regulatory Agency file for the specific milk plant that the milk and/or milk product samples were collected from. These official Regulatory Agency records should be reviewed at an office designated by the Regulatory Agency or if authorized by the Regulatory Agency, the official regulatory records kept and maintained by Regulatory Agency inspectors may be reviewed.*

e) If the Regulatory Agency fails to have copies of the official regulatory vitamin assay results that are required to be kept by the Regulatory Agency in the official Regulatory Agency file for the specific milk plant that the milk and/or milk product samples were collected from, what are the consequences of not having such records that will be considered by the SRO or FDA MS conducting the Regulatory Agency official records review?

*Failure of the Regulatory Agency to collect samples or have copies of the results of assays of milk and/or milk products fortified with vitamin(s) A and/or D; or a milk plant specifically authorized to collect such samples and the milk plant has not collected and submitted the samples, each of the milk and/or milk products fortified with vitamin(s) A and/or D would be evaluated on FORM FDA 2359j, Section B (Page 2), Part II-Milk Plants, Item 7-Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made. Under Item 7 each individual vitamin(s) A and/or D fortified milk and/or milk product that was not sampled and assayed/tested annually for vitamin(s) A and/or D would be given zero (0) for the Number Complying. (Refer to M-a-98 for the milk and/or milk products that have a FDA validated vitamin(s) A and/or D assay testing methodology and which are required to be sampled and tested if fortified with vitamin(s) A and/or D.)*

**NOTE:** *If prior to completing the Regulatory Agency's official records review and leaving the office or State the Regulatory Agency obtains a copy of appropriate annual vitamin(s) A and/or D assay results/reports from either the milk plant or accredited laboratory, the SRO or FDA MS shall consider this information when evaluating Item 7 as cited above. However, because the Regulatory Agency did not have the required annual vitamin(s) A and/or D assay results/reports in their official Regulatory Agency file for the specific*

*milk plant, the Regulatory Agency would not be given Credit on FORM FDA 2359j, Section E (Page 5), Item 3-Category III-Laboratory Records under Milk Plant Records.*

f) When a SRO or FDA MS is reviewing the Regulatory Agency's official records for the annual vitamin assay testing requirement of milk and milk products fortified with vitamin(s) A and/or D as cited within Section 6 of the PMO, what time frames should they be evaluating?

**For Example:** A rating or check rating is conducted 6/14/2016 and the last rating was conducted 9/21/2014.

*The Regulatory Agency's official records would be reviewed back through 9/1/2014. Therefore, annual vitamin assay results/reports conducted anytime in 2014 and anytime in 2015 shall be in the Regulatory Agency's official files for the specific milk plant that is being rated or check rated. Individual vitamin(s) A and/or D fortified milk and/or milk products for which annual vitamin assays are required would be evaluated in accordance to e) above.*

**NOTE:** *If the required annual vitamin assays for 2016 were already conducted for 2016, those results/records shall be in the Regulatory Agency's official files for the specific milk plant that is being rated or check rated and would also be required to be reviewed by the SRO or FDA MS. The SRO or FDA MS shall be aware that if the Regulatory Agency or the milk plant is specifically authorized to collect and ship vitamin(s) A and/or D fortified milk and/or milk products under the direction of the Regulatory Agency for annual vitamin assays, has not collected and submitted all of the vitamin(s) A and/or D fortified milk and/or milk products that are required to be assayed/tested that they have until December 31, 2016 to collect and submit the required samples to be considered to be in compliance for 2016. The SRO or FDA MS shall not debit those vitamin(s) A and/or D fortified milk and/or milk products that have not been assayed/tested for not being in compliance for 2016.*

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

Proposal 219 that was passed at the 2015 NCIMS and incorporated into Section 6 of the 2015 PMO, provides for personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, to average the laboratory test results from multiple samples of the same milk and/or milk products collected from the same producer or processor on the same day. If the industry agrees and the State agrees to have the averaging conducted and reported by the approved laboratory, does there need to be a note in the official Regulatory

Agency ledgers to denote that averaging has been conducted by the laboratory?

*No. The information can be obtained from the laboratory report(s) provided to the Regulatory Agency that indicates the individual sample(s) result(s) and the averaging that was conducted and reported by the laboratory.*

**24. PMO-Section 7, Items 5r and 14r; and MMSR-Section E**

a) A dairy farm stores their first milking in a farm bulk milk tank(s)/silo(s) that is located in the milkhouse and then prior to the next milking, the milk is transferred via the hose port to a milk tank truck that is parked outside the milkhouse without a suitable shelter. The milk hose connection to the milk tank truck is not made from within the milkhouse. This practice of milk storage in a farm bulk milk tank(s)/silo(s) that is in the milkhouse and transferring the milk to the milk tank truck is then repeated for the 2<sup>nd</sup> and 3<sup>rd</sup> milking. Is the dairy farm allowed to make multiple connections to the outlet valve of the milk tank truck over a twenty-four (24) hour or greater time period?

*No. This practice of milk storage in a farm bulk milk tank(s)/silo(s) that is in the milkhouse and transferring the milk to a milk tank truck as cited above is not considered a direct load. Therefore, the milk tank truck would be classified as a milk storage tank and would be required to meet the applicable requirements of Item 5r-Milkhouse – Construction and Facilities of the PMO related to a suitable shelter for the transportation tank. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the milkhouse with respect to construction items, lighting; drainage; insect and rodent control; and general maintenance. In addition, it shall also comply with additional minimum criteria as cited under Item 5r.*

**NOTE:** *If this practice was observed on a rating or check rating, along with all the Item 5r violations cited above without having the required shelter, Item 14r-Protection from Contamination would also be debited on FORM FDA 2359a-Dairy Farm Inspection Report. This dairy farm would also be debited under the Enforcement Rating on FORM FDA 2359j, Section B (Page 2), Item #4-Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections.*

b) If allowed, may the hose and connections be rinsed with sanitizer between connections and fully cleaned once per day?

*No. This practice of milk storage in a farm bulk milk tank(s)/silo(s) that is in the milkhouse and transferring the milk to a milk tank truck as cited above is not allowed within the PMO*

25. **PMO-Section 7, Item 6r**

a) On a dairy farm may air be drawn from a utility room into the milkhouse?

Yes.

b) Would it be a debit if the utility room is unclean?

*Yes. If it is determined to be significant it would be considered a violation of Item 6r-Milkhouse – Cleanliness of the PMO.*

26. **PMO-Section 7, Item 6r**

If a two (2) compartment wash vat or vertical CIP tank, which is not a combination receiving vessel/CIP tank, is found to be dirty with milk solids build-up on a dairy farm would this be considered a violation of Item 6r-Milkhouse-Cleanliness or Item 10r-Utensils and Equipment-Cleanliness?

*Item 6r.*

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

Does the PMO require that dairy farm individual water system samples be collected directly from the well, before a pressure tank and/or any treatment application, such as a water softener or iron filter?

*No. A dairy farm's individual water system supply may be sampled at any location provided the sample can be aseptically collected and is representative of the water being used in the milkhouse and the milking operation.*

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

M-I-16-10 (Question #22(c)):

A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The potable water supply line has a by-pass line around the plate heat exchanger (cooler) that is directly connected to the water pipeline downstream from the exit of the plate heat exchanger (cooler). The water pipeline that exits the plate cooler does not have any submerged water inlets or cross-connections. Is there a requirement for a backflow prevention device to protect the potable water supply and/or the plate heat exchanger (cooler)?

*Yes. An approved back flow prevention device shall be installed in the potable water by-pass line prior to its connection to the water pipeline from the exit of the plate heat exchanger (cooler) to protect the potable water supply.*

The following question relates to M-I-16-10 (Question #22(c)) as cited above:

A dairy farm utilizes a raw milk plate heat exchanger (cooler) which is directly connected to the potable water supply to provide cooling. The potable water supply line has a by-pass line around the plate heat exchanger (cooler) that is directly connected to the water pipeline downstream from the exit of the plate heat exchanger (cooler). Water exiting the plate heat exchanger (cooler) is piped to a reclaimed water tank and distribution system that is in compliance with Appendix D-Standards for Water Sources, Section VI-Water Reclaimed from Heat Exchanger Processes or Compressors on Grade "A" Dairy Farms of the PMO. This reclaimed water is tested every 6 months; is being used for the washing and sanitizing of milking equipment; and recirculated back through the plate heat exchanger (cooler). Would an approved back flow prevention device be required to be installed in the potable water by-pass line prior to its connection to the water pipeline from the exit of the plate heat exchanger (cooler) to protect the potable water supply?

*No. Reclaimed water from the plate heat exchanger (cooler) that is in compliance with Appendix D, Section VI of the PMO would be considered potable water and can be used for potable water purposes, including the washing and sanitizing of milking equipment and recirculated back through the plate heat exchanger (cooler). Therefore, there would not be a cross connection between safe potable water and any unsafe or questionable water supply or other source of contamination and the plate heat exchanger (cooler) would not be required to have a back-flow prevention device installed in the by-pass line around the plate heat exchanger (cooler).*

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

Two (2) separate plate heater exchangers (coolers) on a dairy farm are piped in series with the water exiting the first plate cooler being directly piped and used as the water supply for the second plate cooler. Would this be acceptable?

*No. The water supply feeding all plate coolers is required to be potable water. Water exiting a plate cooler has been determined not to be potable water. Therefore, this practice and installation is not in compliance with the PMO and would be considered a violation of Item 8r-Water Supply of the PMO and would be debited under Item 8r(a)-Constructed and operated according to Ordinance (5 point debit) on FORM FDA 2359a.*

30. **PMO-Section 7, Item 8r; and MMSR-Sections B and E**

While conducting a BTU rating or check rating with an industry field representative or a regulatory inspector, and the dairy producer is not available, if the well cannot be located, is it still FDA's position that this would be considered a violation of Item 8r of the PMO and be debited against the dairy farm since it cannot be inspected?

*Yes. It would be debited under Item 8-Water Supply (a)-Constructed and operated according to Ordinance on FORM FDA 2359a and would be a five (5) point debit.*

**NOTE:** *This dairy farm would also be debited on FORM FDA 2359j, Section B (Page 2), Item #4-Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections.*

31. **PMO-Section 7, Items 8r and 13r; and Appendices D and G**

A dairy farm is capturing the water that exits a plate heat exchanger in a properly constructed and protected storage vessel and this reclaimed water is not being sampled. The reclaimed water collected in this storage vessel is then utilized in their sprinkler pens, using rainbird type sprinklers directed at the underside of the cows to clean the teats prior to milking. At the time of milking, the teats, flanks and bellies are still damp from the non-potable reclaimed water that was sprayed on the cow's teats. The milker does not clean the cow's teats with potable water but just manually wipes the teats dry, sanitizes and dries the teats and the milking unit is attached.

a) Is the reclaimed water from this properly constructed and protected storage vessel for this use as described above required to be "potable" from a supply properly located, protected, operated and of a safe, sanitary supply?

*Yes. In order for this reclaimed water to be considered "potable" and utilized in the manner described above to clean the cow's teats, it shall meet all the criteria cited in Appendix D-Standards for Water Sources, Section VI-Water Reclaimed from Heat Exchanger Processes or Compressors on Grade "A" Dairy Farms of the PMO.*

b) What bacteriological standards is this reclaimed water that is utilized in the sprinkler pens using rainbird type sprinklers as described above required to meet?

*Appendix D, Section VI of the PMO requires this reclaimed water to comply with the Bacteriological Standards of Appendix G-Chemical and*

*Bacteriological Tests, Section II-Reclaimed Water and Recirculated Water – Bacteriological of the PMO.*

**32. PMO-Section 7, Items 8r and 14r**

May non-potable water be sprayed on the outside of milking claws and inflations between individual dairy animals that are being milked? This is being observed as a more common practice with rotary milking installations.

*No. Only potable water is allowed for this milking operation practice.*

**33. PMO-Section 7, Items 8r, 18r, 7p and 17p; and Appendices D, Section 5 and G, Section I**

a) The language in Proposal 226 (2015 NCIMS) which is incorporated into Appendix G-Chemical and Bacteriological Tests of the 2015 PMO states that if an individual water supply is positive for total coliform and E. coli, the water supply is considered unsatisfactory. Could I assume FDA is taking the stance that the water supply may not be used until the dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility resolves the issue and obtains a satisfactory result?

*The private water supply would be considered unsatisfactory but the dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility as applicable, would not be prohibited from using the water supply. The individual water supply would have to be inspected by the Regulatory Agency, any necessary corrections made by the facility, and the water supply would have to be resampled within thirty (30) days of the collection date of the positive sample. (Please refer to M-I-03-13 (Question #11) for additional information.)*

b) In Appendix D, 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 and Category II-Used for Limited Purposes of the 2013 PMO, reclaimed water cannot have a total plate count over 500/mL. However, in reviewing Proposal 226 (2015 NCIMS) language, which is to be incorporated into Appendix G, there is not any discussion on total plate count for reclaimed water. Has this requirement been eliminated or is it still in the reclaimed water section located in Appendix D?

*Both the 2013 and 2015 PMO state in Appendix D that reclaimed water shall comply with the Bacteriological Standards in Appendix G and in addition, shall not exceed a total plate count of 500 per milliliter (500/mL). The bacteriological standard for reclaimed water and recirculated water is contained under the Criteria on page 93 of IMS-a-50 and has been*

*incorporated into Appendix G of the 2015 PMO. The wording in Appendix D remains the same as cited in the 2013 PMO and the Criteria is only being relocated to a new Section within Appendix G.*

*IMS-a-50 cites the entire Proposal 226 as passed. It does not make any reference to Appendix D; therefore, there are not any changes from Proposal 226 to be made to Appendix D.*

**34. PMO-Section 7, Items 8r and 7p; Appendix G, Section I; and MMSR-Appendix A**

Proposal 226 from the 2015 Conference made additions to Appendix G, Section I-Individual Water Supplies – Bacteriological, which were incorporated into the 2015 PMO.

a) **“Corrective Action:** When the laboratory report on the sample is positive for total coliform but negative for the presence of E. coli or indicates a heterotrophic plate count (HPC) of greater than 500 CFU per mL on a sample that had previously been invalidated, the water supply in question shall be considered at risk for pathogenic contamination and shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory...” Does this sentence mean that positive for total coliform is considered an unsatisfactory test?

*No. The water supply shall be considered at risk for pathogenic contamination and shall be inspected by the facility and necessary corrections made by the facility and resampled within thirty (30) days of the date of the positive test result.*

b) Who is responsible for conducting this initial required follow-up inspection and resampling?

*The facility (dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility personnel), as applicable shall conduct the initial follow-up inspection. For a dairy farm, a sampler acceptable to the Regulatory Agency shall conduct the resampling. For a milk plant, receiving station, transfer station or milk tank truck cleaning facility, the Regulatory Agency shall conduct the resampling.*

c) How should this required initial inspection be documented by the facility?

*A written report created by the facility should be used and provided to the Regulatory Agency, which will be placed in the official Regulatory Agency file for the specific dairy producer, milk plant, receiving station, transfer station or milk tank truck cleaning facility inspected. It is recommended that the written*

*report contain the following information and any additional information as determined by the Regulatory Agency:*

- *Name of the permitted dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility, as applicable;*
- *Permit number;*
- *Date of the inspection;*
- *Date and results of the initial positive sample and any subsequent positive samples;*
- *Observations/findings of the inspection;*
- *Corrections that are warranted and any corrections that were made during the inspection;*
- *When other warranted corrections are to be made;*
- *Any disinfection of the individual water source (well) that has been performed since the positive water results (Please refer to Appendix D, Section III-Disinfection of Water Sources.);*
- *If a sample was collected or when the next sample will be collected; and*
- *Name/Signature of the person conducting the inspection.*

d) If the inspection and corrective actions are completed, but the water supply in question is still testing positive for total coliform but negative for E. coli, will inspections, corrective actions and resampling continue until a sample obtains a satisfactory bacteriological result (negative for total coliform)?

*Yes, unless the resampling continues to indicate that the individual water supply (well) is still considered at risk for pathogenic contamination and the Regulatory Agency at their discretion requires that the individual water source (well) will be required to be continuously disinfected/treated so that satisfactory water samples can be obtained on a continuous basis.*

e) What Regulatory Agency action is required following the initial individual water source (well) sample that is positive for the presence of total coliform and negative for the presence of E. coli; the required facility's inspection, corrective action and resampling has been performed within thirty (30) days of the initial positive; and the individual water source (well) continues to be positive for the presence of total coliform and negative for the presence of E. coli:

*The Regulatory Agency would be required to:*

- *Conduct an inspection(s) of the individual water supply (well) within thirty (30) days of the date of the second positive results;*
- *Determine what warranted corrective actions are to be made:*

- *Following the completion of the warranted corrections, resample the individual water supply (well); and*
- *If the resampling continues to indicate that the individual water supply (well) is still considered at risk for pathogenic contamination, the Regulatory Agency at their discretion shall require that the individual water source (well) be continuously disinfected/treated so that satisfactory water samples can be obtained on a continuous basis.*

f) How should these required inspections be documented by the Regulatory Agency?

*A written report utilizing FORM FDA 2359a or a specific form created by the Regulatory Agency should be used and placed in the official Regulatory Agency file for the specific dairy producer, milk plant, receiving station, transfer station or milk tank truck cleaning facility inspected. It is recommended that the written report contain the following information and any additional information as determined by the Regulatory Agency:*

- *Name of the permitted dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility, as applicable;*
- *Permit number;*
- *Date of the inspection;*
- *Date and results of any positive samples;*
- *Observations/findings of the inspection;*
- *Corrections that are warranted and any corrections that were made during the inspection;*
- *Deadline for the warranted corrections that were not made at the time of the inspection;*
- *Any disinfection of the individual water source (well) that has been performed since the positive water results (Please refer to Appendix D, Section III-Disinfection of Water Sources.);*
- *If a sample was collected or when the next sample will be collected; and*
- *Name/Signature of the Regulatory Agency inspector.*

g) How many inspections, corrective actions and resamples are to be conducted before the individual water source (well) is deemed to be unsatisfactory?

*Ultimately it is up to the discretion of the Regulatory Agency. The number of inspections and resampling of the individual water supply (well) will be determined by the Regulatory Agency based on the results of the inspections and the warranted corrections that have been made. Following the completion of the warranted corrections and the resampling continues to indicate that the individual water supply (well) is still considered at risk for*

*pathogenic contamination, the Regulatory Agency at their discretion shall require that the individual water source (well) be continuously disinfected/treated so that satisfactory water samples can be obtained on a continuous basis.*

h) At what point, would this individual water supply be considered unsatisfactory?

*“When the laboratory report on the sample is positive for both total coliform and E. coli, or the facility has failed to complete the water supply inspection within thirty (30) days of the initial positive test result, the water supply is considered unsatisfactory.”*

*Refer to the examples below referencing the classification of water sample bacteriological results from individual water supplies used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities:*

- 1. Negative Total Coliform = **Satisfactory** Test Result and does not require any further action.*
- 2. Positive Total Coliform and Negative E. Coli = **Risk for pathogenic contamination** and triggers an inspection and necessary corrections made and subsequent resampling within thirty (30) days of the date of the positive test result.*

**NOTE:** *If the facility has failed to complete the water supply inspection and/or obtain a subsequent water sample within thirty (30) days of the initial positive test result, the water supply is considered **Unsatisfactory**.*

- 3. Positive Total Coliform and Positive E. Coli = **Unsatisfactory** Test Result and triggers an inspection by the Regulatory Agency with necessary corrections made and subsequent resampling within thirty (30) days of the date of the positive test result.*

### 35. **PMO-Section 7, Items 9r and 13r**

Clarification of M-b-374 (ADF Milking Ltd. Milking Cluster with Variant Liner 1 (Versions 123 and 125) and Variant Liner 2 with Profiled Insert (Versions 223 and 225)), issued February 12, 2015

*Questions have recently been raised concerning M-b-374 (ADF Milking Ltd. Milking Cluster with Variant Liner 1 (Versions 123 and 125) and Variant Liner 2 with Profiled Insert (Versions 223 and 225)), issued February 12, 2015, and if the review conducted by the Pacific Southwest Region Dairy Equipment Review Committee (PSRDERC) included the ADF Milking Ltd. Automatic*

*Dipping and Flushing System. The review conducted by PSRDERC was specific and limited to the Milking Cluster with Variant Liner 1 (Versions 123 and 125) and Variant Liner 2 with Profiled Insert (Versions 223 and 225). It did not include a review or evaluation of the ADF Milking Ltd. Automatic Dipping and Flushing System. This fact is stated in bullet #1 on page 1 of M-b-374.*

*The ADF Milking Ltd. Automatic Dipping and Flushing System was not reviewed by the PSRDERC as regional dairy equipment review committees only review individual pieces of equipment and do not review systems. Therefore, the ADF Milking Ltd. automatic iodine dipping and flushing system would have to be evaluated on a State-by-State basis just as back flush systems and/or dipping a claw into a bucket of iodine are currently being evaluated.*

**NOTE:** *One (1) area of concern that FDA has with the ADF Milking Ltd. Automatic Dipping and Flushing System is that it does not provide a means of separation between the iodine that is being used for dipping and flushing and the milk.*

*Any statement, suggestion or advertisement that implies that the PSRDERC and/or FDA reviewed and accepted the ADF Milking Ltd. Automatic Dipping and Flushing System would be in error and would be considered false and misleading.*

**36. PMO-Section 7, Items 14r and 15p(A); and Appendix H**

Would it be acceptable to have the holder that the final filter is placed on be constructed of woven wire, with the final filter/holder being located upstream from a sanitary check valve, for an air blow that is connected directly to a milk pipeline?

*Yes. All air piping downstream from the sanitary check valve is considered a product-contact surface and shall be of a sanitary design. The final filter and holder is located upstream from the sanitary check valve and would not be in an area that would be considered a product-contact surface.*

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

On dairy farms, a human over-the-counter (OTC) enema (phosphorous in a saline solution) is being observed for use in the milking herd as an IV treatment for reproductive disorders that may be due to hypophosphatemia. What are the PMO labeling requirements or would this human OTC product be exempt from the labeling requirements of Item 15r of the PMO?

*It would be exempt from the labeling requirements of Item 15r of the PMO.*

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

On dairy farms, the ready-to-use (RTU) drug Utresept, labeled as an intrauterine flush, is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?

*Yes. FDA's Center for Veterinary Medicine (CVM) has stated that this is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit.*

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

On dairy farms, the drug UtterFlush labeled for reproductive care for beef and dairy cattle is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?

*Yes. CVM has stated that this intrauterine product is labeled with a structure/function claim and the product is not the subject of a New Animal Drug Application (NADA) approval. It is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit.*

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

On dairy farms, the drug Uterine Capsules labeled for use by administering two (2) to three (3) capsules intrauterine during post-partum to help maintain normal uterine environment is being observed. Would this drug be considered to be in violation of Item 15r of the PMO?

*Yes. CVM has stated that this is an unapproved new animal drug and should not be used or stored on the dairy farm. This unapproved new animal drug would be debited on FORM FDA 2359a under Item 15(d) and would be a five (5) point debit).*

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

On dairy farms, the drug Dura-Pen labeled for use in beef cattle only is being observed. Can it be stored on the dairy farm?

*Yes. It shall be stored with the non-lactating dairy animal drugs.*

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

If a drug is extra-labeled for use (ELU), does Item 15r of the PMO require the ELU label on the drug to specifically cite either the name of the dairy producer or dairy farm that the vet is prescribing the drug to be used on?

*No.*

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

If the human Rx drug Sulfamethoxazole-Trimethoprim is ELU for calf scours, does Item 15r of the PMO require the ELU label on the drug to include the Caution statement: "Not to be used in female dairy animals twenty (20) months of age or older"?

*No.*

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

The label on the container of propylene glycol that is being used in recirculated cooling water systems in either a milk plant or on a dairy farm does not identify the propylene glycol as USP, Food Grade, or contains a statement that all ingredients (components) are GRAS. The letter from the manufacturing company on file at the milk plant or dairy farm contains one (1) of the above appropriate statements (USP, Food Grade, or that all ingredients (components) are GRAS); however, it does not cite or reference the specific propylene glycol product that is being used. Would this letter from the manufacturing company be acceptable for determining that the specific propylene glycol that is being used is in compliance with the PMO and meeting the claim of either being USP, Food Grade or that all ingredients (components) are GRAS?

*No. The letter from the manufacturing company on file at the milk plant or dairy farm shall cite the specific propylene glycol product that it is claiming to either be USP, Food Grade or that all ingredients (components) are GRAS. The letter from the manufacturing company shall match the specific propylene glycol product that is being used in the milk plant or on the dairy farm.*

**45. PMO-Section 7, Item 19r**

Item 19r-Insect and Rodent Control of the PMO requires that all outer milkhouse doors are tight-fitting and self-closing. Does this PMO requirement apply to the doors on dairy farms that are used for the direct loading of milk tank trucks to meet the requirement that the milk hose connection is accessible to and made from within the milkhouse?

*No. It would be expected that the milk tank truck is backed up to the bumper pads that surround the doors that are being used for the direct loading of milk tank trucks before the hose connection is made within the milkhouse. However, if this is observed as not being the practice and the door is being left open when the milk tank truck is backing up or at any other time then this would be considered a violation of Item 19r and would be debited under 19(c)-All milkhouse openings effectively screened or otherwise protected; doors tight and self-closing; screen doors open outward on FORM FDA 2359a and would be a two (2) point debit.*

**46. PMO-Section 7, Item 5p**

Does Item 5p-Separate Rooms of the PMO cite any specific prohibition against having a clean-in-place (CIP) system (tanks), which may or may not include a stand-alone rinse recovery tank(s), and/or cleaned-out-of-place (COP) tank(s) located in the same room or area that pasteurization, processing, cooling, reconstitution, condensing, drying and packaging of milk and/or milk products is taking place?

No.

**47. PMO-Section 7, Item 7p; and Appendix D**

Is a storage vessel/tank required for reclaimed (cow) water that complies with Appendix D, Category I-Used for Potable Water Purposes, Section V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants of the PMO?

No.

**48. PMO-Section 7, Item 7p; and Appendix D, Section V**

Appendix D, V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants, Category I-Used for Potable Water Purposes of the PMO requires a standard turbidity meter or electrical conductivity (EC) meter to be installed at any point in the reclaim water line prior to the storage vessel. For an installation that utilizes an eight (8) inch main reclaim water line to the storage vessel, would a turbidity meter that is less than eight (8) inches in diameter that is installed on a reduced diameter line to accommodate the reduced diameter turbidity meter line that branches off and loops back to the main eight (8) inch reclaim water line to the storage vessel be considered to be in compliance with the PMO requirement cited above?

*No. Because of the location of the turbidity meter on the smaller diameter looped line off the main eight (8) inch reclaimed water line to the storage vessel, it would not be measuring a representative sample of the reclaimed water running through the main eight (8) inch reclaim water line that is feeding the storage vessel.*

**49. PMO-Section 7, Item 7p; and Appendix G**

a) If a milk plant has their own individual water source (well), may an IMS listed laboratory that is listed for Test 24-Dairy Waters test that source water under the IMS program for the milk plant's official regulatory water sampling/testing records?

*Yes. For official PMO regulatory purposes the milk plant's water sample from the individual well shall be representative of the milk plant's water supply and shall be collected by the Regulatory Agency.*

b) If the source water is a shared well within a community water system I would expect that we would not be able to test that source water—but it is still a well—so that is where the questions originated

*If it is determined to be a municipal, community or non-community public water supply by EPA definition and regulations and samples are required to be collected and tested under the EPA Safe Drinking Water Standards then the PMO does not require this milk plant's water source to be sampled and tested in addition to what EPA requires for the water system.*

c) If a milk plant chooses to monitor their individual water source (well) or some other common source community water supply that is being utilized in the milk plant at a greater frequency than what is required in the PMO, could an IMS listed laboratory that is listed for Test 24-Dairy Waters test the submitted samples and identify the results as "unofficial test results".

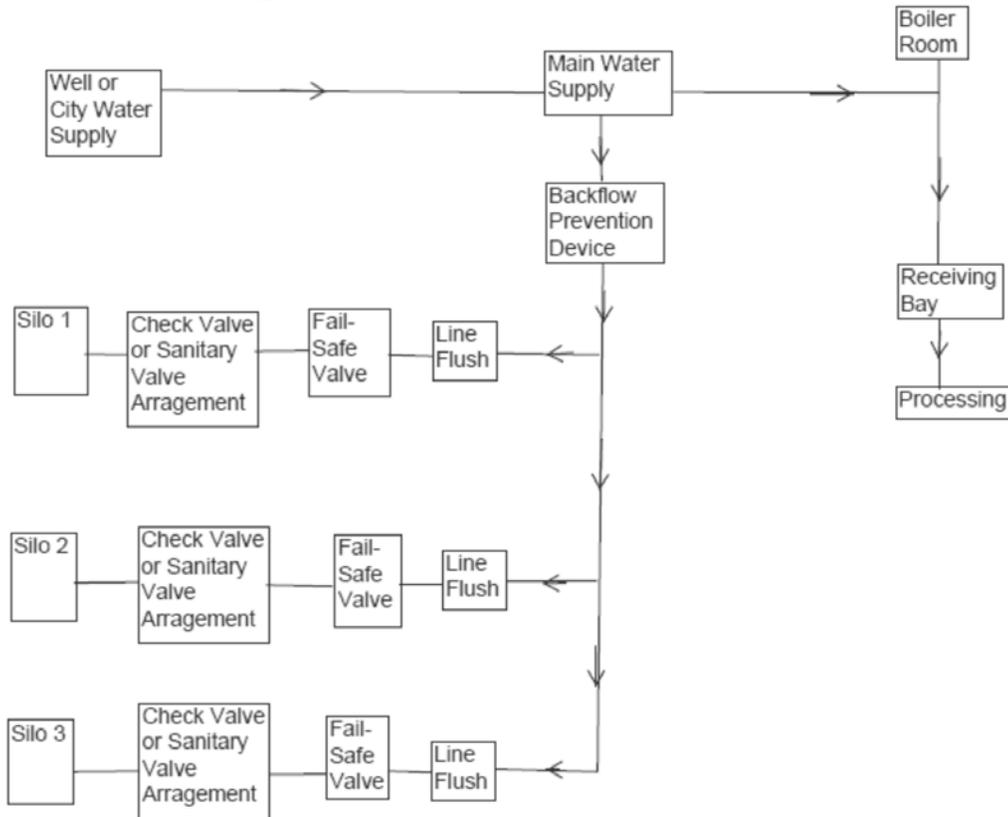
*Yes. The NCIMS laboratory accreditation is required to test and submit official NCIMS regulatory sample results as required by the PMO. This NCIMS laboratory accreditation does not preclude an IMS listed laboratory from conducting quality or patron testing, nor does it preclude private, fee-for-service laboratories, from testing any samples that a customer might submit for personal information. It has even been observed on occasion that State IMS listed laboratories have received samples to be tested just for informational purposes. IMS listed laboratories would be required to either separate these laboratory results from official PMO regulatory results or clearly indicate that they are unofficial.*

50. **PMO-Section 7, Items 7p and 15p**

a) An approved backflow prevention device is properly located and installed on a water line that is only supplying water to individual silo flush lines in a raw milk silo room. The water lines are hard piped and are not broken when circuits are passing by the individual silos with cleaning solutions and/or raw milk. Are backflow prevention devices required on each individual silo flush line?

*No. Provided the raw milk and/or milk product lines and vessels are separated by one (1) fail-safe valve that upon loss of air or power shall move to a position that will close or block the water lines from milk and/or milk product lines and vessels. In addition, a sanitary check-valve or a sanitary valve arrangement(s) that is equally effective shall be located between the fail-safe valve and the milk and/or milk product line(s) and vessel(s).*

**Refer to Flow Diagram below:**



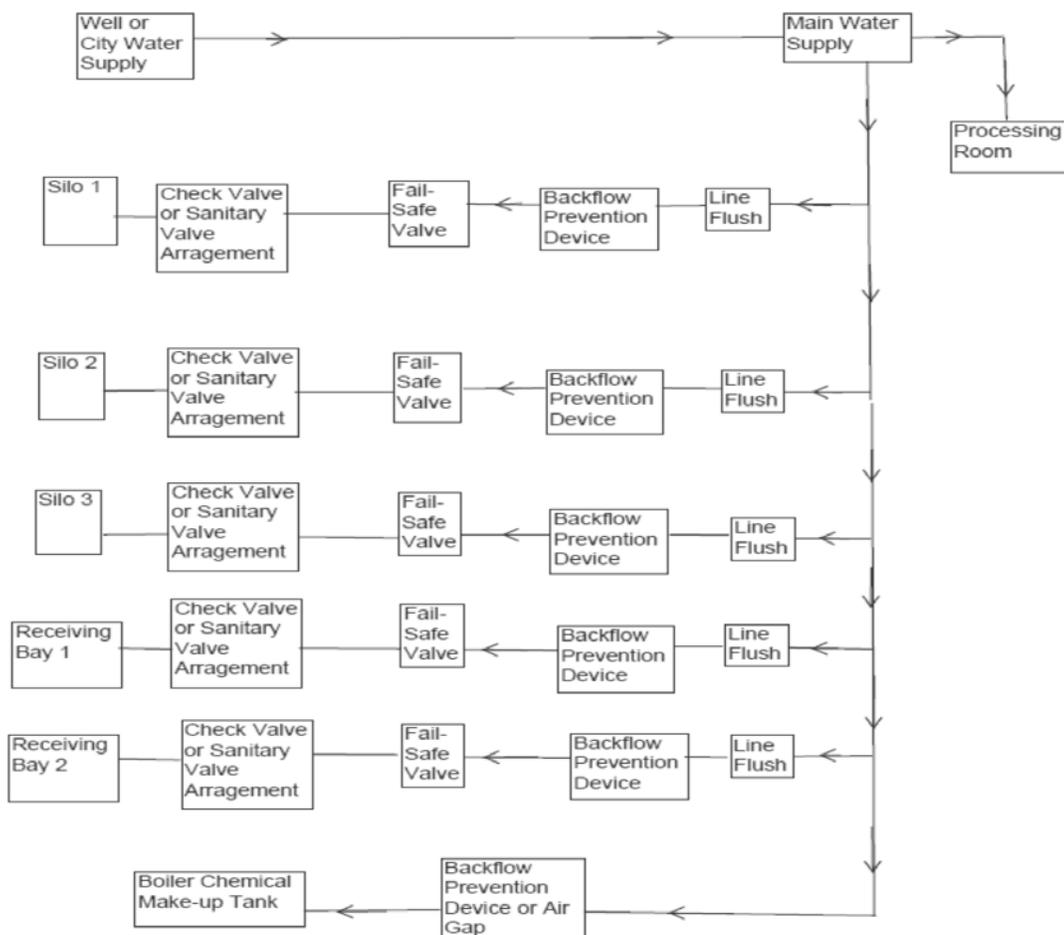
b) Would the fail-safe valve of either a mix-proof valve or other block-bleed-block valve assembly be acceptable for the required backflow prevention device located on the water supply line as cited in a) above?

No.

c) If the water line that supplies water to the silo flush lines in the raw milk silo room continues on and supplies water to pipeline flushes located in the receiving bay and/or other locations throughout the milk plant, are backflow prevention devices required on each individual silo flush line (point of application) located in the raw milk silo room?

*Yes. The fail-safe valves described in b) above will not protect against backflow or backsiphonage. If backflow or backsiphonage were to occur, milk and/or milk product could be drawn into the water line through the fail-safe valves installed on the individual silo flush lines located in the raw milk silo room. If this were to occur, the water supplying the pipeline flushes located in the receiving bay or other locations throughout the milk plant would not be considered safe and of a sanitary quality.*

**Refer to Flow Diagram below:**



51. **PMO-Section 7, Items 7p, 15p(B) and 16p**

If a dry milk plant is reconstituting nonfat dry milk (NFDM) to rework and repasteurize it, is the water required to be pasteurized or pasteurized-equivalent or can it be potable water from the dry milk plant's water supply?

*Since NFDM is going to be pasteurized after reconstitution the water used for the reconstitution may be potable water from the dry milk plant's water supply.*

52. **PMO-Section 7, Items 7p and 17p; and MMSR-Section C**

While conducting a rating or check rating of a milk plant it is observed when reviewing the official Regulatory Agency laboratory ledger/records that the milk plant's individual water system was last sampled and tested greater than six (6) months prior to the date of the rating or check rating. For example, the rating or check rating was conducted 5/12/2016 and the individual water system was last sampled and tested 10/7/2015. Would the SRO or FDA RMS, respectively, debit the milk plant only under the SCR, or only under the ER, or both the SCR and ER?

*Both the SCR and ER would be debited on a rating or check rating. This would be considered a violation of Item 7p-Water Supply and would be debited under (e)-Complies with bacteriological standards on FORM FDA 2359. This would also be debited under Part II-Milk Plant, Item 6-Individual and cooling water samples tested and reports on file as required on FORM FDA 2359j, Section B (Page 2).*

**NOTE:** *This would also be applicable for both the SCR and ER to be debited on a rating or check rating related to the required sampling and testing of recirculated cooling water system(s). This would be considered a violation of Item 17p-Cooling of Milk and Milk Products and would be debited under (d)-Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards on FORM FDA 2359. This would also be debited under Part II-Milk Plant, Item 6-Individual and cooling water samples tested and reports on file as required on FORM FDA 2359j, Section B (Page 2).*

53. **PMO-Section 7, Item 11p**

a) The fill valves of some extended shelf life (ESL) fillers are equipped with multiple use woven wire screens that are CIP and then "sterilized-in-place" (SIP) with water that is greater than 121°C (250°F) and under pressure for thirty (30) minutes. May this SIP process be accepted in lieu of the required autoclaving of these multiple use woven wire screens at 121°C (250°F) for thirty (30) minutes?

Yes.

b) Is a PMO change required in order to accept SIP of multiple use woven wire screens used in fill valves of ESL fillers when the process is performed as described in a) above?

No.

**54. PMO-Section 7, Items 11p and 16p(A)**

May an electric heater coil, as shown below, be used as an airspace heater in a batch (vat) pasteurizer? If it can, what are the construction and size requirements of the electric heater coil?

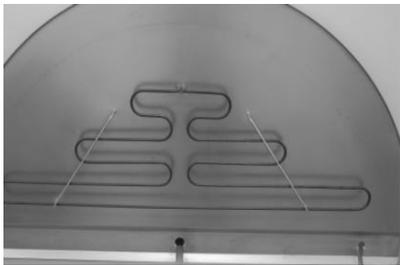
***NOTE:*** *The Regulatory Agency may use the requirements of Section E1.15 and validation data per Appendixes J and K of 3-A® Sanitary Standard 24-03 and the applicable PMO requirements related to material, construction, cleanability, etc. to review and accept, or reject, the use of a radiant heating element for air space heating.*

*After reviewing the pictures that were submitted on the proposed electric airspace heater coils as shown below and additional information provided and gathered by FDA MSs, based on the requirements of the PMO it would be very difficult to accept these electric airspace heater coils for use as airspace heaters in batch (vat) pasteurizers utilized in Grade “A” milk plants. The use of an electric airspace heater coil would not assure the proper heat dispersion throughout the airspace of the batch (vat) pasteurizer. Temperature is directly proportional to the distance that the airspace thermometer sensor is located from the electric airspace heater coil. Therefore, the proper placement of the airspace thermometer in the batch (vat) pasteurizer would be difficult to determine.*

*Airspace temperature is controlled by the temperature of the heated liquid in the batch (vat) pasteurizer and the amount of airspace to be considered. Most milk plants operate their batch (vat) pasteurizer at 160°F-170°F (71°C-77°C), which assures adequate airspace temperatures. If an electric airspace heater coil were to be acceptable to be used as an airspace heater in a batch (vat) pasteurizer, documentation would be required to be provided to properly support installing the airspace thermometer in a location that would assure that the airspace above the milk or milk product is uniformly maintained at least 5°F (3°C) above the minimum required pasteurization temperature. With steam heat, there is evidence that the temperature rapidly spreads out evenly throughout the airspace and is uniform. Radiant heat, such as these elements would provide, is geometrically colder or warmer depending on the distance from the heating element. This would make it very difficult to properly locate*

*the airspace thermometer to adequately assure that the minimum required airspace temperature is being met in all areas of the airspace within the batch (vat) pasteurizer.*

*If and when an electric airspace heater coil is acceptable to be installed inside a batch (vat) pasteurizer, the electric airspace heater coil would be considered a product contact surface. As such, the electric airspace heater coil would have to meet all milk-product contact surface design, material, fabrication, etc. requirements contained within Item 11p-Construction and Repair of Containers and Equipment of the PMO. The electric airspace heater coils as shown below do not meet the milk-product contact surface requirements of Item 11p of the PMO and; therefore, would not be acceptable to be installed inside a batch (vat) pasteurizer.*



The Air Space Heater fits into a 3" Sanitary ferrule and element is self supporting.

**NOTE:** *Batch (vat) pasteurizers that may be equipped with an electric air space heating coil that comply with 3-A® Sanitary Standard for Non-Coil Type Batch Pasteurizer, Number 24-03, will bear a 3-A Symbol, and would be considered acceptable under Item 11p of the PMO.*

#### **55. PMO-Section 7, Item 12p; and Appendix B**

Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO requires whenever a milk tank truck has been cleaned and sanitized, as required by the Regulatory Agency, it shall bear a tag or a record shall be made showing the date, time, place and signature or initials of the employee or contract operator doing the work, unless the milk tank truck delivers to only one (1) receiving facility where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the milk tank truck is next washed and sanitized and kept on file for fifteen (15) days as directed by the Regulatory Agency.

When required, is the wash tag required to be attached to the milk tank truck, i.e., to the outlet valve, or can the wash tag be kept in the cab of the tractor and provided to personnel at the milk receiving facility when the milk tank truck is unloaded?

*Section VI-Milk Tank Truck Permitting and Inspection, Item 5-Wash and Sanitize Record (b), Appendix B-Milk Sampling, Hauling and Transportation of the PMO requires that a cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized.*

***NOTE:*** *FDA has allowed these required wash tags to be placed in an enclosed sample vial to protect them from water damage and the sample vial being located in the compartment of the milk tank truck where the outlet valve is located or for milk tank trucks that do not have a compartment, the sample vial being located near the outlet valve.*

**56. PMO-Section 7, Item 12p; and Appendix B, Section VI**

Item 12p and Appendix B, Section VI of the PMO states: “The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank shall be re-sanitized.”

a) What precise time constitutes “first use” under the ninety-six (96) hour milk tank truck re-sanitization requirement cited above?

*“First use” would be considered when milk is first transferred into the milk tank truck and the time is documented.*

b) Would the meaning of “first use” be different with direct loads versus conventional milk pickups?

*No.*

c) The following question relates to an extended filling time situation such as what may occur with a direct load. A direct load milk tank truck fill time may be twenty-four (24) hours or greater. If the “first use” of a direct load milk tank truck begins prior to the ninety-six (96) hour re-sanitization timeframe but the milk tank truck is not completely filled until sometime after the ninety-six (96) hour re-sanitization timeframe would this be considered a violation of the PMO?

*No. The “first use”, which would be considered when milk is first transferred into the milk tank truck and the time is documented, occurred before the ninety-six (96) hour timeframe had elapsed following the last cleaning and sanitization of the milk tank truck.*

57. **PMO-Section 7, Item 12p; and Appendix H, Section IV**

Item 12p, Administrative Procedures #2 of the PMO states that recording devices which produce records not meeting the specifications of Appendix H- Pasteurization Equipment and Procedures and Other Equipment, IV- Thermometer Specifications of the PMO may be acceptable if the temperature-recording device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle. Are sanitizers included in the “cleaning solution/cleaning chemicals” category?

No.

58. **PMO- Section 7, Item 12p; and Appendix H, Section V**

Does Section V-Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting within Appendix H of the PMO require the use of an uninterruptible power supply (UPS) for computers collecting and storing electronic CIP records?

Yes.

59. **PMO-Section 7, Item 12p; and Appendix H, Section V**

Is there a required or recommended PMO timeframe for verifying the accuracy of computer generated CIP reports whenever changes or updates are made to the electronic data collection, storage and reporting system utilized by a milk plant or when anomalies are observed?

*The PMO does not cite a specified required or recommended timeframe for verifying the accuracy of computer generated CIP reports after changes or updates have been made or when anomalies are observed. Regulatory discretion should be used based on the amount of changes or updates that have been made.*

**NOTE:** *Section V-Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting within Appendix H of the PMO requires that whenever changes, updates or observed anomalies that affect the reliability or accuracy of the reporting system occur following the initial installation of the system, these changes, updates or observed anomalies shall be evaluated and investigated and if corrections are warranted shall be addressed. The records of each evaluation and corrections made shall bear the signature of the vendor or the identified representative from the milk plant. The records shall*

*be maintained and be available for the Regulatory/Rating Agency or FDA RMS when requested.*

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

May chemical barrels of caustics, acids, detergents and sanitizers used in relationship to CIP systems (tanks) be in the same room or area that pasteurization, processing, cooling, reconstitution, condensing, drying and/or packaging of milk and milk products is taking place?

Yes.

***NOTE:*** *Poisonous or toxic materials that are necessary for the maintenance of the milk plant are not stored in any room where milk or milk products are received, processed, pasteurized, condensed, dried or stored; or where containers, utensils or equipment are washed; or where single-service containers, closures, bags, or caps are stored. Provided that, this does not preclude the convenient availability of detergents or sanitizers to areas where containers, utensils and equipment are washed and sanitized.*

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

Do automatically controlled valves with a drainable opening to the atmosphere between the valves, or a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, that are used to separate water from milk and/or milk products required to be position detectable?

*No. Valve(s) used to separate milk and/or milk products from water do not have to be position detectable. They only are required to be fail-safe as cited in Item 15p-Protection from Contamination (A) of the PMO. Both valves and valve seats in the case of single-bodied double seat valves are required to be position detectable when being used to separate milk and/or milk products from cleaning and/or sanitizing solutions as required in Item 15p(B) of the PMO.*

**62. PMO-Section 7, Items 15p(A), 18p and 19p; Appendix J-Item 13; and MMSR-Section C**

Provisions are cited in Section C-Rating Methods for Milk Plants, Receiving Stations and Transfer Stations of the MMSR that allows for packaging equipment in a milk plant to be partially debited (pro-rated) for construction and repair and/or protection from contamination deficiency(ies) that affect only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispensers, sour cream or yogurt containers, etc.; or the

capping of these containers. Only the quantity of all affected milk and/or milk products by the deficiency for the packaging equipment, rather than the entire milk plant's production, is recorded for use in the computation of the milk plant's SCR. For packaging equipment, only Items 18p-Bottling, Packaging and Container Filling and 19p-Capping, Container Closure and Sealing, Dry Milk Product Storage of the PMO are to receive partial debits. At what point in the packaging processes does the conveyance of containers, i.e., blow molded plastic containers, become an Item 18p violation versus an Item 14p-Storage of Single-Service Articles, Utensils and Materials, and/or Item 11p-Construction and Repair of Containers and Equipment violation?

- *For milk plants that utilize container conveyance/alpine systems in which the containers enter the conveyor/alpine in a room/area of the milk plant that is separate from the processing and/or packaging room/area, the conveyor/alpine would be considered to be included with the associated packaging equipment when it passes through the wall or ceiling into the processing and/or packaging room/area.*
- *For milk plants that utilize container conveyance/alpine systems that place the containers on the conveyor/alpine in the same room/area of the milk plant that processing and/or packaging of milk and/or milk occurs, the conveyor/alpine would be considered to be included with the associated packaging equipment when containers are prepped to go on the conveyor/alpine.*

**NOTE:** *If container storage or not being properly handled violations are observed in the conveyance/alpine system in a room/area of the milk plant that is separate from the processing and/or packaging room/area the following would be applicable:*

- *Separate IMS listed single-service containers and/or closures operation: This would be considered a violation of Appendix J, Item 13-Protection from Contamination of the PMO and would be debited under Item 13(a) on FORM FDA 2359c.*
- *The single-service containers and/or closures operation does not have an IMS listing or the room/area is separate from the processing and/or packaging room/area; therefore, this room/area would be included in the inspection of the milk plant. This would be considered a violation of Item 14p and would be debited under Item 14(a) on FORM FDA 2359 and would be a two (2) point debit.*

### **63. PMO-Section 7, Item 15p(B)**

Since the Preventive Controls for Human Food (PCHF) rules of the Food Safety Modernization Act (FSMA) provides for a milk plant to obtain customer assurance that milk and milk products will be re-pasteurized prior to use, will

the PMO continue to require pasteurized equivalent water for flushing pasteurized milk and/or milk product load out lines?

Yes.

**64. PMO-Section 7, Item 15p(B)**

A milk plant is treating their incoming source water with chlorine. This source water is then further treated in some manner to generate pasteurized equivalent water. Does Item 15p(B) of the PMO provide any specific guidance related to the concentration, parts-per-million (PPM), of chlorine that is to be used for treating the milk plant's source water, the residual chlorine concentration (PPM), or the contact time?

*No. The PMO simply requires documentation that the milk plant's source water that is treated with chlorine by the milk plant in this case meets or exceeds the EPA Safe Drinking Water Bacteriological Standards.*

**65. PMO-Section 7, Item 15p(B)**

While conducting a hazard evaluation and safety assessment for pasteurized equivalent water, the milk plant's incoming source water is negative for total coliform and E. coli. How would the milk plant validate that the pasteurized equivalent water generated from the source water supply following additional treatment to destroy or remove bacteria, meets the pasteurized equivalent water requirements contained within Item 15p(B) of the PMO?

*A hazard evaluation and safety assessment shall be conducted of the milk plant's pasteurized equivalent water generated from the source water following additional treatment to destroy or remove bacteria that is acceptable to the Regulatory Agency. The hazard evaluation and safety assessment shall show that the pasteurized equivalent water meets or exceeds the pasteurized water results.*

**66. PMO-Section 7, Item 15p(B)**

If a hazard evaluation and safety assessment was submitted to the Regulatory Agency utilizing a micro-filtration system for generating pasteurized equivalent water, would peer reviewed research provided by the filter manufacturer indicating that the filters that are being used in a micro-filtration system are effective in removing bacteria and viruses eliminate the concern of a damaged filter in a micro-filtration system being used to generate pasteurized equivalent water?

No.

**67. PMO-Section 7, Item 15p(B)**

When alarmed steam block(s) are used to separate milk and/or milk products from cleaning and/or chemical sanitizing solutions as cited in Item 15p(B) of the PMO, the steam block shall be equipped with a visible steam trace that exits at the “bottom” of the steam block. If the steam block utilizes piping to extend the steam trace vent, is the intent of the word “bottom” to mean that this extended steam trace vent shall be installed vertically (straight down) directly below the steam block?

*No. The visible steam trace shall exit at the lowest point of the steam block. If the steam trace vent is extended it shall have a downward slope, which may be vertical (straight down) or angled diagonally from the steam block, provided the extension does not allow condensate to collect.*

**68. PMO-Section 7-Items 15p(B) and 18p**

During a routine Regulatory Agency inspection, or rating or check rating of a milk plant, if it is observed during packaging that there is a cross connection between the packaging machine’s pipelines and/or equipment used to contain or conduct milk and/or milk products and tanks/silos and/or circuits containing cleaning and/or sanitizing solutions, would this PMO violation be considered a debit under Item 15p(B) or Item 18p-Bottling, Packaging and Container Filling of the PMO?

*It would be considered a 15p(B) violation and it would be debited under Item 15b-Cross Connection (c)-No direction connection between milk or milk products and cleaning and/or sanitizing solutions on FORM FDA 2359 and would be a five (5) point debit.*

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

a) Is there a requirement for a third (3<sup>rd</sup>) party validation of an ultraviolet (UV) light disinfection system that is intended to be used to create pasteurized equivalent water?

*No. Item 15p(B) of the PMO requires that the source water used to produce pasteurized equivalent water shall meet or exceed the EPA Safe Drinking Water Bacteriological Standards. If UV light technology is used to treat this source water to produce pasteurized equivalent water, the UV light disinfection system shall comply with the requirements of Appendix H, Section IX-Accepted Process for the Creation of Pasteurized Equivalent Water of the PMO.*

b) If an independent validation is not required, what means of substantiating the UV light disinfection system's sizing as required in the PMO is acceptable?

*The manufacturer or vendor shall demonstrate to the Regulatory Agency that the criteria of Appendix H, Section IX of the PMO is met.*

c) The PMO addresses the use of UV light for continuous disinfection of incoming milk plant source water for water reclaimed from milk and/or milk products and for plate heat exchanger water. What purposes may pasteurized equivalent water be used for?

*Pasteurized equivalent water may be used to "push" or "flush" pasteurized milk or milk products.*

d) Is it acceptable to use UV light pasteurized equivalent water to make a Grade "A" milk or milk product or to reconstitute milk constituents to make a reconstituted Grade "A" milk or milk product without the Grade "A" milk or milk product being pasteurized following the addition of the pasteurized equivalent water?

No.

**70. PMO-Sections 7-Items 16p and 18p**

a) An IMS listed milk plant is receiving Grade "A" dried whey and reconstituting the dried whey with water, processing it through an evaporator and re-drying the whey. This dried whey is labeled Grade "A". Would the reconstituted whey be required to be pasteurized prior to entering the evaporator?

Yes.

b) Could only the water that is being used to reconstitute the dried whey be pasteurized to meet the requirement of Item 16p of the PMO that the reconstituted whey shall be pasteurized prior to entering the evaporator?

No.

**71. PMO-Section 7, Item 16p(B)**

Item 16p.(B)-High-Temperature-Short-Time (HTST) Continuous-Flow Pasteurization, Administrative Procedures 2-Automatic Milk Controller, b-FDDs (6) of the PMO requires that the FDD shall be located downstream from the holder. The flow-control sensor shall be located in the milk or milk product

not more than 46 centimeters (18 inches) upstream of the FDD. Where is this eighteen (18) inches measured from in relationship to the FDD?

*3-A® Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature-Short-Time and Higher-Heat-Shorter-Time Pasteurizer System, Number 603-07 states that for HTST systems, the safety-thermal-limit-recorder (STLR) temperature sensor connection shall be no more than 18.0 inches (457 mm) upstream from the inlet of the flow-diversion device (FDD). Therefore, this measurement would be taken from the STLR temperature sensor connection to the downstream piping connection to the inlet to the FDD.*

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

A higher-heat-shorter-time (HHST) pasteurization system is utilizing indirect heating and a differential pressure switch is required to be located at the end of the holding tube to assure that the heated milk or milk product in the holding tube remains in the liquid phase. This differential pressure switch shall be set to cause the FDD to move to the divert position at 69 kPA (10 psi) above the boiling pressure of the heated milk or milk product in the holding tube, with a minimum setting of 69 kPA (10 psi). Any drop of pressure at the exit of the holding tube below this minimum setting of 69 kPA (10 psi) will cause the FDD to move to the divert position.

If a HHST pasteurization system that is utilizing indirect heating includes a flow promoting pump, such as a non-bypassed homogenizer located downstream of the holding tube, would this differential pressure switch, if tested and sealed in compliance with Appendix I-Pasteurization Equipment and Controls – Tests, Test 13-Setting of Control Switches for Milk and/or Milk Product Pressure in the Holding Tube of the PMO, be sufficient protection to assure that negative pressure could not be created between the holding tube and the inlet to the non-bypassed homogenizer as required in Item 16p-Pasteurization, Aseptic Processing and Packaging, and Retort Processed after Packaging (B)-High-Temperature-Short-Time (HTST) Continuous-Flow Pasteurization, 2-Automatic Milk Controller, f-Flow-Promoting Devices of the PMO?

**16p.(B),2.f. Flow-Promoting Devices:**

(1) The pump or pumps and other equipment which may produce flow through the holding tube shall be located upstream from the holding tube, provided that pumps and other flow-promoting devices may be located downstream from the holding tube, if means are provided to eliminate negative pressure between the holding tube and the inlet to such equipment....

Yes.

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

a) Item 16p(D)-Pasteurization Records, Equipment Tests and Examination of the PMO requires that cut-in and cut-out milk or milk product temperatures be checked and recorded daily by the HTST operator at the beginning of the run on the temperature recording charts. May this required daily cut-in and cut-out milk or milk product temperature checks conducted by the HTST operator be performed a distance away where the HTST controls and temperature recording charts are located utilizing a camera that is observing and recording the position of the FDD without physically observing the position of the FDD at the HTST pasteurization system installation?

Yes.

b) Would the utilization of a camera for the required quarterly HTST pasteurization system tests, including the FDD test cited above, conducted by the Regulatory Agency be acceptable under the PMO?

*No. During the required quarterly equipment testing of HTST pasteurization systems there should be an appropriate number of Regulatory Agency and milk plant personnel available to perform all the required test in the traditional manner by physically observing the tests being performed and the results and not through the use of a camera.*

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

Appendix I, Test 1-Indicating Thermometer – Temperature Accuracy of the PMO provides an exception to the Criteria to this Test for a batch (vat) pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at a temperature above 71°C (160°F), whereas the indicating thermometer shall be accurate to within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ). When conducting this quarterly required batch (vat) pasteurizer test for this Criteria exception is the test required to be conducted at a temperature above 71°C (160°F)?

Yes.

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

Does Item 17p-Cooling of Milk and/or Milk Products of the PMO require a Grade “A” high acid whey, with a pH  $\leq 4.6$  and titratable acidity (TA)  $>0.40\%$  at approximately 20% solids, to be cooled to 45°F (7°C) or less prior to storage and/or transporting?

No.

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

a) A Grade “A” milk plant utilizes a single whey buffer tank that receives whey from the cheese making operation and supplies whey to the separator to separate the whey cream from the whey. Does this whey buffer tank have to be equipped with a temperature recording device to monitor and record the temperature of the whey and document that this whey tank is emptied, cleaned and sanitized after each four (4) hours of use when the temperature is above 45°F (7°C) or below 135°F (57°C)?

No.

b) Is the whey cream tank that is used to heat whey cream that will be commingled with whole milk in the cheese milk HTST constant-level tank required to be equipped with a temperature recording device?

No.

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

If a milk tank truck load of Grade “A” milk or milk product is received at a manufacturing grade dairy plant that has an IMS listed receiving station, would the milk or milk product be required to meet the cooling temperature requirement of 45°F (7°C) or less as cited within Item 17p of the PMO?

Yes.

**78. PMO-Section 7, Item 17p; and Appendix D**

Does the PMO require a tube chest heat exchanger that is used to exchange heat between an open cooling tower water system and an intermediate cooling media loop to be equipped with a pressure differential controller?

No.

**79. PMO-Section 7, Item 17p; and M-a-97**

If a manufacturer of one (1) of the antimicrobials approved and listed in M-a-97 (Specified Microbial Inhibitors and/or Preservatives Accepted by FDA for Use in the Production of Cottage Cheese that will be Filled at 13°C (55°F) or Less, Cooled to 10°C (50°F) or Less Within Twenty-Four (24) Hours of Filling, and Cooled to 7°C (45°F) or Less Within Seventy-Two (72) Hours of Filling) wants to change the inactive (non-antimicrobial) ingredients in the formulation, such as to replace corn starch with nonfat dry milk, do they need to inform FDA and seek approval for the new formulation?

*Yes. The manufacturer would have to conduct a new study and submit the data for FDA review and acceptance before it can be used and added to M-a-97 (Revision #).*

**80. PMO-Section 7, Item 19p**

A Grade "A" milk plant would like to use a hand-held suction cup lifting device on the non-product contact surface of the lids/closures to manually place the lids/closures on filled 5-gallon buckets of Grade "A" yogurt. The lids are then pressed down by mechanical equipment to ensure a liquid-tight seal for the 5-gallon buckets. Would this be considered a violation of Item 19p-Capping, Container Closure and Sealing and Dry Milk Product Storage of the PMO?

*No. Provided the hand-held suction cup lifting device is used in a sanitary manner. Any placement of lids/closures on the filled 5-gallon buckets by hand, without the use of the hand-held suction cup lifting device, and/or "correcting" by hand of any filled 5-gallon bucket(s) that are imperfectly capped would be considered to be hand capping of milk containers and would be considered a violation of Item 19p of the PMO.*

***NOTE:*** *The use of a hand-held suction cup lifting device as cited above should be one of the last options as there currently are acceptable mechanical packaging and capping equipment available for 5-gallon buckets.*

**81. PMO-Section 7, Item 19p**

A milk plant that produces extended shelf life (ESL) milk and/or milk products discovered a potential foil tamper evident seal issue by an hourly lab check of finished milk products packaged in plastic bottles. This potentially affected a large number of plastic bottles located in the cooler. The milk plant brought in additional staff to look for improperly sealed plastic bottles. The staff removed the caps/closures by hand, squeezed each plastic bottle, and examined for leaks with the foil tamper evident seal that had been applied. The improperly sealed plastic bottles were discarded. Plastic bottles where leaks were not detected had the cap/closure manually hand tightened back onto those plastic bottles.

a) Would the above situation be considered "not in substantial compliance" with regards to the requirement of "hand capping shall be prohibited" as cited in Item 19p of the PMO?

*Yes. However, this is a unique situation and is not the normal routine practice conducted by the milk plant for the filling, applying the foil tamper evident seal and mechanical capping of these plastic bottles. If the foil tamper evident seal was found to be intact it would be up to the Regulatory Agency's*

*discretion if they will allow the caps/closures to be applied by hand and tightened for this unique situation.*

b) What is considered the cap/closure, the foil tamper evident seal that is applied first to the mouth of the plastic bottles or the cap/closure that is applied following the foil tamper evident seal being applied?

*Both are considered the cap/closure because once the foil tamper evident seal is removed by the consumer then the cap/closure becomes the primary cap/closure for the plastic bottle. Both the foil tamper evident seal and the cap/closure are required to be applied in a sanitary manner on approved mechanical capping, closing and/or sealing equipment as required within Item 19p of the PMO. Hand capping is prohibited.*

**82. PMO-Appendix B, Section I**

Does Appendix B-Milk Sampling, Hauling and Transportation of the PMO require bulk milk hauler/samplers to wear beard nets if they have a mustache or beard?

No.

**83. PMO-Appendix B, Section VI**

Appendix B of the PMO requires that when regulatory samples for official laboratory analysis are transported or shipped by individuals that an appropriate sample chain-of-custody shall be established and utilized to assure sample identification and handling. Historically, that has been accomplished by a signed sample chain-of-custody form that accompanies the regulatory samples to the official laboratory. May a Regulatory Agency utilize an electronic submission form that requests laboratory analysis of the laboratory samples that are being submitted, which utilizes electronic signatures to establish an appropriate PMO sample chain-of-custody to assure sample identification and handling?

*It would be up to the discretion of the Regulatory Agency. The Regulatory Agency shall be assured that any required regulatory action can be taken with the utilization of electronic signatures to establish an appropriate PMO sample chain-of-custody to assure sample identification and handling.*

**84. PMO-Appendix D, Section IV**

Within Appendix D-Standards for Water Sources, Section IV-Continuous Water Disinfection, Ultraviolet Light Disinfection of Water of the PMO, what is

the difference between Criteria #2 and #6 for the acceptability of an ultraviolet (UV) light water disinfection unit?

Criteria #2: A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.

Criteria #6: An automatic flow control valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that the entire volume of water receives the minimum dose required above.

*Criteria #2 requires a flow or time delay mechanism which will prevent the flow stop or divert valve from assuming the forward flow position until after the minimum required UV dose has been delivered.*

*Criteria #6 requires an automatic flow control valve that will restrict the flow to the maximum designed flow of the UV light water disinfection unit, so that the entire volume of water receives the minimum required UV dose.*

**85. PMO-Appendix F**

May propylene glycol (USP/Food Grade/GRAS) be used as a sanitizer for milk product-contact surfaces?

*Yes. The propylene glycol shall be registered with EPA for use as a sanitizer for non-porous food contact-surfaces, without a final water rinse, and shall be used according to the manufacturer's directions.*

**86. PMO-Appendix I**

Does Appendix I-Pasteurization Equipment and Controls – Tests, Test 15-Electro-Magnetic Interference from Hand-Held Communication Devices of the PMO apply to Variable Frequency Drives (VFDs) that are utilized on booster pumps, stuffing pumps or timing pumps within HTST and HHST pasteurization systems?

*No. Test 15 is specific to electronic control devices used to assure compliance with public health safeguards on HTST and HHST continuous-flow pasteurization systems.*

87. **PMO-Appendix J; MMSR-Sections A and D; and PROCEDURES-Sections III, IV and V**

When a single-service containers and/or closures manufacturer changes legal ownership (not just a cosmetic name change), is the existing IMS listing from the previous ownership still valid, or is a new IMS certification required to be conducted?

*The current IMS listing would no longer be valid because the previous ownership's signed Permission to Publish, which authorized the release and publishing of their IMS listing certification, on Form FDA 2359d-Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) for their IMS listing would no longer be valid. The Rating Agency or single-service consultant (SSC), as applicable, shall immediately withdraw the single-service containers and/or closures manufacturer from the IMS List.*

*A new IMS listing certification would be required if the new ownership wishes to have their single-service containers and/or closures manufacturing facility IMS listed. The new ownership would be required to follow one (1) of the procedures cited below:*

- *A U.S. manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a request to the State Rating Agency in their own State.*
- *A foreign manufacturer of single-service containers and/or closures for milk and/or milk products desiring a certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a request to a TPC or SSC that is listed on the IMS List.*

88. **PMO-Appendix J, Sections A, B and D-Item 16**

**Background:** The tails, handle cutouts and clean, rejected bottles from the blow molding process of single-service milk containers are subject to regrinding and the regrind is commonly reintroduced into the resin stream for blow molding into new single-service milk containers. In the regrinding process, a certain amount of the plastic material is separated as "fines" as the material is blown into a cyclone-type separator. These fines have traditionally been collected in plastic lined Gaylord shipping boxes for resale to plastic processing plants that do not manufacture food contact packaging containers and/or closures. A manufacturer has come forward claiming that their plant has a process for re-pelletizing these "fines", which are suitable for reintroduction into the resin stream for the blow molding of single-service milk containers and/or closures. The manufacturer claims that these reprocessed

pellets would be tracked and segregated to ensure that the original resin source compliance documents from which the reprocessed pellets were obtained from (Title 21 CFR Parts 174 to 178) would remain valid. According to Appendix J, Section B-Definitions, Item 15-Regrind of the PMO requires that regrind, when transported from one (1) approved plant to another, shall be shipped in suitable, clean, sealed, properly labeled containers.

a) Would the pellets that are tracked, segregated, reprocessed, labeled and handled in accordance with the information as cited in the Background above be allowed to be used in the manufacture of single-service containers for milk and/or milk products from an IMS listed single-service containers manufacturer?

Yes.

b) Would the re-pelletizing facility be required to be IMS listed?

No.

c) Would a re-pelletizing facility of this type be eligible for an IMS listing?

No.

d) Would the re-pelletizing process and use of the reground/reprocessed pellets be subject to compliance with a protocol that has been reviewed and accepted by FDA?

No.

e) Would the facility that is regrinding and re-pelletizing the resin also have to make a claim that their re-pelletized resin meets 21 CFR Parts 174-178 along with the original CFR letter from the original manufacturer of the resin from which the reprocessed pellets were obtained?

Yes.

**89. PMO-Appendix J, Sections A and D-Item 20**

a) Is the area(s) of a paper mill that is utilized to manufacture laminated paperboard that will be used for the manufacturing of single-service paper milk cartons for the packaging of Grade "A" milk and/or milk products required to be IMS listed?

Yes.

b) If an IMS listed paper mill is manufacturing laminated paperboard that will be used for the manufacturing of single-service paper milk cartons for the packaging of Grade "A" milk and/or milk products and the labeling on the outer wrapping of the shipped laminated paperboard states only "Made in the U.S.A." does this comply with Appendix J, Section D-Fabrication Plant Standards, Item 20-Identification and Records a. of the PMO?

*No. Item 20. a. requires that the outer wrapping shall be identified with the name, city and State of the plant where the contents are fabricated, except those manufactured in, and which are for use in the same facility. For foreign manufacturing plants, the outer wrap shall also be identified with the country. Where several plants are operated by one (1) firm, the common firm name may be utilized, provided that the location of the plant at which the contents, in this situation were laminated, is also shown either directly or by the Federal Information Processing Standards (FIPS) numerical code on the outer wrapper.*

**90. PMO-Appendix J, Sections B and C**

The manufacturing of gable top paper milk cartons requires two (2) processes for the complete assemblage of the paper milk container. It first goes through a press that cuts, creases, and prints onto the flat carton blank where the ink must cure or set before the carton can then be folded and seamed through a side seam sealer to complete the final process of converting the paper carton into a sleeve. If the manufacturing plant utilizes five (5) presses and two (2) side seam sealers, at what point within this process would sample sets be required to be collected from each manufacturing line to meet the requirements of Appendix J, Section C of the PMO?

*A sample set of four (4) containers, when the rinse test is used, or a minimum of four (4) 250 cm<sup>2</sup> areas of surface, when the swab test is used, would be required to be collected at the end of the side seam sealer unit(s) when the paper carton assemblage is completed and ready for shipment. With all the containers coming from the five (5) presses and two (2) side seam sealers (manufacturing line), one (1) sample set per sampling event is sufficient. It is recommended that when different machines are being utilized, they should be sampled in a rotating fashion.*

**91. PMO-Appendix J, Section C; MMSR-Section D**

a) Would it be acceptable for official regulatory single-service containers and/or closures sample sets to be submitted for analysis to a non-IMS listed laboratory?

*No. Single-service containers and/or closures sample sets shall be analyzed at an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency.*

b) What is the consequence for a single-service containers and/or closures manufacturer's IMS listing if it is encountered during an IMS certification or FDA audit that official regulatory single-service containers and/or closures sample sets were analyzed at a non-IMS listed laboratory?

*Proposal 309 passed at the 2015 NCIMS Conference will incorporate the following into the MMSR , Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 1-Collection of Data, b-Recording of Laboratory and Other Test Data, 1.) of the PMO: Certifications shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency, Single-Service Consultant (SSC), or single-service containers and/or closures manufacturers, as applicable, for the necessary tests.*

*If this is the initial certification conducted for an IMS listing of the single-service containers and/or closures for milk and/or milk products manufacturer, then the SRO or SSC shall not grant a certification for IMS listing. If this is the certification conducted of an IMS listed single-service containers and/or closures for milk and/or milk products manufacturer, then the SRO or SSC shall immediately withdraw the manufacturer's IMS listing. If this is a FDA audit conducted of an IMS Listed single-service containers and/or closures for milk and/or milk products manufacturer, then the FDA MS shall immediately notify the Regulatory Agency or SSC, as applicable, to withdraw the manufacturer's IMS listing.*

**92. PMO-Appendix J, Sections C and D-Item 20; MMSR-Section D; and PROCEDURES-Sections IV and V**

a) When conducting certifications/listings or FDA audits of single-service containers and/or closures for milk and/or milk product manufacturers please explain when Item 20(c)-Required bacteriological tests on file; maintained as required; and in compliance (11 points) on FORM FDA 2359c would be debited in comparison to when the Bacterial Count (5 points) and/or Coliform Count (10 points) on FORM FDA 2359e-Status of Manufacturing Plants would be debited in relationship to single-service containers and closures that are not in compliance with Appendix J, Section C-Bacterial Standards and Examination of Single-Service Containers and/or Closures of the PMO?

*As currently written, Appendix J, Section D, Item 20(c) of the PMO requires that the records of all required bacteriological tests of containers and/or closures shall be maintained at the plant of manufacture for two (2) years and*

*the results shall be in compliance with Appendix J, Section C of the PMO. Therefore, based on the records reviewed if the last sample set results on file indicate that the sample set of containers and/or closures, as applicable, are not in compliance with either the microbial (bacterial) and/or coliform limits contained within Appendix J, Section C of the PMO, Item 20(c) would be debited (11 points).*

*Based on the records reviewed, if two (2) of the last four (4) sample set of containers and/or closures results, as applicable, exceed the microbial (bacterial) and/or coliform limit, and the last sample set result is in violation this would be debited under Bacterial Count (5 points) and/or Coliform Count (10 points), as applicable, on FORM FDA 2359e in accordance with Section D-Certification/Listing Methods for Single-Service Containers and/or Closures for Milk and/or Milk Product Manufacturers of the MMSR.*

b) What would be the criteria for re-certifying/listing a single-service containers and/or closures manufacturer following their IMS certification/listing being withdrawn because of a SCR of less than eighty (<80), which included the debiting of Item 20(c) on FORM FDA 2359c? The Item 20(c) debit involved the last sample set results on file indicating that the sample set of containers and/or closures, as applicable, were not in compliance with the microbial (bacterial) and/or coliform limits contained within Appendix J, Section C of the PMO.

*A U.S. manufacturer of single-service containers and/or closures for milk and/or milk products desiring a re-certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a written request to the Rating Agency in their own State.*

*A foreign manufacturer of single-service containers and/or closures for milk and/or milk products desiring a re-certification of their single-service containers and/or closures for the purpose of interstate listing shall submit a written request to a Third Party Certifier (TPC) or Single-Service Consultant (SSC), as applicable, that is listed on the IMS List.*

*This written notification requesting a re-certification/listing shall be from an authorized representative of the single-service containers and/or closures for milk and/or milk products manufacturer to the Rating Agency or SSC, as applicable, stating that the single-service containers and/or closures for milk and/or milk products manufacturer is in substantial compliance. To be in substantial compliance the single-service containers and/or closures for milk and/or milk products manufacturer would be required to sample their single-service containers and/or closures until a sample set of single-service containers and/or closures, as applicable, are in compliance with the microbial (bacterial) and coliform limits as cited within Appendix J, Section C*

*of the PMO. The re-certification/listing shall be completed in not more than fifteen (15) days, from the date of receipt of the written notification, unless the Rating Agency or SSC, as applicable, has a reason to believe a new certification within a lesser time would result in an acceptable certification/listing.*

c) What would be the criteria for re-certifying/listing a single-service containers and/or closures manufacturer following their IMS certification/listing being withdrawn because of a SCR of less than eighty (<80), which included the debiting of either the Bacterial Count (5 points), or Coliform Count (10 points), or both (15 points) because two (2) of the last four (4) sample set results exceeded the microbial (bacterial) and/or coliform limit, and the last sample set result was in violation?

*Refer to the answer in b) above. However, based on this scenario, to be in substantial compliance the single-service containers and/or closures for milk and/or milk products manufacturer would be required to sample their single-service containers and/or closures, as applicable, until they are in a situation where two (2) of the last four (4) sample set results do not exceed the microbial (bacterial) and/or coliform limit, and the last sample set result is not in violation.*

d) When conducting certifications/listings or FDA audits of single-service containers and/or closures for milk and/or milk product manufacturers please explain when Item 20(d)-Required bacteriological and chemical test records for all component parts used in final assembled product on file (11 points) on FORM FDA 2359c would be debited?

*Appendix J, Section D, Item 20(d) of the PMO requires that it is the responsibility of the inspected/certified and listed single-service containers and/or closures for milk and/or milk product manufacturer to maintain records verifying the bacterial and chemical safety of all component parts utilized in their final assembled single-service containers and/or closures, as applicable. The single-service containers and/or closures for milk and/or milk product manufacturer shall have a supplier control program that includes letters of guarantee or certificates of analysis (COAs) from all their component parts suppliers in their files that verify the bacterial and chemical safety of all component parts that they are receiving and utilizing in the assembly of their final single-service containers and/or closures, as applicable. Therefore, based on the records reviewed if a letter of guarantee or COA from each component part supplier utilized in the final assembly of their single-service containers and/or closures, as applicable, is not available in their files this would be considered a violation of Item 20(d) on FORM FDA 2359c (11 points).*

e) Will the SCR from certifications/listings conducted by SROs or SSCs be published on the *IMS List*?

*No. Single-service containers and/or closures manufacturers shall achieve a SCR of 80 percent (80%) or higher in order to be eligible for a listing on the IMS List. SCRs for single-service containers and/or closures manufacturers will not be identified on the IMS List.*

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

Does Appendix J of the PMO require equipment surfaces such as rollers, dies, belts, tables, cutters, mandrels, transfer tubing and other contact surfaces to be sanitized?

*No.*

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

Are air tubes on resin silos that are located outside, which are used to convey resin, required to be locked when not in use.

*No. Appendix J, Item 15-Fabrication Equipment of the PMO requires that these air tubes shall have end caps, attached by a chain or cable that prevents contamination.*

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

Appendix J, 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.

96. **PMO-Appendix J, Section D, Item 20**

Does the letter from the manufacturer(s) of the resin(s) that is being utilized to produce IMS listed single-service containers and/or closures for milk and/or milk products that is on file at the single-service containers and/or closures manufacturing facility required to be on the resin manufacturer's letterhead, dated and signed by a representative of the resin manufacturer or can it just be a form letter without a signature?

*The letter needs to be on the resin manufacturer's letterhead, reference the resin(s) being utilized, dated and signed by a representative of the resin manufacturer.*

97. **PMO-Appendix N**

A Grade "A" dairy farm direct ships loads of milk to a milk plant. The direct shipped milk tank truck load of milk is properly agitated at the milk plant in accordance with the milk plant's agitation study, which has been approved by the Regulatory Agency; sampled; and the required Appendix N testing is conducted. The Appendix N testing confirms that the milk tank truck load of milk is Positive. The Regulatory Agency where the dairy farm is located is notified and suspends the milk producer's Grade "A" permit as required within Appendix N-Drug Residue Testing and Farm Surveillance of the PMO. Following their permit suspension, the dairy farm brings in their next direct shipped milk tank truck load of milk to the milk plant, so a clearing sample can be taken following proper agitation in accordance with the milk plant's agitation study.

a) If that clearing sample collected after proper agitation in accordance with the milk plant's agitation study is determined to be None Found (NF), may the milk be immediately offered for sale and the milk plant receive the milk?

*Yes. The Regulatory Agency shall be immediately notified of the None Found (NF) result.*

b) If that clearing sample collected after proper agitation in accordance with the milk plant's agitation study is determined to be Positive, may that milk tank truck load of milk leave the milk plant and **NOT** be considered for sale at that time? The milk tank truck load of milk will be properly discarded/dumped as directed by the Regulatory Agency.

*Yes, as the milk producer's Grade "A" permit is still suspended. The Regulatory Agency shall be immediately notified of the Positive result.*

**98. MMSR-Section E; and Appendix A**

On ratings and check ratings when calculating the "Number Complying" for the following Items on FORM FDA 2359j-Section B-Report of Enforcement Methods (Page 2) what procedure should be utilized?

**DAIRY FARMS-PART I**

- Item 2-All dairy farms inspected once every six (6) months or as required in Appendix P;
- Item 6-Water samples tested and reports on file as required; and
- Item 9-Sampling procedures approved by PHS/FDA evaluation methods.
  - Dairy Farm Sampling Procedures, Item 5-Samplers evaluated every two (2) years and reports properly filed on FORM FDA 2359j-Section C-Evaluation of Sampling Procedures (Page 3).

**MILK PLANTS-PART II**

- Item 2-Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plants and transfer station(s) once every six (6) months;
- Item 5-Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.);
- Item 6-Individual and cooling water samples tested and reports on file as required; and
- Item 8-Sampling procedures approved by PHS/FDA evaluation methods.
  - Milk Plant Sampling Procedures, Item 5-Samplers evaluated every two (2) years and reports properly filed on FORM FDA 2359j, Section C (Page 3).

When reviewing the official Regulatory Agency's records, does a new complete routine inspection date; a new water (individual water supply or recirculated or reclaimed) sample collection date with not found (NF) laboratory results; a new complete pasteurization equipment testing date, or a new sampler evaluation date conducted prior to the month in which the inspection, sample collection, equipment testing or sampler evaluation is due automatically change the time frame that is utilized for determining compliance with the Item cited above when calculating Enforcement Ratings for dairy farms, milk plants, receiving stations and transfer stations?

Yes.

**For Example:**

**DAIRY FARMS-PART I**

- *Item 2-All dairy farms inspected once every six (6) months or as required in Appendix P:*

*Credit shall be given for the remaining days of the month in which the inspection is due.*

<u>Inspection Date</u>	<u>Next Inspection is Due to Grant Compliance</u>
10/24/2015	4/30/2016
2/12/2016	8/31/2016
7/28/2016	1/31/2017

- *Item 6-Water samples tested and reports on file as required:*

*Credit shall be given for the remaining days of the month in which the sample is due.*

**Individual Water Supply (Every three (3) years)**

<u>Sample Collection Date</u>	<u>Next Sample is Due to Grant Compliance</u>
10/24/2012	10/31/2015
2/12/2014	2/28/2017
7/28/2016	7/31/2019

**Recirculated Cooling and Reclaimed Water (Every six (6) months)**

<u>Sample Collection Date</u>	<u>Next Sample is Due to Grant Compliance</u>
10/24/2015	4/30/2016
2/12/2016	8/31/2016
7/28/2016	1/31/2017

- *Item 9-Sampling procedures approved by PHS/FDA evaluation methods.*
  - *Dairy Farm Sampling Procedures, Item 5-Samplers evaluated every two (2) years and reports properly filed on FORM FDA 2359j, Section C (Page 3).*

Credit shall be given for the remaining days of the month in which the evaluation is due.

**Individual Sampler (Every twenty-four (24) months)**

Sampler Evaluation Date      Next Evaluation is Due to Grant Compliance

10/24/2013	10/31/2015
2/12/2015	2/28/2017
7/28/2016	7/31/2018

**MILK PLANTS-PART II**

- *Item 2-Milk plant and receiving station(s) inspected once every three (3) months, aseptic and retort milk plants and transfer station(s) once every six (6) months;*

Credit shall be given for the remaining days of the month in which the inspection is due.

**Milk Plants and Receiving Stations**

Inspection Date      Next Inspection is Due to Grant Compliance

10/24/2016	1/31/2017
12/12/2016	3/31/2017
2/28/2017	5/31/2017

**Aseptic and Retort Milk Plants and Transfer Stations**

Inspection Date      Next Inspection is Due to Grant Compliance

10/24/2015	4/30/2016
2/12/2016	8/31/2016
7/28/2016	1/31/2017

- *Item 5-Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.);*

Credit shall be given for the remaining days of the month in which the equipment testing is due.

**HTST, HHST and Batch (Vat) (Every three (3) months)**

<u>Testing Date</u>	<u>Next Testing is Due to Grant Compliance</u>
10/24/2016	1/31/2017
12/12/2016	3/31/2017
2/28/2017	5/31/2017

**HTST and HHST-Holding Time (Every six (6) months)**

<u>Testing Date</u>	<u>Next Testing is Due to Grant Compliance</u>
10/24/2015	4/30/2016
2/12/2016	8/31/2016
7/28/2016	1/31/2017

- *Item 6-Individual and cooling water samples tested and reports on file as required;*

*Credit shall be given for the remaining days of the month in which the sample is due.*

**Individual Water Supply and Recirculated Cooling and Reclaimed Water (Every six (6) months)**

<u>Sample Collection Date</u>	<u>Next Sample is Due to Grant Compliance</u>
10/24/2015	4/30/2016
2/12/2016	8/31/2016
7/28/2016	1/31/2017

- *Item 8-Sampling procedures approved by PHS/FDA evaluation methods.*
  - *Milk Plant Sampling Procedures, Item 5-Samplers evaluated every two (2) years and reports properly filed on FORM FDA 2359j, Section C (Page 3).*

*Credit shall be given for the remaining days of the month in which the evaluation is due.*

**Individual Sampler (Every twenty-four (24) months)**

Sampler Evaluation Date      Next Evaluation is Due to Grant Compliance

10/24/2013

10/31/2015

2/12/2015

2/28/2017

7/28/2016

7/31/2018

**99. MMSR-Section H**

A milk plant is using microfiltration of skim milk to produce micellar casein that is then dried and wishes to be listed for this product on the *IMS List*. What Product Code should this product be IMS listed under?

**NOTE:** Micellar casein concentrate produced from skim milk is a concentrated liquid colloidal suspension consisting mainly of casein in micellar form, lactose, minerals and a minor amount of whey proteins.

*Product Code #22-Dry Milk and Milk Products.*

**100. MMSR-Section I**

If the Regulatory Agency is not conducting routine regulatory inspections (quarterly, semi-annually or annually) of an IMS listed single-service containers and/or closures manufacturing facility, is the SRO or SSC that certifies/lists the single-service containers and/or closures manufacturer for twelve (12) months on the *IMS List* required to answer Item #7-Agency or SSC, as Applicable, Providing Routine Inspection on FORM FDA 2359d?

*No.*

**101. PROCEDURES-Sections I and V**

Does the *Procedures* allow Grade "A" dairy farms that are permitted, inspected and regulated by two (2) separate State Regulatory Agencies to be included and rated in one (1) IMS listed BTU?

*Back in the 1980s through the 1990s there was a strong push by FDA for State Regulatory/Rating Agencies to utilize State-line permitting, inspection and ratings of BTUs. Many States agreed to that and have continued to conduct State-line ratings of BTUs. There still may be a few States that have continued to conduct ratings of BTUs that include dairy farms located in two (2) or more States.*

*It has been FDA's position all along that the State Regulatory Agency in which the dairy farm is located shall permit, inspect and regulated all the dairy farms in their State. FDA strongly recommended during this time frame that State Regulatory/Rating Agencies utilize State-line permitting, inspection and ratings of BTUs (Area and Individual) and still does today.*

*In the 1999 revision of the Procedures, a Definitions section was added which clarified that an "Area Rating", "Bulk Tank Unit (BTU)" and "Individual Rating" were to either consist of more than one producer group; a dairy farm or group of dairy farms; or a single producer group, respectively, operating under the supervision of a single Regulatory Agency. These definitions in the latest revision of the Procedures still cite that same requirement.*

*Section V-Qualifications and Certifications, A-Supervision Requirements of the Procedures also requires that the milk shipper to be rated shall be under the full-time supervision of a State or TPC Regulatory Agency.*

*For those few States that may still be conducting ratings of BTUs that include dairy farms located in two (2) or more States, FDA believes it is time for those States to utilize State-line inspections and ratings for all IMS listed BTUs. It is recommended that for those IMS listed BTUs that the States involved wait until the next rating is to be conducted to make this change to State-line inspections and ratings.*

## **102. PROCEDURES-Section IV**

A milk plant is officially closing and has an inventory of dry milk powder (Product Code #16-Nonfat Dry Milk (NFDM) and #17-Dried Buttermilk) that will remain after the facility shuts its doors. At the time of production, the milk powder was labeled Grade "A" and was produced in a licensed and IMS listed milk plant. When the milk plant closes, does the Rating Agency immediately remove their IMS listing and the Regulatory Agency just address calls regarding the status of the milk plant and the Grade "A" milk powder or because of the Grade "A" milk powder's shelf life, does the Rating Agency keep the current milk plant's IMS listing on the *IMS List* until it expires?

*Because of this existing inventory of Grade "A" dry milk powder and the ability of the company to continue to sell these Grade "A" dry milk powders, it is recommended that the milk plant remain on the IMS List until their current IMS listing expires. At the time of closing, the company shall provide to the Regulatory Agency the amount of Grade "A" dry milk powder (NFDM and Dried Buttermilk) that they have in their existing inventory along with production dates and lot numbers. The facility or warehouse that the Grade "A" dry milk powder is stored in shall be licensed by the Regulatory Agency and inspected to ensure the conditions under which the Grade "A" dry milk*

*powder is being stored. After the current IMS listing expires, the closed milk plant cannot be rated and the company shall again provide to the Regulatory Agency the amount of Grade "A" dry milk powder (NFDM and Dried Buttermilk) that they have in any existing inventory along with production dates and lot numbers so that the Regulatory Agency may address calls regarding the status of the milk plant and the Grade "A" milk powder.*

**103. PROCEDURES-Section IV**

a) Is there any prohibition with having Regulatory/Rating Agency personnel being FDA certified as both an SRO and LEO?

No.

b) Would there be a conflict of interest if the SRO rated a milk plant in which he/she evaluated the laboratory as the LEO earlier in the year?

No.

**104. PROCEDURES; and MMSR**

May a FDA check rating and a State or TPC rating be conducted concurrently?

No.