TO: All Regional Food and Drug Directors
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 2015

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 2015.

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

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

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

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

a) CFSAN’s Office of Nutritional Labeling and Dietary Supplements (ONLDS) has provided the following comments in response to a request for assistance regarding the appropriate statements of identity for the milk products of a proposed manufacturing process by a milk plant.

The proposed process uses raw Grade “A” skim milk as the starting ingredient. The minor protein fractions lactoferrin and lactoperoxidase will be removed using ion exchange technology. The lactoferrin and lactoperoxidase will be further purified and processed to be sold as dairy powders in both domestic and international markets. The milk plant plans to utilize what remains of the skim milk after the ion exchange process to manufacture “skim milk powder” (SMP) and “milk protein concentrate” (MPC).

The milk product to be labeled “skim milk powder” is considered a non-standardized milk product in the United States. Consequently, FDA would object to labeling this milk product “skim milk powder” for domestic use, as it could easily be confused with the standardized milk product “nonfat dry milk” in 21 CFR 131.125. In addition, the terms “skim” and “nonfat” can be used interchangeably under certain conditions (Ref. 21 CFR 101.4 (b)(3) and 21 CFR 101.62(b)). However, FDA would not object to labeling this milk product for domestic use as “nonfat milk solids.”

In the international marketplace, this milk product is intended to be marketed as “skim milk powder” under the Codex standards. Since FDA’s authority regarding food labeling and standards is limited to products sold only domestically, we are not providing comments related to this product’s compliance with Codex. Food products which are intended for export that would otherwise be considered misbranded if sold in the United States must comply with requirements in § 801(e)(1) of the Federal Food, Drug, and Cosmetic Act. One of these requirements is that the food must be labeled on the outside of the shipping package that it is intended for export.

The milk product that is to be sold domestically and label “milk protein concentrate” is also a non-standardized milk product in the United States. Though concentrated to varying degrees, milk protein concentrate is commonly understood to contain milk protein representative of the full complement of milk proteins in the same ratios as they are found naturally occurring in milk. Consequently, FDA would object to the use of the term “milk protein concentrate” without qualification to disclose the absence or reduction of lactoferrin, an important whey protein, and lactoperoxidase in this milk product. The milk plant may be referred to 21 CFR 102.5 regarding the general principles and requirements for the common or usual name of non-standardized foods for guidance in renaming this milk product.
b) Could the milk products as labeled above, “Nonfat Milk Solids” and “Milk Protein Concentrate” with a qualifying statement disclosing the absence or reduction of lactoferrin, an important whey protein, and lactoperoxidase in this milk product be labeled Grade “A”?

Yes. If the milk plant chooses to label the milk products Grade “A” the milk products would be required to be produced under the Grade “A” Milk Safety Program and come from an IMS Listed milk plant. In fact, if they are to be used in the manufacturing of a Grade “A” defined milk product they would be required to be labeled Grade “A”.

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

The following is ONLDS completed review of a submitted brand 2% Reduced Fat Milk label that cites “with Probiotics” and makes the claim that it “Improves Digestion”:

Our interpretation of this issue has not substantially changed since 2010.

As previously indicated, milk is a food for which a definition and standard of identity has been prescribed by regulation. The standard of identity for milk in Title 21 Code of Federal Regulations 131.110 describes milk as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows” and it lists the vitamins and other ingredients that may be added. According to the product label, the product contains ingredients (Probiotics) not permitted by the standard; therefore, the product does not conform to the standard of identity for “milk”.

We note that “Reduced Fat Milk” is a food subject to the requirements of 21 CFR 130.10, which permits standardized foods to be modified in order to make a nutrient content claim, e.g., reduced fat milk. We see no provision under 21 CFR 130.10 that provides for the addition of “probiotics” to the food named by the nutrient content claim “reduced fat” and the standardized food name “milk”. The regulation permits the addition of ingredients not found in the standardized food so that the product is not nutritionally inferior to the standardized food and so that the modified product performs at least one of the principal functions of the standardized product substantially as well as the standardized product. In this case, “Probiotics” are neither ingredients used to make the modified food nutritionally equivalent nor to enhance the performance characteristics of the modified food; therefore, “Probiotics” are not permitted in reduced-, low- or non-fat milk.

If “Probiotics” are added to the standardized food “milk” with the nutrient content claim of “reduced fat milk”, the name of the food must be called something else to distinguish it from the standardized food “milk” with the nutrient content claim of “reduced fat milk”.

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Alternatively, this product may be appropriately named “reduced fat cultured milk” if it conforms to the applicable requirements of 21 CFR 131.112 “cultured milk” and 21 CFR 130.10. The milk would need to be cultured by the addition of aroma- and flavor producing microbial culture (Acidophilus and Bifidus), contain not less than 8.25 percent milk solids not fat, have a titratable acidity of not less than 0.5 percent (expressed as lactic acid), and comply with the requirements for a reduced fat nutrient content claim in 21 CFR 101.62 (b)(4). The Acidophilus and Bifidus bacteria would perform a dual purpose in this case, by being both aroma- and flavor-producing as well as probiotic. The manufacturer must be able to substantiate the probiotic claim. Traditionally, “acidophilus cultured milk” has been a product that conforms to the standard in 21 CFR 131.112.

The combined statements “with probiotics” and “improves digestion” appear to be a structure/function claim. We do not object to a label statement about probiotics in cultured milk provided the statement is truthful and not misleading. We will continue to evaluate label statements such as these on a case-by-case basis.

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

A modified milk product is produced through a specific series of filtration processes, the first filtration being the ultrafiltration (UF) of raw milk to produce a retentate high in milk proteins and a permeate consisting mainly of water, lactose, minerals, and other low molecular weight milk components. The milk components present in the UF permeate are subsequently concentrated using nanofiltration and reverse osmosis (RO). These in turn are added back to the UF retentate to create a product with modified protein, calcium, and lactose components of raw milk. For example, higher protein, higher calcium, and lower lactose. The finished milk product may be standardized to various milk fat levels and pasteurized. What is an appropriate statement of identity for this modified milk product?

The following answer was provided by FDA’s Center for Food Safety and Applied Nutrition (CFSAN), Office of Nutrition Labeling and Dietary Supplements (ONLDS):

As further explained below, this modified milk product does not comply with the standard of identity for milk (21 CFR 131.110). Thus, the statement of identity for this modified milk product must be a term that adequately and accurately describes its basic nature or characterizing properties or ingredients. This modified milk product is essentially an ultrafiltered milk with the addition of milk components recovered from the ultra-filtration permeate using nanofiltration and reverse osmosis processes. Appropriate statements of identity for this modified milk product may be “ultrafiltered milk”, “dairy beverage”, or “milk beverage”. If this modified milk product is standardized
to contain fat levels that satisfy the requirements for nutrient content claims for fat as specified in 21 CFR 101.62, terms such as “skim”, “reduced fat”, or “low fat” must be added as part of the above suggested statements of identity as appropriate. For example “reduced fat ultrafiltered milk”, “skim milk beverage”, or “low fat dairy beverage”, etc.

As noted above, this modified milk product does not comply with the standard of identity for milk. The standard of identity for milk (21 CFR 131.110) does not encompass a food that is prepared by separating the nonfat portion of the milk into its various components and subsequently remixing these separated components to create a specific profile. In addition, the separation and subsequent remixing are not minimum deviations from the ingredient and non-ingredient provisions of the milk standard (21 CFR 131.110) necessary to qualify for a nutrient content claim while maintaining similar performance characteristics (21 CFR 130.10(c)). Therefore, this modified milk product cannot be called “milk”, “high protein milk”, “high protein, high calcium, reduced sugar milk”, or similar variations.

4. PMO-Sections 1 and 7, Item 13r; and Appendix Q, Item 13r

A traditional rotary milking system is utilizing a robotic arm to only prep the teats of cows before milking and/or for the post dipping of teats after the cows have been milked. Would this milking system be considered an Automatic Milking Installation (AMI) under the AMI definition contained within Section 1-Definitions of the PMO and; therefore, require a teat prep protocol to be submitted to FDA for their review and acceptance prior to it being implemented in the milking operation as address in Item 13r-Milk – Flanks, Udders and Teats, Appendix Q-Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization, Ultra-pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging of the PMO?

No. This milking system and operation would not meet the definition of an AMI as defined in the Grade “A” Pasteurized Milk Ordinance (PMO). Therefore, a teat prep protocol would not be required to be submitted to FDA for their review and acceptance prior to it being implemented in the milking operation.

NOTE: The protocol for the post dipping of teats after milking in a traditional milking system or an AMI is not required by the PMO to be submitted to FDA for their review and acceptance prior to it being implemented in the milking operation.
5. **PMO-Section 3; and Appendix N**

a) A Grade “A” milk plant has chosen to strictly utilize their on-site Appendix N screening or confirmation laboratory and not rely on any other Appendix N testing laboratory. Before this milk plant can be permitted by the Regulatory Agency is the milk plant required to have their on-site Appendix N screening or confirmation laboratory approved or accredited by a Laboratory Evaluation Officer (LEO)?

Yes. For a milk plant that has chosen to strictly utilize their own on-site Appendix N screening or confirmation laboratory for the testing of all milk received/utilized in the milk plant to be issued a permit by the Regulatory Agency, the milk plant shall be in compliance with the PMO, which would include the ability to conduct official Appendix N drug testing for all raw milk received/utilized as required by the PMO.

b) Are all Grade “A” milk plants required to have their own on-site Appendix N testing facilities (screening or confirmation laboratory)?

Not if they receive only pasteurized milk and/or milk products or all of the raw milk and/or milk products received have been previously tested (none found) for drug residues in an approved or accredited screening or confirmation laboratory at another location.

**NOTE:** If tested at another location, the weight ticket, Bill of Lading, shipping statement that accompanies the individual milk tank truck loads of raw milk and/or milk products must indicate the results of the drug residue testing, date of testing and the approved or accredited screening or confirmation laboratory performing the drug residue testing (name and address or by IMS laboratory code/number).

6. **PMO-Section 3**

If a milk plant only processes milk and/or milk products one (1) day a week and a milk and/or milk product is in a three (3) out of five (5) status for exceeding the PMO standards, i.e., permit suspension or stoppage of sale of the specific milk and/or milk product, how would enforcement compliance be evaluated addressing the required PMO accelerated milk and/or milk product sampling on ratings and check ratings?

*Accelerated sampling within Section 3-Permits of the PMO requires that samples shall be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform, somatic cell count and temperature. The Regulatory Agency shall reinstate the permit upon compliance with the*
appropriate standard as determined in accordance with Section 6-The Examination of Milk and/or Milk Products of the PMO.

With this scenario of being able to only collect one (1) milk and/or milk product sample per week, the accelerated sampling will need to be extended if during the first (1st) three (3) weeks a positive result is obtained so as to clear the milk and/or milk product from a potential three (3) out of five (5) situation for exceeding the PMO standards. This may involve a fourth (4th) or fifth (5th) week of sampling to clear the milk and/or milk product.

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

A milk plant wishes to label their Grade “A” yogurt and sour cream as “gluten-free”. Yogurt and sour cream are inherently gluten-free. Would they be allowed to be labeled as “gluten-free”?


8. **PMO-Section 4; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Sections C and D**

a) If a milk plant is IMS listed for the production of a given Grade “A” milk and/or milk product, for example “heat treated cream” or “raw cream”, are these Grade “A” milk and/or milk products required to be sold as Grade “A” or can they be shipped without the Grade “A” designation to a non-Grade “A” facility that is making butter and other foods?

All Grade “A” milk and milk products for which a milk plant is IMS listed for are considered Grade “A” and are required to be labeled as Grade “A” on their individual containers or if shipped out of the milk plant in bulk, the Bills of Lading (shipping statements) shall identify the milk and/or milk product as “Grade “A” along with the name of the milk and/or milk product no matter where the Grade “A” milk and/or milk product is being shipped to. If the Grade “A” milk and/or milk products are not labeled Grade “A” on their individual containers or on Bills of Lading (shipping statement) then that individual Grade “A” milk and/or milk product would be debited under Item 3—All milk and milk products properly labeled under the Individual Shipper Rating, Part III on FORM FDA 2359j, Section B-Report of Enforcement Methods (Page 2).

b) Would the answer to a) above also apply to Grade “A” non-fat dried milk (NFDM), skim milk powder or other dried milk or milk products that are produced for export only?
No. These Grade “A” milk and/or milk products must be labeled on the outside of the shipping packaging that it is intended for export.

9. PMO-Section 6

A milk plant is receiving Grade “A” pasteurized condensed milk and/or milk product(s) for further processing and/or use as an ingredient in a Grade “A” milk and/or milk product. Is the Regulatory Agency required to collect samples of this Grade “A” pasteurized condensed milk and/or milk product(s), which they receive, in accordance with Section 6 of the PMO at the receiving milk plant?

No.

10. PMO-Section 7, Item 1r; and Appendix Q, Section 1r

a) Does the PMO require an AMI to divert a cow’s milk due to conductivity; color detected in the milk; or from a treated cow?

The PMO does not require milk to be diverted to the dump line for conductivity. However, conductivity could be used as a tool by the dairy producer in his or her management of their dairy herd and control of an AMI divert system. Color detection would be considered a means in which an AMI is using to detect “Abnormal Milk: Milk that is visibly changed in color, odor and/or texture”. “Abnormal Milk” and milk from treated cows are required to be diverted to the dump line in AMIs.

b) If the milk from any of these scenarios cited above is detected in one (1) or more quarters, may the AMI divert only the milk from the detected quarter(s) to the dump line and the milk from the other quarters to the good (saleable) milk line?

For color detection and treated cows, FDA’s position is that quarter milking and subsequent dumping of only the affected quarter’s milk is not permitted. All milk from all quarters from that dairy animal must be diverted to the dump line. The milk is considered abnormal and is not saleable.

11. PMO-Section 7, Item 8r

A dairy farm is proposing to have a potable water supply line pass through potable water stored in a properly constructed and enclosed storage tank that is used to exchange heat between recirculated glycol and Freon heating/cooling systems in which their lines also pass through the water in this storage tank. The water storage tank is considered a bubble in the potable water system. The purpose of passing the potable water supply line through the water in the storage tank is to pre-heat the potable water supply
prior to entering a hot water heater. Would this be considered a violation of the PMO?

No. The potable water supply line that passes through the water stored in the storage tank shall be corrosion resistant, continuous piping and without any joints or welds.

12. **PMO-Section 7, Item 8r; and Appendix G-Section I**

If a dairy farm’s individual water supply has an ultra-violet (UV) light system installed, how often is the individual water supply required to be sampled and tested in accordance with the PMO?

If the water supply sample is satisfactory, the individual water supply shall be sampled and tested at least every three (3) years as required for a dairy farm’s individual water supply.

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

Under the Environmental Protection Agency’s (EPA) Reduction of Lead in Drinking Water Act that became effective January 4, 2014 are backflow preventers, i.e. dual check valves with an intermediate atmospheric vent, that do not meet the new definition of lead free that are currently installed on water supply systems on dairy farms and at milk plants required to be replaced with ones that meet the new definition of lead free?

No. According to EPA’s “Frequently Asked Questions” related to this topic, the new lead free requirement does not require existing installed back flow preventers to be replaced until they are in need of repair or if the dairy producer or milk plant chooses to replace existing installed back flow preventers.

14. **PMO-Section 7, Items 8r and 7p; and Appendices D, Section IV and G, Section 1**

a) A dairy farm or milk plant is treating their individual well water supply with chlorine and they utilize a retention tank to achieve the appropriate contact time for the water with the chlorine. Is it required for the individual collecting the required samples to use the sample containers that contain sodium thiosulfate to inactivate the chlorine for testing purposes?

Yes. The presence of chlorine can affect the bacterial count so the individual needs to use a sample container with sodium thiosulfate added.

b) What about a dairy farm or milk plant that is treating their recirculated cooling water system (chill or sweet water) with chlorine in accordance with
the PMO recommended levels, is it required for the individual collecting the required samples to use the sample containers that contain sodium thiosulfate to inactivate the chlorine for testing purposes?

Yes.

15. **PMO-Section 7, Items 9r**

Are woven wire filter screens allowed to be used with air injectors located on milk pipelines or within a CIP pipeline system?

Yes. Air injectors, if provided, admit clean air into the pipeline during the washing process and are designed, installed and operated so that air is not admitted during milking. Air injectors shall be located in the milkhouse or room of equivalent cleanliness, or shall be provided with an appropriate filter and properly protected from contamination. Air injectors do not come in direct contact with milk and/or cleaning solutions and are not cleaned during the CIP cleaning process. They would be required to be manually cleaned when they become dirty. Because of this, FDA has taken the position that woven wire screens can be used in air injectors for the purpose of keeping insects out of the air injector or to help keep the filter material in place.

16. **PMO-Section 7, Item 14r; and Appendix Q, Item 14r**

The AMS Galaxy Astrea 20.20 AMI uses an air actuated valve located in the central unit to create a disconnect between the clean-in-place (CIP) system and the milking system. This CIP disconnect valve is a stand-alone valve that when open, creates a physical break between CIP and milk, and when closed, closes that loop.

The AMI process computer checks the CIP disconnect valve position at the end of each milking and before the next milking starts. If the CIP disconnect valve is not in the correct position an alarm is generated and a separation cleaning is conducted. This is a detailed attached procedure. It is not real time monitoring.

The position detection monitoring of this CIP disconnect valve is only conducted at the end of each milking and before the next milking starts. During the actual milking cycle, the CIP disconnect valve position is not monitored. If the CIP disconnect valve was moved during milking, nothing would happen until the cow is done milking. When the cow is done milking, the computer will check the position of the CIP disconnect valve and generate an alarm if it is in the wrong position.

**NOTE**: Milk is not pumped to the tank unless the CIP disconnect valve is in the correct position. If the CIP disconnect valve is in the wrong position, the
milk will be automatically sent to the drain. The system and program is designed to protect milk quality and safety, but also keep the cow healthy by letting her milk from start to finish without interruption.

Is this CIP disconnect valve required to have real-time monitoring so that if/when the CIP disconnect valve moves to the closed position during milking, creating a connection between CIP and milk, the AMI generates an alarm and immediately stops the milking system?

No. If the CIP disconnect valve operates as cited above as explained by AMS Galaxy it meets the requirements of the PMO. Therefore, there would not be a need to monitor the CIP disconnect valve position during milking.

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

A milk plant utilizes multiple floor foam sprayers located throughout the milk plant. At each of these locations a one (1) gallon container of sanitizer is being utilized, which is connected to the same common water line that runs throughout the milk plant. Would these floor foam sprayer installations be considered a violation of Item 7p-Water Supply?

No.

18. **PMO-Section 7, Items 9p and 11p; and FORM FDA 2399**

While conducting an evaluation of the milk tank trucks that were being unloaded during a milk plant inspection, it was repeatedly found that the dust cover hinge area was dirty and soiled. The dust cover included a rubber star vent that was difficult to remove. Does the construction of this dust cover comply with 3-A® Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, Number 05--?

Yes. This milk tank truck tanker design currently holds an unchallenged 3-A® Symbol. If the dust cover hinge area is found to be dirty and soiled during a milk plant inspection, this observation would be considered under Item 9p-Milk Plant Cleanliness of the PMO.

**NOTE:** If the dust cover hinge area is found to be dirty and soiled during a milk tank truck inspection this would be debited on FORM FDA 2399-Milk Tank Truck Inspection Report, Item 4-Exterior Condition of Tank.

19. **PMO-Section 7, Item 11p; and Appendix J**

a) An IMS listed single-service containers manufacturing plant sells containers to another facility that breaks down the bulk shipment of
containers into smaller lots. This repackaging facility then sells these smaller lots of containers to IMS listed milk plants. Is this repackaging facility also required to be IMS listed?

Yes.

b) Which facility is required to be identified by either the name and city of the plant/facility or assigned plant/facility code on the outer wrapping or carton as required under Item 20-Identification and Records, Section D of Appendix J-Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the PMO?

The identification of the manufacturing plant by both the name and city (to include State, Providence, Country, etc., if applicable) of the plant or assigned plant code shall appear on the outside of the outer wrap or carton, and it is recommended that the identification of the repackaging facility also appear on the outside of the outer wrap or carton.

c) Would the containers that this IMS Listed repackaging facility sells be required to be sampled and tested?

No. These containers are required to be sampled at the manufacturing plant.

20. PMO-Section 7, Item 11p; and Appendix S

A single-service container manufacturing facility is producing blow molded bottles that are palletized in multi-layered bundles utilizing a thick, cardboard tray liner that comes in contact with the food contact pouring surface of the blow molded bottles on one (1) or more layers of the bundles. These blow molded bottles are shipped to an aseptic milk plant where they are filled with aseptic milk or milk products. In accordance with the PMO, would it be acceptable to utilize single use cardboard dividers in contact with the food contact pouring surface of the blow molded bottles?

These containers would be regulated in accordance with the applicable provisions of 21 CFR Parts 110 and 113.

NOTE: Item 11p-Construction and Repair of Containers and Equipment of the PMO exempts all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged or retort processed after packaging from this Item and Appendix J of the PMO.
21. **PMO-Section 7, Item 11p; PROCEDURES-Section IV; and MMSR-Section A**

Is it acceptable for a milk plant that is listed on the IMS List for Product Code #9-Yogurt to utilize single-service glass containers that come from a non-IMS listed single-service containers manufacturer (domestic or foreign) to package their yogurt in if their sales are only intrastate?

*No. This IMS listed milk plant shall comply with all the regulations of the Grade “A” Milk Safety Program.*

22. **PMO-Section 7, Item 11p; PROCEDURES-Section IV; and MMSR-Section A**

If a milk plant that is IMS listed for Product Code #9-Yogurt has a documented wash and sanitize procedure for the one (1) time use of single-service glass containers, would this exempt the single-service glass container manufacturer from having to be IMS listed?

*No.*

23. **PMO-Section 7, Items 11p and 12p; and Appendix J, Sections B and C**

A milk plant is conducting the complete assemblage of gable top paper containers with the incorporation of a plastic pour spout/cap attachment and the subsequent filling of the gable top paper containers with milk and/or milk products. Is the milk plant required to sample these assembled single-service gable top paper containers in accordance with Item 12p-Cleaning and Sanitizing of Containers and Equipment and/or Section C-Bacterial Standards and Examination of Single-Service Containers and/or Closures, Appendix J of the PMO?

*No. The plastic pour spout/cap attachment is considered a “closure”; therefore, the required sampling of the plastic pour spout/cap attachment shall be conducted at the single-service closure manufacturing facility.*

24. **PMO-Section 7, Items 11p and 12p; Appendix J; and 2015 MMSR-Section I**

a) Of the four (4) IMS Listing criteria that are cited in Section E-Criteria for Listing Certified Single-Service Manufacturers on the IMS List, Appendix J of the PMO, which IMS Listing criteria allows for the sampling and testing of single-service containers and/or closures under the direction of the Regulatory Agency?
**NOTE:** Proposal 309 that was passed at the 2015 NCIMS Conference moved the Criteria for Listing Certified Single-Service Manufacturers on the IMS List 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 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).

**Criteria #3 and #4:** Both of these criteria would allow for the sampling and testing of single-service containers and/or closures under the direction of the Regulatory Agency as they only address single-service containers and closures manufacturers that operate as separate entities and do not include single-service containers and closures manufacturers that operate in conjunction with an IMS Listed milk plant.

**NOTE:** Item 12p of the PMO requires that if containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J, from each manufacturing line, as defined in Appendix J, 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, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the Milk Laboratory Control Agency specifically for the examinations required under Appendix J.

b) Are single-service containers and/or closures manufacturing plants that are IMS Listed as a separate entity and have been granted the authority for the sampling and testing of single-service containers and/or closures under the direction of the Regulatory Agency required to send laboratory test results to the Regulatory Agency? Or are they just required to maintain the records at the manufacturing plant as cited in Item 20.c?

The Regulatory Agency, at their discretion, may require IMS Listed single-service containers and/or closures manufacturing plants to send laboratory test results to them.

**NOTE:** In accordance with Item 20.c. of Appendix J of the PMO, the records of all required bacteriological tests of containers and closures shall be maintained at the plant of manufacture for two (2) years and results shall be in compliance with Section C, Appendix J of the PMO. Multi-plant corporations may have all of the required information at a central location as long as it can be transmitted to the site upon request.
25. **PMO-Section 7, Item 12p; and Appendix J, Sections B and C**

A single-service container manufacturer is producing a container that contains two (2) wells, where milk or milk product, i.e. yogurt, cottage cheese, etc. is to be packaged in either one (1) of the wells and a non-dairy product, i.e., fruit, nuts, granola, etc. is to be packaged in the other well. Is the testing laboratory required to test both wells or just the well that contains Grade “A” milk or milk products in accordance with Item 12p and Section C of Appendix J of the PMO?

The IMS listed single-service container contains two (2) wells and the single-service container manufacturer does not readily distinguish between which well is used for which product. Therefore, both wells need to be tested.

26. **PMO-Section 7, Items 12p and 16p(D); Appendix H, Section V**

If a milk plant utilizes an electronic data collection, storage and reporting system, are they required to provide the Regulatory Agency with an anomaly report that lists the specifics to the regulatory requirements cited in Section 7, Items 12p and 16p(D)-Pasteurization Records, Equipment Testing and Examination of the PMO?

Yes. The milk plant’s electronic data collection, storage and reporting system is required to provide an anomalies report indicating any system or communication failure that could have affected the validity of the required reports. This anomalies report shall be automatically attached to any report that may have been affected by the system anomaly. A separate error log or system log shall not suffice for meeting this requirement, since any anomaly requires an evaluation and investigation to correlate the anomaly. Default system logs that do not filter regulatory anomalies would not suffice, meaning that an anomalies report that lists the specifics for evaluating the status of the regulatory requirements cited in Items 12p and/or 16p(D) of the PMO are required to be furnished to the Regulatory Agency when requested.

27. **PMO-Sections 7, Item 16p**

Does the PMO allow for a High-Temperature-Short-Time (HTST) pasteurization system to have dual temperature cut-in/cut-out set points, one (1) for HTST pasteurized milk and/or milk products and one (1) for aseptic milk and/or milk products?

Dual temperature set points for pasteurized milk and/or milk products have been evaluated and found acceptable provided that the milk plant’s pasteurization system operator conducts Appendix I-Pasteurization
Equipment and Controls – Tests, II-Test Procedures, Test 10-Milk or Milk Product-Flow Controls and the Milk or Milk Product Temperature at Cut-In and Cut-Out, 10.1-HTST Pasteurization Systems of the PMO to confirm those cut-in/cut-out set points for the pasteurized milk and/or milk product being processed that day.

For aseptic milk and/or milk products, the milk plant’s process authority would be responsible to evaluate and accept the cut-in/cut-out set points and to confirm that the time and temperature specified in the filed scheduled process are being met when aseptic milk and/or milk products are being processed.

**NOTE:** The system shall be designed, constructed, maintained and operated to comply with **BOTH** the PMO pasteurization requirements **AND** all applicable Low Acid Canned Food (LACF) requirements within 21 CFR Parts 108 and 113. For technical reasons related to the required HTST times, temperatures and pressures, it may not be practical to design a pasteurization system that could meet **BOTH** the PMO requirements for a traditional HTST pasteurization system **AND** also comply with all applicable LACF requirements within 21 CFR Parts 108 and 113 for aseptic milk and/or milk products. This may be technically easier to accomplish if a Higher-Temperature–Shorter-Time (HHST) pasteurization system or an Ultrapasteurization (UP) system would be utilized.

28. **PMO-Section 7, Item 16p**

Has FDA determined honey to be a safe and suitable sweetener or flavoring ingredient that can be added to yogurt post-pasteurization?

Yes, provided the honey sweetener or flavoring ingredient when added has a water activity of 0.85 or less and the pasteurized yogurt maintains a pH of 4.6 or below during its declared shelf-life.

29. **PMO-Section 7, Item 16p**

In a milk plant that is IMS Listed for aseptically processed and packaged and UP milk and/or milk products, would it be acceptable to start the aseptic/UP processing system on a Grade “A” UP milk or milk product, then switch to a Grade “A” aseptic milk and/or milk product without performing a full clean-in-place (CIP) cleaning and sterilization of the aseptic/UP processing system?

**NOTE:** The aseptic/UP processing system operates the exact same for aseptic milk and/or milk products as it does for UP milk and/or milk products, with the exception of milk product storage vessel(s), filling and packaging.
The final approval of this processing system operation and the requirements for conducting such a process would be dependent on the milk plant’s Processing Authority’s written recommendations and guidance.

30. **PMO-Section 7, Item 16p**

Is a vacuum breaker and an automatic means of preventing negative pressure required if an evaporator is located downstream of the flow-diversion device (FDD) and the FDD is included as a part of a Magnetic Flow Meter Based Timing System that does not have a regenerative section(s)?

Yes. *When an evaporator or other vacuum equipment is located downstream from the holding tube and FDD, an effective vacuum breaker plus an automatic means of preventing negative pressure in the line between the FDD and the evaporator or other vacuum equipment is required. There currently are two (2) PMO acceptable means of preventing this negative pressure:*

- Installing an automatic shut-off valve that is located downstream from the vacuum breaker, which will automatically close when the FDD is in the diverted flow position.
- Having a dual stem FDD that is located downstream from the holding tube and the FDD’s leak detect line discharges to either the atmosphere or to the constant-level tank. The FDD’s leak detect line shall have a sight glass that is located in the vertical portion of the leak detect line.

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

The connection at the end of a holding tube to the FDD on a pasteurization system is a vertical piece of piping that changes pipe diameter from a three (3) inch holding tube to a two (2) inch FDD. This change in pipe diameter is made with a conical reducer connection. The vertical pipe provides the required continuous upward slope for the holding tube; however, would there be an issue that the reduction in pipe diameter is conical rather than sloped only on one (1) side to avoid the possibility of air being trapped and causing an issue with the holding time?

*This should not be an issue as the installation is meeting the requirement of Item 16p(B)-High-Temperature-Short-Time (HTST) Continuous-Flow Pasteurization of the PMO as having a continuous upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch per foot).*
32. **PMO-Section 7, Item 16p(B)**

a) Item 16p(B), Administrative Procedures 2.b-FDDs of the PMO cites specifications with which all FDDs used in continuous-flow pasteurization systems shall comply with and also makes the statement or equally satisfactory specifications. Are there any other alternative means, i.e., equipment changes, procedural operations, etc. that would be acceptable to FDA that would allow the pasteurization system as described in b) below to go back into production after diverted flow without a thorough pasteurization system cleaning following the flow diversion?

*At the current time we are not aware of any alternative to Item 16p(B), Administrative Procedures 2.b.(8) of the PMO that has been identified and been demonstrated to be equally satisfactory by the Regulatory Agency in consultation with FDA.*

b) Item 16p(B), Administrative Procedures 2.b-FDDs (8) of the PMO requires that in the case of continuous-flow pasteurization systems, which have the FDD located downstream from the regenerator and/or cooler and are inter-wired or computer controlled to thoroughly clean the pasteurization system, including the divert pipeline before the re-starting of production. A cooling section, which is not self-draining, may be present in the divert pipeline. The final cooling section is cleaned during a full cleaning at the end of an extended run, but is not cleaned after a pasteurization system divert that occurs during the extended run. Would this be considered a violation of Item 16p(B) of the PMO?

*Yes.*

c) In the pasteurization system described in b) above, may the recirculation of 82°C (180°F) water for sixty (60) seconds be substituted for the required full pasteurization system cleaning?

*No.*

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

Are metal air-line fittings, as shown below, to which plastic air tubes are attached, by pushing a plastic air supply tube onto a metal fitting and securing the air tube to the fitting using threaded nuts, acceptable for use as air-line connections for air supply lines to a FDD in a continuous-flow pasteurization system?
34. **PMO-Section 7, Item 16p(B); and Appendix I**

Item 16p(B), Administrative Procedures 2.b-FDDs (7) of the PMO requires that the FDD be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this Ordinance. The location of the temperature sensing element from the vacuum chamber, which is used to verify the temperature at the vacuum chamber during thermal-limit-controller sequence logic is critical. This temperature sensing element location is vital to accurately perform Appendix I, II-Test Procedures, Test 12-Thermal-Limit-Controller For Control - Sequence Logic, 12.2-Pasteurization - Direct Heating of the PMO. Has FDA evaluated the location of the thermometer utilized in the new Tetra Pak vacuum chamber, which has a conical top with the vacuum going down a tube in the middle of the vacuum chamber, for use in HHST and UP continuous-flow pasteurization systems?

Yes. This new style Tetra Pak vacuum chamber has been inspected during FDA check ratings and has been determined to be in compliance with Item 16p(B) of the PMO. The location of the temperature sensing element has also been determined to be appropriate when performing Test 12.2 regarding thermal-limit-controller sequence logic.

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

a) A milk plant is making a Grade “A” non-standardized milk product. The Grade “A” milk product does not meet a Standard of Identity (SOI) for a milk product and is typically not a cultured product. The milk plant would like to hot-fill this Grade “A” milk product as they would culture the Grade “A” milk product in order to hot fill as addressed in Item 17p-Cooling of Milk and Milk Products, as cited within exception “1. Those to be cultured” of the PMO. Would exception “1. Those to be cultured” allow for this Grade “A” milk product to be hot filled?
No. Refer to the answer provided for b) below for additional information.

b) Is the cooling exception language cited in Item 17p of the PMO specific to only 2-Cultured Sour Cream, 3-Acidified Sour Cream, 4-All Yogurt Products, 5-Cultured Buttermilk and 6-Cultured Cottage Cheese or does “1. Those to be cultured” include all non-standardized milk products that could be cultured.

“1. Those to be cultured” covers all cultured products that are held at higher temperatures during their culturing and incubation period. This Item does not cover the temperature that cultured products shall be held at following incubation, e.g. prior to filling/packaging and during the packaging process. The only cultured products that are allowed to be above the 7ºC (45ºF) following incubation and prior to filling/packaging are those listed under 2-6 as cited above. These specific exceptions were all based on scientific data provided by industry to FDA following specific proposals submitted to the NCIMS for consideration.

For this milk plant to “hot-fill” this new Grade “A” non-standardized cultured milk product, they would be required to first provide the scientific data (pathogenic growth studies, package sizes, etc.) to support an exception to the 7ºC (45ºF) cooling requirement to FDA for their review and acceptance. It was also mention that this Grade “A” milk product currently is not cultured. Therefore, this Grade “A” milk product shall meet the 7ºC (45ºF) PMO requirement at all times.

36. PMO-Appendix B, Section VI

Appendix B-Milk Sampling, Hauling and Transportation, VI-Milk Tank Truck Permitting and Inspection, 3.b.(3) of the PMO states that it is allowable to pick up multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each day’s used. Refer to the two (2) scenarios described below. Would either of these two (2) scenarios be considered a violation of the PMO?

Scenario #1:

- Hauler delivers a load at 10:00 AM.
- Milk tank is washed and sanitized at 11:30 AM and a wash tag is affixed to the milk tank truck.
- Hauler leaves the milk plant and picks up multiple producers over the next several hours and delivers back into the milk plant at 4:00 PM. Hauler unloads, but doesn’t wash and sanitize the milk tank; however, the hose and pump are washed and sanitized.
- Hauler leaves the milk plant at 5 PM with the milk tank not washed and picks up milk from several more producers that evening.
Hauler stops picking up milk at 8 PM and parks the milk tank truck for the night.
The hauler then delivers the load back into the milk plant at 7:00 AM the next morning, which is 19.5 hours since the last wash/sanitization of the milk tank.
After unloading, the milk tank truck is washed and sanitized and a wash tag is affixed to the milk tank truck prior to leaving the milk plant.

No.

Scenario #2:

Hauler delivers a load at 10:00 AM.
Milk tank is washed and sanitized at 11:30 AM and a wash tag is affixed to the milk tank truck.
Hauler leaves the milk plant and picks up multiple producers over the next several hours and delivers back into the milk plant at 4:00 PM. Hauler unloads, but doesn’t wash and sanitize the milk tank; however, the hose and pump are washed and sanitized.
Hauler leaves the milk plant at 5 PM with the milk tank not washed and picks up milk from several more producers that evening.
Hauler stops picking up milk at 8 PM and parks the milk tank truck for the night.
At 7 AM the next morning, after washing and sanitizing the pump and hose, the hauler picks up a couple producers to finish the load.
The hauler then delivers the load back into the milk plant at 9:00 AM the next morning, which is 21.5 hours since the last wash/sanitization of the milk tank.
After unloading, the milk tank truck is washed and sanitized and a wash tag is affixed to the milk tank truck prior to leaving the milk plant.

Yes. This pickup practice would not be considered as complying with the allowance for picking up multiple loads continuously within a twenty-four (24) hour period as cited within Appendix B of the PMO.

37. PMO-Appendix I, Section II

When conducting Test 11.2A-Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flow Meter Based Timing System – Pasteurization Holding Time of the PMO and six (6) successive salt test results are not within .5 seconds of each other, what should be done?

If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified
industry personnel, acceptable to the Regulatory Agency, in compliance
with Item 16p.(D); or on an emergency basis, an industry temporary testing
and sealing program, authorized by the Regulatory Agency, in compliance
with Item 16p.(D).

38. **PMO-Appendix J, Sections A and C**

a) Are paper mills that supply paper stock to IMS Listed single-service
containers and/or closures manufacturers for the manufacture of single-
service containers and/or closures for milk and/or milk products required to
be IMS Listed?

No.

b) Are paper mills that supply paper stock to IMS Listed single-service
containers and/or closures manufacturers for the manufacture of single-
service containers and/or closures for milk and/or milk products required to
have their paper stock tested? If so, what testing standard will they be
required to comply with?

Yes. Paper stock shall meet the bacteriological standard of not more than
two hundred fifty (250) colonies per gram as determined by the
disintegration test. The paper stock supplier shall certify that their paper
stock was manufactured in compliance with this Standard. This applies only
to the paper stock prior to lamination.

c) Is the TAPPI Test Method T499 om-14 an acceptable test for the testing
of paper stock for determining that the paper stock complies with the PMO
bacteriological standard of less than two hundred fifty (250) colonies per
gram?

No. The TAPPI Test Method T449 om-14 is not currently recognized by the
NCIMS and is not listed in the 17th Edition of Standard Methods for the
Examination of Milk Products (SMEDP).

d) Is this required testing of the paper stock required to be conducted in an
IMS accredited laboratory?

No.

e) What is the required frequency of testing paper stock that is supplied to
an IMS Listed single-service containers and/or closures manufacturers for
the manufacture of single-service containers and/or closures for milk and/or
milk products?
With each shipment of paper stock that a paper mill supplies to an IMS Listed single-service containers and/or closures manufacturer, they will need to certify that the paper stock complies with Appendix J, Section C of the PMO. Therefore, a representative sample of the paper stock in each shipment will be required to have been tested in order to make such a certification.

f) May paper mills that are supplying paper stock to IMS Listed single-service containers and/or closures manufacturers conduct the required testing cited in b) and e) above in-house?

The Regulatory Agency, at their discretion, may accept in-house testing.

39. **PMO-Appendix J, Section B**

Within Appendix J of the PMO, is “Olefin Polymer” (HDPE) resin allowed to be used in the production of single-service containers (blow mold gallon jugs)?

Yes. The single-service container fabrication plant shall have on file information from the supplier of the “Olefin Polymer” (HDPE) resin (manufacturer or distributor) indicating that it complies with the requirements of 21 CFR Parts 174-178, specifically Section 177.1520 (Olefin polymers) paragraph (c) 2.2.

40. **PMO-Appendix J, Sections B and D**

Is it acceptable to add calcium carbonate polyolefin concentrate at usage levels of up to 50% by weight of concentrate to resin that is being used to produce IMS Listed single-service containers, closures and/or articles?

Yes. The single-service containers and/or closures manufacturing plant shall have on file information from the supplier of the calcium carbonate polyolefin concentrate indicating that the material(s) comply with the requirements of 21 CFR Parts 174-178. The supplier of the calcium carbonate polyolefin concentrate may also provide a certification letter (Food Contact Substance (FCS) Notification (FCN)) stating the calcium carbonate polyolefin concentrate complies with the FDA requirements.

**NOTE:** A FCN is an effective premarket notification for FCS that has been demonstrated to be safe for their intended use. The FCN shall include the FCS, the notifier, the manufacturer of the FCS, the intended use, the limitations on the conditions of use for the FCS and its specifications, the effective date, and its environmental decision. Under section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (h)(2)(C)) a FCN is only effective for the manufacturer or supplier identified in the FCN.
Companies that market a FCS based on an effective FCN must be able to demonstrate that the FCN is effective for their FCS. All persons who purchase a FCS manufactured or supplied by a manufacturer or supplier identified in an effective FCN may rely on that FCN to legally market or use the FCS for the use that is the subject of the FCN, consistent with any limitations in that FCN.

41. **PMO-Appendix J, Section D, Item 7**

   a) Does the recirculated cooling media used in plastic film cooling rollers/drums or used in the head of blow mold machines required to be protected and tested?

   *Not unless the recirculated cooling media is also used in another application which does require protection and testing.*

   b) Is it required that the recirculated cooling media used in plastic film cooling rollers/drums or used in the heads of blow machines be USP Grade, Food Grade or generally-recognized-as-safe (GRAS)?

   *No.*

42. **PMO-Appendix J, Section D, Item 17**

   Are inks that are applied to single-service containers and/or closures required to be food grade?

   *Appendix J, Section D-Fabrication Plant Standards, Item 17-Waxes, Adhesives, Sealants, Coatings and Inks c. of the PMO require that inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surfaces shall comply with the requirements of 21 CFR Parts 174-178.*

   Inks are not specifically cited in the CFR. Therefore, one (1) of the following measures shall be addressed to comply with the PMO requirement cited above:

   - **A safety verification protocol shall be instituted for inks that are applied to single-service containers and/or closures. A means to verify safety is to provide assurance that there is not any visible transference of any of the components of the ink to product contact surfaces either through the package (bleed through from the outside to the inside through the container wall) or from the outside of one (1) container to the inside of another (such as in the case of “nested” containers). This may be accomplished by requiring the ink manufacturer to provide documentation from a migration challenge study where a barrier layer**
may or may not be applied over the inks to protect the milk product contact surface from ink transference.

**NOTE:** Normally the cause of the visible transference of any of the components of the ink is an easily solvable problem regarding application, drying or curing of the ink.

- The single-service containers and/or closures manufacturing plant shall have on file information from the supplier of the ink indicating that the ink complies with the requirements of 21 CFR Parts 174-178. The supplier of the ink may also provide a certification letter (Food Contact Substance (FCS) Notification (FCN)) stating the ink material complies with 21 CFR – Part 174.

**NOTE:** A FCN is an effective premarket notification for FCS that has been demonstrated to be safe for their intended use. The FCN shall include the FCS, the notifier, the manufacturer of the FCS, the intended use, the limitations on the conditions of use for the FCS and its specifications, the effective date, and its environmental decision. Under section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (h)(2)(C)) a FCN is only effective for the manufacturer or supplier identified in the FCN. Persons who market a FCS based on an effective FCN must be able to demonstrate that the FCN is effective for their FCS. All persons who purchase a FCS manufactured or supplied by a manufacturer or supplied by a manufacturer or supplier identified in an effective FCN may rely on the FCN to legally market or use the FCS for the use that is the subject of the FCN, consistent with any limitations in that FCN.

43. **PMO-Appendix N, Section II**

If a Regulatory Agency is utilizing the 10% sampling option cited in Appendix N, II-Regulatory Agency Responsibilities, Monitoring and Surveillance of the PMO during quarterly milk plant inspections for monitoring the milk plant’s drug testing surveillance program activities, after the Regulatory Agency has collected the samples can the Regulatory Agency have the milk plant conduct the analysis of the samples collected from the bulk milk pickup tankers and/or raw milk supplies that have not been transported in bulk milk pickup tankers?

No. This is a designated Regulatory Agency responsibility as required in Appendix N of the PMO that is used to monitor the milk plant’s drug testing surveillance program activities. This Regulatory Agency analysis to monitor/audit the milk plant’s drug testing surveillance program activities shall be performed in an Official Laboratory using the same test as being used by the milk plant.
While conducting the Appendix N review of a bulk tank unit (BTU) for determining compliance with the requirement of Appendix N during a rating, the Sanitation Rating Officer (SRO) identified a single milk producer as having a load of raw milk rejected due to a growth inhibitor being found in their raw milk. According to the inspection reports a note was made and a letter was sent; however, the milk producer’s permit was not suspended for this action nor was the permit properly reinstated following a negative sample prior to resuming milk shipments. Also, the Regulatory Agency did not conduct an investigation/inspection to determine the cause of the residue and actions to be taken to prevent future violations from occurring. What actions should be taken against this milk producer, BTU and Regulatory Agency?

This is an Appendix N violation and if determined to be significant the entire BTU should be withdrawn from the IMS List because of noncompliance with Appendix N.

From the information provided, it appears that the SRO has determined that this is not a common practice and actually is an isolated occurrence within this BTU and State; therefore, the SRO has determined to not withdraw the BTU from the IMS List.

However, this milk producer should be debited on the Enforcement Rating on FORM FDA 2359j-Section B (Page 2) under Part I, Item 10-Permit issuance, suspension, revocation, reinstatement, hearings and/or court actions taken as required utilizing Section D-Dairy Farm Enforcement Action and Records Evaluations (Page 4) of FORM FDA 2359j. On Section D of FORM FDA 2359j under Dairy Farm Enforcement Procedures this milk producer should be debited under Category II-Permit Suspension for not having their permit suspended as required and also under Category IV-Permit Reinstatement because they were never cleared by having a negative milk sample for drug residues as required following a permit suspension for a drug residue within Appendix N of the PMO.

The Regulatory Agency needs to make sure that this Appendix N violation is properly recorded and noted on this milk producer’s official Regulatory Agency records/files and that any subsequent enforcement procedures related to any additional Appendix N violations include this occurrence. Also, the Regulatory Agency needs to review their violative Appendix N policies and procedures to determine what went wrong and correct them to make sure that this does not happen again.
Finally, this occurrence should be cited within the State’s next triennial Regulatory/Rating Agency Program Evaluation as not following the requirement of Appendix N of the PMO.

45. **PMO-Appendix N; Evaluation of Milk Laboratories (EML)-Section 1; and FDA/NCIMS 2400 Forms**

The following questions relate to Question #80 from M-I-15-3:

a) May an Appendix N testing laboratory switch to a different testing method reader than what was used for the presumptive milk tank truck testing (EZ reader to ROSA reader or vice-a-versa) when conducting the Appendix N milk tank truck confirmation process?

Yes. If the laboratory uses a different reader than what was used to get the presumptive positive when conducting the milk tank truck confirmation and the reader fails, the laboratory may switch back to the original reader. The reader’s check set and controls must be re-run before using the original reader. As long as the original reader can be shown to be functioning properly and correct results are obtained from the reader check set and controls, confirmation testing may be concluded.

**NOTE:** A different reader may not be used between the initial positive and the completion of the presumptive (duplicate) testing for the same reason that the same analyst is required to complete the presumptive testing.

b) If an Appendix N testing laboratory has access to both an EZ reader and a ROSA reader, and the EZ reader fails for some reason during a milk tank truck confirmation is that Appendix N testing laboratory permitted to complete the milk tank truck confirmation on the ROSA reader?

As a normal course of action, if the initial milk tank truck load presumptive positive was started on one (1) reader it has to be completed (confirmation) with that reader. Allowances are always provided and made if something fails. If a reader would fail, not if the Appendix N testing laboratory simply wishes to switch readers, then they could, as long as it is available and working, use another reader. It would be up to the Regulatory Agency to determine if this is the case. The Laboratory Proficiency Evaluation Team (LPET) would expect to see some documentation that shows the reader failed and that the Regulatory Agency authorized the change. If not, then the Appendix N testing laboratory would be held to task and the testing results would not be valid.

c) If so, at what point would they need to restart the milk tank truck confirmation testing?
It is not possible to consider all the possible scenarios that might occur; however, given the question it is most likely that they would need to repeat the initial test and complete the process with the reader that is working. Because of a reader failing, LPET would question results obtained prior to when the reader failed.

**NOTE:** Appendix N testing laboratories shall not change readers for any reason unless the LEO or other qualified Regulatory Agency authority is notified and grants the laboratory permission. The integrity of the test results are at stake when a reader fails for any reason. The LEO or other qualified Regulatory Agency authority shall provide the proper course of action to the laboratory if the reader fails for any reason.

46. **PROCEDURES-Section IV**

May a check rating be conducted on an IMS Listed BTU that has an Enforcement Rating of less than ninety (90) on its most current rating? The check rating would be conducted within the six (6) month period between the rating and the re-rating.

Yes. This answer would also apply to IMS Listed milk plants, receiving stations and transfer stations with an Enforcement Rating of less than ninety (90).

47. **PROCEDURES-Sections IV and V**

An IMS Listed shipper (BTU) was removed from the IMS List following a Rating with a Sanitation Compliance Rating of 87 and an Enforcement Rating of 87, with an authorized representative of the BTU not signing the Permission to Publish. The re-rating was conducted following the Rating Agency receiving written notification from an authorized representative of the BTU stating that the BTU is in substantial compliance. The re-rating was conducted with a Sanitation Compliance Rating of 94 and an Enforcement Rating of 85. The Rating Agency received a signed Permission to Publish from an authorized representative of the BTU. Is this re-rating valid and can the BTU be listed on the IMS List with consecutive ratings that have an Enforcement Rating of less than 90?

Yes. The 1st rating conducted of this BTU resulted in a withdrawal of the BTU’s listing because of a Sanitation Compliance Rating of 87. Therefore, this 1st rating would not have been submitted for publication on the IMS List without a signed Permission to Publish. The protocol for the re-rating would follow the procedures for requesting a re-rating as cited in Section V-Qualifications and Certifications, J-Individual Ratings, 2. of the Procedures. Following this protocol, the re-rating resulted in a Sanitation Compliance Rating of 94 and an Enforcement Rating of 85; therefore,
resulting in a listing with a six (6) month expiration date from the date of this re-rating on the IMS List, with a signed Permission to Publish. The next rating shall follow the protocol cited in Section V-Qualifications and Certifications, J-Individual Ratings, 4. and Section IV-Oversight and Responsibilities, B-State and TPC Responsibilities, 1-Ratings and Single-Service Containers and Closures Manufacturer Listings, e. of the Procedures.

48. PROCEDURES-Sections III and IV; and MMSR-Section A

May an FDA certified SRO routinely collect official regulatory samples from a dairy farm’s and/or a milk plant’s water supply and/or recirculated cooling water system(s); and/or Section 6 raw milk samples from a dairy farm; and/or Section 6 finished milk and/or milk product samples from a milk plant, respectively, that the SRO rates for inclusion on the IMS List?

No.