HHS:PHS:FDA:CFSAN:OFS:DDFPS:DEB:MST

5100 Paint Branch Parkway
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M-I-08-7

May 7, 2008

TO: All Regional Food and Drug Directors

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Questions And Answers From The Southeast Regional Milk Seminar And FDA Training Courses Held In FY'07

Following are questions and answers from the Southeast Regional Milk Seminar and FDA training courses held in FY'07.

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

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

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

/ss/

CAPT Robert F. Hennes, RS, MPH

QUESTIONS AND ANSWERS
FROM THE
SOUTHEAST REGION MILK SEMINAR-NASHVILLE, TN
(NOVEMBER 6-9, 2007)
AND
FDA TRAINING COURSES HELD IN FY 2007

1. **PMO-Section 1**

   May hydrogen peroxide (H_2O_2) be added to liquid whey to bleach (lighten the color) of the whey prior to drying?

   Yes. CFR Section 184.1366 provides specific limitations for the use of H_2O_2 as a bleaching agent for colored (annatto) cheese whey. The maximum treatment level in food (percent) for this application is 0.05%.

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

   FDA's review of the submitted formulation for the slurry used to make Nestlé's Chocolate Reduced Fat Milk, which contains 3.0% water by weight in the finished product. This water is used to liquefy the dry ingredients into a slurry. The purpose of this review was to determine if the amount of water utilized in the formulation of the chocolate slurry was excessive.

   Upon FDA's review of the submitted formulation, it has been determined that the relative volume of water used is similar to the volumes of water used in cocoa slurry formulations that have been previously reviewed and accepted.

   Therefore, we would not object to the volume of water, as stated in the submitted formulation (3% by weight in the finished product), being used to produce Chocolate Reduced Fat Milk.

   This determination does not apply to any other product, recipe, or formulation currently available or proposed by Nestlé.

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

   Is Skyr (pronounced "skeer") considered a Grade "A" milk or milk product or is it a cheese?

   It is considered a fresh cheese and would not be considered a Grade "A" milk or milk product.

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

What is Laban and is it considered a Grade “A” milk product?

Laban is also known as Laben, Lebben, Leben, Lben and Liban.

Today, the product has only lactic acid fermentation, although historically it had a slight alcoholic fermentation as well.

According to the specifications given by the firm manufacturing the product, it would fall into the alternate culture yoghurt standard found in the Fermented Milk, Section 243-2003 of the Codex Standard. The manufacturing process does not remove whey, one of the hallmarks of cheese making, thus it is not considered a cheese product.

Based on the ingredient information provided, the indication is that the product is similar to a yogurt as defined within 21 CFR 131.200. This product appears to be a type of yogurt and thus a Grade “A” milk product.

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

Where are the legal butterfat standards for 1%, 2%, 3% and all milks located?

There are no legal definitions for differing percentages of milk. However, the following regulatory history of milk may help to answer this question.

The standard of identity for milk is located in 21 CFR 131.110. This standard provides for a minimum level of milkfat (3.25%). Prior to 1996, FDA had several standards of identity for lower fat milks in Part 131. However, in 1996, FDA published a final rule that removed the standards of identity for lower fat milks. After these standards were revoked, lower fat milks were covered by the general standard in 21 CFR 130.10. This general standard allowed for the naming of a food using a nutrient content claim (i.e., “low fat”) and a standardized term (i.e., “milk”). In other words, “130.10 foods” as they are called, are standardized foods, which under certain criteria can make a nutrient content claim such as “low fat” (21 CFR 101.62). Even though labels of these foods are not required to list the amount of milkfat in the name of the food, FDA has not objected to labels that bear the percent of milkfat in the food (i.e., “contains 2% milkfat”). A food stating the percent of milkfat on the label must not be false or misleading and the declaration must meet the claim requirements under 21 CFR 101.13 (i).

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

Is Dry Cream required to be labeled as Grade "A"?

No. Dry cream may be Grade "A" if the plant wishes to label and sell it as such and then it must be made from Grade "A" milk and/or milk products from an IMS Listed Source and the milk plant must be IMS Listed. If it is used as an ingredient in a Grade "A" milk or milk product then it must be a Grade "A" product and be made from Grade "A" milk and/or milk products from an IMS Listed Source and the milk plant must be IMS Listed. Therefore, if they do not plan to label it as Grade "A" or offer or utilize it as an ingredient in a Grade "A" milk or milk product it would not be required to be Grade "A".

NOTE: *21 CFR 131.149-Dry Cream, provides for Emulsifiers, Stabilizers, Anti-caking Agents, Antioxidants and Nutritive Carbohydrate Sweeteners, Flavoring Ingredients without color (can be fruit and fruit juice), etc. in the optional ingredient statement.*

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

What is ultrafiltration (UF) and what Grade "A" milk or milk products can ultrafiltered product(s) be added to?

Ultrafiltration (UF)*: It involves the separation of components from a fluid stream based primarily on size using a membrane under pressure to serve as a selective barrier. The pressure gradient across the membrane forces solute and smaller molecules through the pores in the membrane, while the larger molecules/particles are retained. Thus, one feed stream is split into two product streams. The retained stream (referred to as the "retentate" or "concentrate") will be enriched in the retained larger macromolecules, 10-200 Å (about 0.001-0.02 µm) in size. The fraction going through the membrane (referred to as the "permeate") will be depleted of the macromolecules. The retentate will also contain some of the permeate solutes. Ultrafiltration can be looked at as a method for simultaneously purifying, concentrating, and fractionating macromolecules or fine colloidal suspensions.*

The usable range for ultrafiltration overlaps the usable range for reverse osmosis (RO) when dealing with small particles and overlaps the usable range for microfiltration when dealing with larger particles. The distinction between these three processes is somewhat arbitrary and has evolved with usage and convention. However, with ultrafiltration membranes, it is customary to refer to the "molecular weight cut off" (MWCO) instead of the particle size. Using this terminology, ultrafiltration covers particles and molecules that range from about 1000 in molecular weight to about 500,000 Daltons.

In common dairy applications using ultrafiltration, protein is concentrated in the retentate. Skim milk retentate can be concentrated to a maximum of

about 42% solids. Cheese whey with an initial protein content of 10-12% (dry matter basis) can be concentrated to produce 35%, 50% and 80% protein products. (Source: "Ultrafiltration and Microfiltration Handbook", Munir Cheryan, 1998)

Labeling/Usage: *(Refer to M-I-03-13 (Question 2)-10/3/2003 for additional information.)*

Milk that has undergone ultrafiltration is distinctly different from the starting ingredient milk in that ultrafiltration typically results in the loss of some of the water, lactose, minerals and water-soluble vitamins that are present in milk. The resulting ultra-filtered milk; therefore, is distinctly different from the starting ingredient milk and cannot be called simply "milk". Pending comments on an upcoming proposal related to the use of UF milk in standardized cheeses, FDA/ONLDS has tentatively determined that the appropriate name for UF milk is "ultra-filtered milk".

Ultra-filtered milk is being proposed by dairy processors to be added to increase the percentage of protein in fluid milk as a method of fortifying proteins in fluid milk. This allows the flavor and mouth feel enhancing properties of milk proteins to be achieved naturally as opposed to adding non-fat dry milk (NFDM), which often leaves a cooked flavor in the fluid milk as well as increased sweetness from the excess lactose in NFDM. The resulting non-fat or lowfat varieties have the flavor and mouth feel of whole milk product without the higher fat.

FDA regulation 21 CFR 101.4 requires ingredients of a food to be declared by their specific common or usual name in the ingredient statement of the finished food. This regulation permits the use of a collective term in the case of a few specific ingredients. For example, skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk" (see section 101.4(b)(3)). This specific provision, however, does not extend to include ultra-filtered milk (whole, lowfat, reduced fat, skim). Therefore, when used in foods, ultra-filtered milk must be declared by its specific common or usual name, i.e., "ultra-filtered milk".

The standard of identity for milk permits the addition of certain specific milk-derived ingredients for the purpose of adjusting the milk solids not fat and milk fat content of the milk. However, the standard for milk does not encompass a food that is prepared by separating the non-fat portion of milk into its various components and by subsequently remixing these separated components to create a specific profile. Similarly, the separation and subsequent remixing are not modifications to prevent nutritional inferiority and are not covered under the provisions that permit minimal deviations in the ingredient and non-ingredient provisions of the standard to permit the modified food to have similar performance characteristics to the standardized food. Therefore, a product which is prepared by passing the

milk through various filtration processes, including ultrafiltration, and then remixing the separated components, does not comply with either the standard for milk in 21 CFR 131.110 or the minimal modifications provided under the general standard in 21 CFR 130.10.

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

The following questions address a recently introduced milk product into the market place. The product is "Fat Free Milk with Plant Sterols, Vitamins A and D Added". Their intent is to add plant sterols (0.4 g per 8 fl. oz. serving) to non-fat fluid milk for the purpose of making cholesterol reducing claims. CFR 101.83 authorizes reduced risk of heart disease claims, as specified, for plant sterol esters added to spreads and dressings for salads. There is no mention of fluid milk.

In a February 14, 2003 letter from the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) it says FDA would exercise regulatory enforcement discretion on the addition of plant sterols to other foods pending publication of the final rule. Based on this letter, petitions were submitted to FDA regarding GRAS status of plant sterols added to non-carbonated drinks, including milk.

a) Regarding the ingredient, "Plant Sterols", and the following statements: "Helps Reduce Cholesterol", and "Promotes A Healthy Heart!" is it permissible to add Sterols to milk and still label it as “milk”?

The standard of identity for milk in 21 Code of Federal Regulations (CFR) 131.110 does not provide for the use of plant sterols. However, as described in the response to question b) below, plant sterols can be added to milk labeled in accordance with 21 CFR 130.10.

b) Would you please take a look at their product name and associated health claims on the label and let us know if they are acceptable?

"Fat Free Milk with Plant Sterols, Vitamins A and D Added";
"Helps Reduce Cholesterol"; and "Promotes A Healthy Heart!"

CFSAN has taken the position in the past that when the term “with plant sterols” is used in the label of a food in a nutritive context, the term “with” is synonymous with a “contains” claim, which is a defined nutrient content claim subject to FDA regulation (21 CFR 101.54). The definition of “contains” is dependent on the existence of a Reference Daily Intake (RDI) or Daily Reference Value (DRV) for the substance that is the subject of the claim. There is not a RDI or DRV for plant sterols. Consequently, “with Plant Sterols” is not a nutrient content claim that may be used in the statement of identity of a standardized food modified and named under 21 CFR 130.10.

However, 101.13(i)(3) provides for a nutrient content claim for a substance that does not have an RDI or DRV. We would not object to a statement of identity that incorporates a claim that is consistent with 101.13(i)(3) (i.e., "fat free milk with 0.4 g of plant sterols, vitamins A and D added".)

We have no objection to the health claim.

c) Are the health claims authorized under CFR 101.83 allowed for only the esterified form of plant sterols added to only the specific foods listed in the regulation, or does FDA still not object to the addition to other foods, including nonfat milk at a reduced level of 400 mg phytosterols per reference amount?

The enforcement discretion letter of 2/14/03 that expanded upon 21 CFR 101.83 is still current. This letter provides for free forms of plant sterols and stanols and mixtures of sterols and stanols.

(Refer to: http://www.cfsan.fda.gov/~dms/ds-ltr30.html).

d) Is the health claim limited to reducing the risk of coronary heart disease as specified in CFR 101.83, or can health claims concerning the reduction of cholesterol be made?

Information about plant sterols affect on serum cholesterol is optional information that can be included in the phytosterol/(CHD) health claim.

(Refer to: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=77ed7da9463357d9a09892213e5c74db&rgn=div8&view=text&node=21:2.0.1.1.2.5.1.14&idno=21)

e) The Company is claiming that the plant sterols are not ingredients in the milk, that this is a two (2) component food, milk and the plant sterol. It is similar to Fat Free Plus, which has skim milk and other ingredients, these other ingredients were also not listed as optional ingredients in the standard of identity. If they call it "milk" does it not still have to conform to the Standard of Identity for "Milk"?

We have given the opinion that in order to use the standardized term "milk" a food needs to comply with either the original standard of identity for milk as described in 21 CFR 131.110 or the original standard as modified by 21 CFR 130.10. A 21 CFR 130.10 milk product must comply with the applicable parts of 21 CFR 131.110 and 130.10 and is named using the standardized term, "milk", and one or more nutrient content claims (i.e., as previously stated "fat free milk with ___ g plant sterols").

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

Since the release of the response by ONPLDS to the questions cited in 8. above, some members of industry have interpreted this to mean that any "functional ingredient" may be added to milk, provided it is labeled in the manner that was described (i.e., "milk with ___ g of _____"). Is such an interpretation accurate? Would ONPLDS please clarify the intended scope of their response on the added plant sterol issue addressed in 8. above.?

It is not an accurate interpretation to extend our answers to the specific questions noted in 8. above on "Fat Free Milk with Plant Sterols" to mean that any "functional ingredient" may be added to milk and the finished food called "milk". "Milk" and "fat free milk" are governed by different regulations. As noted in our response in 8. above, "fat free milk" is governed under 21 CFR 130.10 and is a modified standardized food based on the core standard for "milk" as regulated in 21 CFR 131.110. As such, there are additional provisions that must be considered in determining whether "fat free milk with ___ g plant sterols" is properly labeled.

Further, we have specifically considered the use of plant sterols in beverages, including milk, and the appropriateness of a health claim and have decided to exercise enforcement discretion and permit the claim under specified conditions. Thus, there are several factors that were considered in developing the answers provided in 8. above. Consequently, we would discourage generalizing our answers in 8. above to other products.

10. **PMO-Sections 1, 4 and 11; and Appendix L**

a) May a nonfat plain yogurt have 1% sodium caseinate added to it as a stabilizer and still be labeled as “nonfat yogurt”?

In response to the original inquiry, the standard of identity for nonfat yogurt (21 CFR 131.206) provides for the use of "stabilizers" as optional ingredients. Sodium caseinate can function as a stabilizer and; therefore, may be used as a stabilizer in nonfat yogurt within good manufacturing practice and at the amount necessary to accomplish the intended technical effect. The use of sodium caseinate for a purpose other than as a stabilizer (for example, to increase the protein levels) is not permitted by the standard.

b) Is the sodium caseinate, used as a stabilizer in nonfat yogurt, required to come from a Grade “A” source?

No. There currently is not a source of Grade “A” sodium caseinate; therefore, we cannot require it.

11. **PMO-Sections 3 and 6**

A Grade "A" fluid milk plant with an IMS Listing that includes Product Codes #1-Raw Cream and #4-Pasteurized Cream sells their excess cream to an ice cream plant. The bulk cream sold is a blend of pasteurized cream and raw cream. The pasteurized cream and raw cream are stored in separate tanks within the milk plant and are transferred to a milk tank truck through separate lines.

a) May the firm sell a blend of raw and pasteurized cream as a bulk Grade "A" product?

Yes. Cream as defined in the PMO that is sold from an IMS listed plant, in this case with Product Codes #1 and/or 4, must be sold as Grade "A".

b) If so, how should they label the bulk cream blend?

Grade "A" Raw Cream

c) What would be the Section 6 sampling/testing requirements of the PMO for this bulk blend of Grade "A" raw and pasteurized cream from this Grade "A" shipping plant?

There would not be any additional samples required to be collected under Section 6 of the PMO at the shipping plant.

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

The following questions relates to the first Table in Appendix E. Is there a typo in the date that now reads 3/15? Should it be 3/5? You may take two (2) samples in the same month once in a six (6) month period as long as they are separated by twenty (20) days, how is it possible that the Table shows a sample collected 3/15 and then again on 3/25?

No, this date is not a typo. The PMO does not state that you cannot collect samples for official purposes unless they are separated by twenty (20) days. A State may chose to collect an official regulatory sample whenever they choose, i.e., every day of the month, if they so desire. The statement that is addressed in the question, "separated by twenty (20) days", specifically relates to determining if the sampling frequency for any consecutive six (6) month period has been met for rating and check rating purposes.

13. **PMO, Section 4**

May milk and milk products be labeled "No Antibiotics"?

Below is related information from CFSAN's Office of Nutritional Labeling and Dietary Supplements (ONLDS) that addresses the labeling of Grade "A" milk and milk products as "Antibiotic Free". CFSAN would also relate this information to the use of "No Antibiotics" on the labels of Grade "A" milk and milk products.

May milk and milk products be labeled "Antibiotic Free"?

We do not have specific regulations governing the use of this term in food labeling. However, any statements made on the label or in labeling of foods must be truthful and non-misleading. Because milk does not contain antibiotics as ingredients, the use of "antibiotic free" in the labeling of milk could be misleading to consumers and we would determine the appropriateness of such statements in the context of the entire food label.

The fact that an existing test for antibiotics in milk does not indicate the presence of antibiotics does not mean that the milk tested is "free" of antibiotics. To assure by testing that milk is antibiotic free would require testing for every antibiotic that is or can be used to treat lactating dairy animals.

For milk to be labeled "antibiotic free", the dairy firm must provide evidence satisfactory to the Regulatory Agency that the milk producers providing the milk to the dairy firm do not use antibiotics on the cattle in their dairy herds.

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

May the term "Fresh" be used on the labeling for yogurt products?

The use of the term "fresh" in the labeling of foods is governed by the regulation in 21 CFR 101.95, which provides, in part, that "fresh" may be used in the labeling of foods if the term does not suggest or imply that a food is unprocessed or unpreserved; for example, "fresh" can be used to describe pasteurized milk because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized) (see § 101.95). The regulation specifically lists "pasteurized milk" (but not other pasteurized dairy products) as an example for when "fresh" does not imply that the food is unprocessed.

The term "fresh", when used in the labeling of foods in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation (see § 101.95(a)). Certain exceptions are provided, but have no relevance to the yogurt question.

The standards of identity for yogurt, lowfat yogurt, and nonfat yogurt (21 CFR 131.200, 131.203, and 131.206, respectively) permit heat treatment of yogurt after the culturing process. In addition, while these standards do not specifically provide for the use of preservatives in the manufacture of yogurt, under an Agency action in 1982 that stayed some provisions within these standards, current industry practices for the manufacture of yogurts may include the use of preservatives. The standards also require pasteurization or ultra-pasteurization of the food prior to the addition of bacterial cultures. Flavoring ingredients may be added after pasteurization or ultra-pasteurization (21 CFR 131.200).

The use of ultra-pasteurization, heat-treatment after culturing, or preservative ingredients is not consistent with the provisions of § 101.95(a). Therefore, any yogurt (full-fat, lowfat, or nonfat) that is ultra-pasteurized prior to culturing, heat-treated after culturing, or made using preservative ingredients cannot be labeled "fresh". Yogurt, lowfat yogurt, or nonfat yogurt that is pasteurized prior to culturing, not heat-treated after culturing, does not contain preservatives, and otherwise complies with the provisions of § 101.95 may be labeled as "fresh".

15. **PMO-Section 6**

The following are questions related to M-I-06-6 (Application and Standard Operating Procedures (SOPs) for the Installation and Use of Approved In-Line Samplers (ISO-LOK, Anderson Instruments and QMI) for the Collection of Dairy Farm Samples from Direct Load Tankers as Required in Section 6 of the Grade “A” PMO):

a) M-I-06-6 refers to an application for the installation of the ISO-LOK sampler, is the application also mandated for the other samplers?

Yes, M-I-06-6 also addresses and provides an example of an application for the installation of the other two (2) cited acceptable in-line samplers.

b) The M-I also speaks to an application approval by FDA. Does FDA want to see each application?

No, unless the application form is significantly different to what was submitted, reviewed and accepted by LQAT and the NCIMS Laboratory Committee and cited in M-I-06-6.

c) The State is developing an SOP for the Anderson Instruments sampler. Does FDA need to review and approve the SOP before the sampler is used?

The SOPs provided with M-I-06-6 are the protocols that were studied, submitted for review by LQAT and the NCIMS Laboratory, and accepted by

FDA and the NCIMS Laboratory Committee. These SOPs and applications are what are to be used for each individual specific in-line sampler. The M-I states on page 3: "Future users of the ISO-LOK, Anderson Instruments and/or QMI In-Line Sampler(s) will have to make application and follow the applicable approved SOP prior to use as agreed to by the NCIMS Laboratory Committee."

If the SOP that is developed is significantly different than what is in M-I-06-6, it would be required to be submitted to LQAT for review and appropriate data would also need to be provided for LQAT and the NCIMS Laboratory to review prior to its acceptance.

The State is only looking at the possibility of utilizing a small refrigerated room, like a walk-in cooler, in which the sampler and sample container would be located, instead of in a refrigerator. As long as they can meet the SOP Refrigerator Requirements we would not view this as a significant change in the protocol.

d) May in-line samplers be used for official samples at farms other than "direct load"?

At the current time, the only data submitted for review was from direct load tankers; therefore, that is the only application that official sample collection is approved for.

e) Must the sampler refrigerator temperature be 40ºF or less? What is magical about 40ºF?

The 40ºF (4.4ºC) is the upper sample temperature requirement specified in FORM FDA 2399, 2400 Forms, the PMO and the SOPs. The studies were conducted using 0º-4.4ºC (32º-40ºF) to maintain the samples on the farm.

f) May sampler containers be multi-use or must they be single-service?

They can be either. Item #5, under Device Requirements, allows for the State Regulatory Agency to approve an appropriate method for the cleaning and sanitizing of the sample container.

g) Item #6 under Device Requirements states the sample container size must be adequate so overflow does not occur. What criteria should be used to determine the sample container size? Length and volume of each milking or tanker size? Is this based on one (1) container per tanker load?

The size of the container will have to be based on the farm's milking volume and in-line sampler flow rate set to capture the proportionate sample over the course of the milking. The Company should be able to help them with

this. As far as multiple containers, i.e., collecting milk from each milking in a separate container when it takes multiple milkings to fill a tanker, this is not addressed in the SOPs. A single large container would be preferable to avoid temptations to try to proportionally mix multiple containers and/or contaminate or vary temperatures.

h) Should the sample collected, utilizing the sampler container identified in g. above, be required to represent the entire tanker load that may include several milkings; or can the farmer just collect one (1) sample that represents one (1) complete milking, regardless of how many milkings per day or how many days (milkings) it takes to fill the tanker?

The sample collected and tested must represent the entire tanker load, just as it does when it would be collected and tested from a bulk milk tank or silo at the farm.

i) What is the importance of determining milk weight protocol? Is this requiring milk weight to be determined at the farm?

This is important because the specific protocol, established per installation, will provide the amount of milk that is being shipped from the farm and paid by the milk handler. No, it can be determined at the farm or at the receiving facility.

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

a) With the use of an approved in-line sampler on farm direct load milk tank trucks, may the sample from the in-line sampler be used for Appendix N?

Yes.

b) May this sample from an approved in-line sampler be used for or as the trace back sample?

Yes. This applies to farm direct load milk tank trucks (i.e., single producer) only.

17. **PMO-Sections 6 and 7**

Acid whey collected from Grade “A” cottage cheese processing is being pasteurized and then ultrafiltered. The Grade “A” lactose-containing permeate is to be shipped in bulk. The product will be listed as Product Code #42 (UF Permeate from Whey) in the IMS List. What test(s) and standard(s) would be required for this Grade “A” lactose-containing permeate?

Samples of the bulk product that are being shipped must be collected at the shipping plant to meet the sampling frequency requirements of Section 6- The Examination of Milk and Milk Products of the PMO, which states during any consecutive six (6) months, at least four (4) samples of pasteurized product shall be collected, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. The only tests that will be required to be conducted on the samples will be for Temperature (≤45ºF (7ºC)) and Coliform, with a Standard for the bulk product being shipped not to exceed 100 per mL.

18. **PMO-Section 7**

A Grade "A" producer plans to milk both cows and goats on a permitted dairy farm. They are suggesting having one (1) parlor, with a system for cows on one (1) side and a system for goats on the other side of the parlor. They plan to use the same equipment, with the exception of separate milking claws and bulk tanks for each species of milk, but wash the equipment between species. Are they required to have two (2) completely separate milking systems or can they wash and sanitize the shared equipment between milking the different species?

The PMO does not directly address this scenario. It does not specially cite either the acceptance of washing and sanitizing between the milkings of different species or the requirement for completely separate milking systems. The PMO does; however, address concerns related with the potential adulteration of milk with a known food allergen (people allergic to cow's or goat's milk) or the potential mislabeling of milk that may contain milk from different species.

The producer must demonstrate to the satisfaction of the State Regulatory Agency that whatever milking system or process that is planned to be utilized will adequately address the potential adulteration/mislabeling issues contained within the PMO.

The ultimate determination as to whether a completely separate milking system will be required, or whether the equipment can be washed and sanitized between species, lies with the State Regulatory Agency that will issue the permit to this Grade "A" dairy farm.

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

Item 5r-Milkhouse - Construction and Facilities of the PMO allows for the use of a transportation tank to be used for the cooling and/or storage of milk on the dairy farm, with or without a suitable shelter.

a) Could a suitable shelter be defined as a smooth floor constructed of concrete or other equally impervious material that is graded to drain, has only overhead protection and adequate natural light and/or artificial lighting?

No. The term "suitable shelter" has always required an enclosed room since its original wording, which was first cited in the 1965 Revision of the Grade "A" Pasteurized Milk Ordinance (PMO). The 1965 Revision addressed a suitable shelter as encompassing all of the milkhouse construction standards including lighting, drainage, insect control, and general maintenance. A typographical error occurred during editing when combining the DMO into the 2003 PMO. The error changed a semicolon (;) from the 2001 PMO to a colon (:); subsequently, incorrectly changing the intent of the statement and the requirements. The correction of this error will be addressed with the next editing and publication of the 2007 PMO.

b) What item(s) would be considered in violated if it is determined that a dairy farm does not comply with all of the Items associated with a "suitable shelter" addressed in Item 5r, Administrative Procedures #16 of the PMO?

If the farm does not have an enclosed shelter, when one is required, this would be debited under Item 5r-Miscellaneous Requirement-Suitable Shelter for Transport Truck as Required (f) on FORM FDA 2359a-Dairy Farm Inspection Report.

If the farm has an enclosed shelter, then it would be treated like an extension of the milkhouse, even though it cannot be a part of the milkhouse, and would be debited in a similar manner that a milkhouse would be debited, i.e., floor construction would be debited under 5r-Floors; wall construction would be debited under 5r-Walls and Ceilings; cleanliness would be marked under Item 6r-Milkhouse Cleanliness, etc.

20. **PMO-Section 7, Item 8r; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Appendix B**

The following questions relate specifically to a 2-compartment wash vat or CIP/wash vat located on a dairy farm:

a) Is a hose attached to a water line, which terminates below the flood rim of the wash vat, a water debit, provided that the drain is not plugged or there is not any water in the vat?

No. (Refer to M-I-06-4 (Question 24) for the same question and answer.)

b) Is a hose attached to a water line, which terminates below the flood rim of the wash vat, a two (2) point-minor water debit, if the drain is plugged and there is not any water in the vat?

Yes.

c) Is a hose attached to a water line, which terminates below the flood rim of the wash vat, a two (2) point-minor water debit, if the drain is plugged and there is water in the vat; however, the hose is not submerged in the water?

Yes.

d) Is a hose attached to a water line, which terminates below the flood rim of the wash vat, a five (5) point-major water debit, if the hose is submerged in water?

Yes.

21. **PMO-Section 7, Item 8r; and MMSR-Appendix B**

The following questions relate to the installation and use of frost free hydrants:

a) May a frost free hydrant be mounted directly on top of a well head?

No. This would be considered a five (5) point major water debit.

b) A frost free hydrant is located within ten (10) feet of a well; must the threads be cut off to be in compliance with the PMO?

No; however, that is one (1) acceptable method of protection. It may have an approved atmospheric vacuum breaker or back flow prevention device installed that will effectively prevent water from being drawn back through the frost free hydrant.

c) A frost free hydrant is located greater than ten (10) feet from the well; must it be equipped with an acceptable back flow prevention device?

No. An acceptable backflow prevention device would be required if a hose is attached and it is submerged to provide a direct means of cross contamination.

22. **PMO-Section 7, Items 8r and 7p; and MMSR-Appendix B**

If a well casing does not rise at least twelve (12) inches above the surrounding earth is it automatically considered a five (5) point major water debit?

No. The PMO does not specifically cite twelve (12) inches. It only requires that the casing of every well terminate above the ground level. Appendix B

of the MMSR cites that the well casing terminating below or at ground level is a five (5) point major water debit.

NOTE: *In a situation where a well is exposed to possible flooding, Appendix D-Standards for Water Sources of the PMO requires that the sanitary well seal shall be either water tight or elevated at least two (2) feet above the highest known flood level; or it shall be water tight and equipped with a vent line, whose opening to the atmosphere, is at least two (2) feet above the highest known flood level.*

23. **PMO-Section 7, Items 8r and 7p; and MMSR-Appendix B**

Is a backflow prevention device required on each and every hose station or hose bib, which has a hose attached?

No. On a rating or check rating you would only debit such a situation if the hose is submerged, i.e., stuck in a bucket or a floor drain, etc., and there is not an appropriate backflow prevention device installed to protect the water line.

24. **PMO-Section 7, Items 8r and 7p; and MMSR-Appendix B**

Is there a water debit in relationship to the following scenario?

A well head discharge pipe comes out from the well and then tees off via a manifold in four (4) places. Each tee off the main line has an acceptable backflow device installed so that nothing from that tee branch can get back into the main line and; therefore, into the well. There are not any cross connections at any point served by any of the four (4) teed lines.

No.

25. **PMO-Section 7, Item 9r**

On a recently installed new rotary parlor, we observed that the CIP line from the milkhouse to the CIP connection on the rotary parlor was supplied by a sanitary flexible hose that was more than ten (10) feet long. Would the use of this sanitary flexible hose be acceptable?

Item 9r-Utensils and Equipment-Construction, Administrative Procedures #12 of the PMO allows for the use of sanitary flexible plastic/rubber hoses for the filling of bottom and top filled bulk milk storage tank. We believe that the intent of Administrative Procedure #12 is also to encompass these types of applications.

If the sanitary flexible hose meets the criteria of Administrative Procedure #12, such that the hose is drainable, as short as practical, has sanitary fittings, and is supported to maintain uniform slope and alignment, it would be acceptable within the PMO.

26. **PMO-Section 7, Items 10r and 11r**

Does the PMO require that a farm bulk milk tank/silo must be emptied at least every seventy-two (72) hours and cleaned and sanitized as required of raw storage tanks/silos in milk plants?

No, with the exception of partial pick-ups from bulk milk tanks/silos equipped with a seven (7) day recording device as cited in Item 10r of the PMO. The bulk milk tank/silo shall be cleaned and sanitized when empty and shall be emptied at least every seventy-two (72) hours. If this requirement for partial pickups is not met then it would be considered a violation of Items 10r and 11r.

27. **PMO-Section 7, Items 10r and 11r**

The following question relates to on-farm milk tank partial pick-up.

Situation: Farm tank #1 does not have a recording thermometer. Bulk tank #1 is filled and milk is then switched to tank #2. The bulk milk hauler partially empties tank #1. Prior to the end of milking, milk is again added to tank #1. Both tanks are emptied, cleaned and sanitized prior to the next milking. Is this a violation of Item 10r and 11r?

Yes. Once a partial pick-up has occurred from a tank without a recording thermometer, the intent of the PMO is that the tank shall be emptied, cleaned and sanitized prior to the addition of milk.

28. **PMO-Section 7, Items 11r and 12p**

Are there any PMO concerns with using chlorine dioxide for the sanitization of dairy equipment?

Chlorine dioxide sanitizers used on equipment (inanimate objects) are regulated by EPA and must consist of one of the solutions (178.1010 (b) (34) or (46)) and corresponding concentrations (178.1010 (c) (29) and (40)) contained in 21 CFR 178.1010. They must have an EPA Registration Number, directions for use in the intended industry, and the name and address of the manufacturer. EPA requires the directions for use to be in compliance with 21 CFR 178.1010. These are the requirements of a sanitizer, which may be permitted to drain off equipment, as for dairy equipment.

FDA's authority to regulate surface sanitizers was passed on to EPA back in 1996. EPA has recodified 21 CFR 178.1010 into 40 CFR 180.940. The use conditions should be the same; only the organization of the regulation is different.

If the chlorine dioxide sanitizer meets the above criteria, the PMO would not have an objection to its use for sanitizing dairy equipment.

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

a) Is it legal to extra label trimethoprim for lactating animals?

Trimethoprim is usually marketed in combination with a sulfonamide, such as sulfamethoxazole. It is not legal to extra-label a sulfonamide for use in lactating dairy cattle.

b) Has there been any movement toward banning gentamicin usage, extra-labeled, in lactating animals?

Gentamicin is not on the FDA AMDUCA prohibited list. We do not encourage its use in cattle but under AMDUCA it can be extra-labeled by a licensed veterinarian for use in dairy cattle (lactating or non-lactating).

The American Association of Bovine Practitioners (AABP) and the Association of Feedlot Consultants (vet group) both have "resolutions" that discourage the use of gentamicin and other unapproved aminoglycosides (drug class for gentamicin) in beef and dairy cattle. The primary reason is the long tissue residue (kidney) time. It takes 18-24 months or longer for gentamicin and some other aminoglycosides to clear a cow's system (kidneys).

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

What is the common brand (trade) name for an animal drug that contains flunixin meglumine?

The original trade name is Banamine. It first came on the market for use in horses only. The firm got it approved and it is still the only flunixin product approved for lactating dairy cattle. Flunixin meglumine is the active ingredient. It's an anti-inflammatory drug. There are some generic flunixin products on the market that are labeled only for horses. Some times they are used extra-label in cattle.

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

What animals are considered major or minor species in relationship to CVM's Compliance Policy Guide #615.115 in relationship to extra-labeled use of animal drugs and medicated feeds?

Major species are cattle, horses, swine, chickens, turkeys, dogs, and cats. Minor species are all animals other than the major species, which includes zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish, and honeybees. Since water buffalo, in the case of milking, are agriculture animals used for human food they would fall in with sheep, goats, catfish and honeybees. The "minor species program" has advantages geared towards getting drug approvals for those species.

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

What is the current status of the use of formaldehyde topically (digital dermatitis-hairy heal warts) in bovine medicine?

AMDUCA requires a veterinarian who chooses to prescribe a drug off label, extra-label-use (ELU), to select only FDA approved human or animal drugs. As there are only three (3) approved drugs that contain formaldehyde, to be in compliance with AMDUCA, a veterinarian is limited to the ELU of an approved formaldehyde drug to treat hairy heel warts.

Industrial grade formaldehyde is not an FDA approved drug; therefore, AMDUCA does not apply. The unavailability of the approved drug products does not apply as AMDUCA does not apply. This industrial grade formaldehyde is considered a chemical and is regulated by EPA.

If a veterinarian uses the chemical grade for hairy heel warts, they establish the intended use of the chemical as a new animal drug without an FDA approval. In this case they are now in violation of other provisions of FDA's laws because they have established the product as an unapproved new animal drug. Veterinarians do so at their own risk. To legally use it they would have to get it approved by FDA.

Under the PMO and its coded memoranda (M-I-06-5), industrial formalin used as a foot bath is exempted from drug labeling and storage requirements. In other words, under the PMO there is no objection to such use. The PMO does not say it is OK, it simply does not object to its topical use at this time.

FDA is not going to say it is OK to use industrial grade formaldehyde to treat animals nor is FDA going to say it is not OK to use it. In some situations it may be necessary for FDA to take action on its use due to factors such as

human or animal safety or misbranding by promotion, sale or advertising as a new animal drug. Again, veterinarians do so at their own risk.

Be aware that some State laws will not allow its use on dairy farms because they do not want inspectors exposed to the formalin fumes.

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

We have read about a new drug from Pfizer called Draxxin (tulathromycin) that is labeled and prescribed for respiratory Myco/Pneumonia in heifers. May it be extra-labeled by a veterinarian for the prescribed use for Respiratory Myco/Pneumonia in lactating cows?

Yes. This is not an AMDUCA prohibited drug; therefore, veterinarians may extra-label it for food animals, including lactating dairy cattle. The extra-label must include the veterinarian's name and address, directions for use, dosage, any cautions, and most importantly, a withdrawal time for milk and meat. It is a macrolide antibiotic similar to tylan and erythromycin

34. **PMO-Section 7, Items 15r; and MMSR-Section D**

If during a State Rating or Check-Rating you come across a drug labeling problem (i.e., multiple vets on the label, but no one is identified as the prescribing veterinarian) and this is found on multiple farms, are we instructed to only mark it once and then raise the deficiency to the Regulatory Agency for compliance via the cover letter or should the item be marked off at every farm?

If it is a significant drug violation on a farm it should be debited against the farm(s) no matter if it is a repeat situation (like describe above) or not. If you are finding only one (1) or two (2) drugs of many drugs reviewed with this common violation, then you should use professional judgment to determine if it is significant or not. We generally have said that this situation of only one (1) or two (2) drugs with this common violation probably does not warrant a drug violation on a farm(s).

As for the Enforcement Rating, it may not be warranted to take off every farm for this common violation if that is the only interpretation issue per farm. In this situation, taking off a farm or two (2) for interpretation would be justified and definitely the situation must be brought forward to the Regulatory Agency and citing it in the cover letter would be an appropriate means to address the issue.

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

Are there any provisions in the PMO which would prohibit the freezing of goat or sheep's milk?

No. This practice is used widely across the country as the goats or sheep dry off and producers are collecting and storing milk for further processing. With the freezing of milk, it must be adequately handled, stored and protected at all times; and during the thawing process it must be under controlled temperature conditions so that the milk does not exceed 45ºF.

36. **PMO-Section 7, Items 10p and 11p**

a) May woven wire filters be used to strain raw milk in receiving areas of a milk plant or receiving stations and if so must these filters be cleaned and autoclaved?

No. Woven wire construction, single or multi-use, is not acceptable for a milk contact surface; within a CIP system; or for the straining of milk.

b) The language in Item 11p, Administrative Procedures #8 of the PMO provides for woven wire use and "cleaning by such methods that thoroughly clean..." Would this apply to woven wire filters, screens, parts, etc. on raw milk receiving lines in receiving areas of milk plant or receiving stations?

No. Item 11p, Administrative Procedure #8 of the PMO, provides an exemption for the use of woven wire for functional reasons inherent to the production of certain products, such as buttermilk, whey, dry whey and dry milk products where it is impractical to use perforated metal. If woven wire parts are used in these applications they must be mechanically (CIP) cleaned by such methods that thoroughly clean the woven wire part and do not contaminate the product.

NOTE: *This cleaning provision is addressing the exemption and FDA's acceptance of woven wire parts (screens) in packaging machine filler nozzles. It does not apply to woven wire filters, screen or parts for milk contact surfaces, within a CIP system or for the straining/filtering of milk.*

c) Woven wire screens used on packaging machine filler nozzles, if reused, must be cleaned and autoclaved between uses. Does this include the cleaning and autoclaving of woven wire multi-use inline filters, screens, parts, etc. in raw milk receiving lines?

No. Other than the exemption provided above, FDA has only accepted the use of woven wire screens in packaging machine filler nozzles. If the woven wire screens are reused, they must be cleaned, then autoclaved. Section K of 3-A Standard 17-07 states they should be autoclaved at 250 F for 30

minutes. Item 11p would be debited if these conditions are not met and the screens are reused.

CONCLUSION: *If a woven wire part (filter, screen, etc.) is identified as being utilized, other than the exemption or packing machine filler nozzles as provided for above, on a milk pipeline, CIP system or for the straining/filtering of milk, it would be considered a violation of either Item 10p or 11p of the PMO, depending on the specific application and/or installation.*

37. **PMO-Section 7, Items 10p and 12p**

Please address the use and cleanability of a sintered stainless steel gas sparger used to introduce gases into milk and milk products.

Two abstracts from the manufacturer's cleaning instructions for this porous metal implement may be instructive. These are:

1. "THE PORE STRUCTURE
... A series of interconnected, and sometimes disconnected, passageways of irregular size and shape leading from one surface to another. Some of these passageways, or pores, are relatively large and lead directly from one surface to another in a tortuous path which is continuously interrupted by obstacles of metal particles. Others can be smaller or lead to dead ends..."

2. "TESTING FOR EFFECTIVENESS
...It may not be necessary to clean to the extent of new media…only to the point necessary to make the part serviceable."

The above text does not describe cleanable multiuse equipment.

This sparger is normally used in non-food applications such as the removal of volatile organic compounds from waste streams, pH control in waste process streams, bleaching paper pulp, etc.

To date, a method has not been documented and verified for the effective cleaning and sanitizing of sintered metal for sanitary re-use in milk or milk products. Based on the definition of cleanability from 3-A and how it is interpreted in the PMO, a sintered steel sparger does not meet the construction and cleanability requirements of the PMO. Until an effective cleaning and sanitizing regimen is verified, it would not be acceptable to use sintered stainless steel for any application that involves cleaning and reuse in milk or milk products.

Single-Use Applications of Sintered Material:

1. It has been reported that a single-use plastic sparger has been successfully used for the injection of CO_2 into yogurt.

2. One single-use application of a sintered stainless steel probes is allowed under "3-A Sanitary Standards for Equipment for Packaging Dry Milk and Dry Milk Products Number 27-05" for de-aeration in bulk containers of powdered milk and milk products. This application was accepted by 3-A after this equipment was rejected for cleaning and re-use in such dry applications.

3. The use of a single-use application of a sintered stainless steel probe to introduce gases into yogurt products would only be acceptable if used according to an established protocol accepted by the State that will assure that these probes will not be reused.

38. **PMO-Section 7, Item 12p**

How is Item 12p of the PMO enforced for pasteurized surge/storage tanks/silos that are used throughout the day in a Grade "A" milk plant? These tanks would be cleaned at the end of each day's use and not used to store product overnight. During the day, these tanks might be used for the temporary storage of pasteurized whole milk, skim milk or chocolate milk prior to packaging. These tanks would be emptied before each separate product is added to the tanks.

We were not able to determine from our reading of Item 12p whether this is an acceptable practice, i.e. washing these pasteurized storage tanks at the end of every day or whether these tanks would have to be washed at the end of each specific product. We believe the intent of 12p is the former, but need your advice.

FDA would consider pasteurized tanks used in this manner to be classified as surge tanks and not storage tanks. Therefore, a pasteurized product tank that is being used as a surge tank, i.e., putting product(s) in and pulling product(s) out of the surge tank for packaging throughout the day, would need to be properly cleaned and sanitized after its use as a surge tank at least once every day of such use and prior to product being put into the tank for storage purposes, if applicable.

39. **PMO-Section 7, Item 12p**

May pasteurized milk be stored in a pasteurized storage tank/silo for up to seventy-two (72) hours?

Yes.

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

Some co-ops and milk tank truck owners/operators are interpreting the ninety-six (96) hour re-sanitizing requirement for milk tank trucks, cited in Item 12p and Appendix B of the PMO, to mean that milk may be stored or otherwise remain on the milk tank truck for ninety-six (96) hours before being emptied, cleaned and sanitized. What does the ninety-six (96) hour limitation in Item 12p actually address?

*PMO, Appendix B, III, 3.b. (1) and (2) reference Section 7, Item 12p which states: "When the time elapsed **after cleaning and sanitizing**, and before its first use, exceeds ninety-six (96) hours the tank must be re-sanitized." This specifically applies only to milk tank trucks that have been previously emptied, cleaned and sanitized and does not have any relationship to milk remaining on the milk tank truck for 96 hours prior to being emptied, washed and sanitized.*

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

How long may a milk tank truck have milk or milk product stored in it before it has to be washed and sanitized? (Give consideration to the milk tank trucks that are moving milk or milk products across the US.)

The PMO does not address or set a time limit for the length of time milk or milk products may be stored in a milk tank truck. (Other factors may influence the acceptance of the milk or milk products by the receiving plant such as temperature, age and quality.)

- *Item 12p of the PMO cites Appendix B for additional information on the cleaning and sanitizing requirements for milk tank trucks. Appendix B of the PMO address the requirement for the re-sanitization of the bulk milk truck prior to its next used if there is a time lapse that exceeds 96 hours since the time the tanker was previously cleaned and sanitized.*

- *Item 12p of the PMO requires the washing of tanks/silos every 72 hours and would only apply to a milk tank truck if the milk plant or receiving facility had specifically designated the milk tank truck as a storage tank for milk or milk products for use in the facility or the bulk shipment of milk or milk products from the facility. If a milk tank truck is designated as a storage tank in this manner, then it would be required to meet all of the requirements of the PMO associated with storing milk or milk products.*

42. **PMO-Section 7, Item 12p; and Appendix J**

Please define a single service sample set (four (4) containers and closures). Such as: If a milk plant has both a gallon machine and a ½ gallon machine, could a sample set consist of two (2) one (1)-gallon containers and two (2) ½-gallon containers?

The sample set must consist of four (4) containers of the same size, with closures, from an individual blow mold machine. With this scenario, we have two separate blow mold machines; therefore, this would not be acceptable.

43. **PMO-Section 7, Item 12p; and Appendix J**

Are metal aerosol containers/cans (single-service or multi-use) required to meet the sampling/testing requirements addressed in the PMO of at least four (4) samples collected and tested in any consecutive (6) month period?

Yes.

44. **PMO-Section 7, Item 12p; and MMSR-Section D**

Question 22 from M-I-07-3 states:

What are the frequency requirements for the sampling of cleaned and sanitized empty multi-use glass milk containers and what enforcement actions should be taken when the containers are in violation of either the coliform or residual bacterial count standards, cited within Item 12p-Cleaning and Sanitizing of Containers and Equipment of the PMO?

During any consecutive six (6) month period, the State Regulatory Agency shall collect and test at least four (4) sample sets in accordance with Item 12p of the PMO.

All violative results should be followed promptly by an inspection conducted by the Regulatory Agency to determine and correct the cause. It is recommended that the Regulatory Agency also resample and test the containers for compliance with the standards of the PMO.

When conducting an inspection, rating or check rating, if the last sample results indicate residual bacteria count and/or coliform levels exceeding the standard this would be considered a violation of Item 12p of the PMO.

a) Is this a five (5) or ten (10) point debit under Item 12p?

This would be a considered a five (5) point debit marked under Item 12(c)-Approved Sanitization Process Applied Prior to Use of Product-Contact Surfaces on FORM FDA 2359-Milk Plant Inspection Report.

This determination is based on the lack of samples or the presence of a residue bacterial count or Coliform organisms that exceed the standard as cited in Item 12p, Administrative Procedures #6a, and would be considered an indication of an inadequate sanitization process. This is consistent with a five (5) point debit under 12(e)-Multi-use Plastic Containers in Compliance on FORM FDA 2359-Milk Plant Inspection Report.

b) Should Part II-Milk Plants, Item 7-Sampling of Each Plant's Milk and Milk Products Collected at Required Frequency and All Necessary Laboratory Examinations Made, FORM FDA 2359j-Milk Sanitation Rating Report, Section B-Report of Enforcement Methods, include glass bottles?

No. We do not believe that this would be debited under Item 7, Part II-Milk Plant on FORM FDA 2359j, Section B-Report of Enforcement Methods. This Item specifically addresses the milk plant's milk and milk products and not the containers that are utilized to packaged the milk or milk products. However, it would be appropriate to debit Item 4-Requirements Interpreted in Accordance with PHS/FDA PMO as Indicated by Past Inspections, PART II-Milk Plant on FORM FDA 2359j, Section B. if the required sampling frequency was not met. Utilizing the procedures developed for calculating this Item, this would also constitute a five (5) point debit.

45. **PMO-Section 7, Item 15p; and Appendix H**

May a milk processing facility use filtered air to blow air into plastic milk jugs that are slightly imploded before filling them with milk?

Yes, as long as the air being used is free of oil, dust, rust, excessive moisture, extraneous materials and odor and complies with the applicable requirements of Appendix H of the PMO and there is also a final filter located in the air line upstream from and as close as possible to the point of application. The air nozzle must also be protected from potential sources of contamination during use and storage.

46. **PMO-Section 7, Item 16p(D)**

Do double and triple tube heat exchangers that are used for heat exchange purposes between raw and pasteurized milk and milk products, have to be designed and operated in accordance with the provisions of Item 16p(D) of the PMO?

Yes.

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

Milk plants would like to pre-cool incoming raw milk in the receiving bay and then use the same cooling media on the HTST cooling section. Would pressure instrumentation be required on this type of cooling system that cools both raw milk and pasteurized milk in the same loop?

No.

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

a) How often (Daily, Monthly, Weekly) should the cooling profile of sour cream (cultured or acidified), cultured buttermilk or yogurt be monitored in order to meet the temperature requirements of Item 17p of the PMO?

Although there are not specific frequency requirements cited within the PMO, a review of the cooling profile(s) should be checked and reviewed during routine inspections, ratings and check ratings.

NOTE: *Prior to initiating such a program to facilitate utilizing the temperature requirement exceptions cited in Item 17p of the PMO, the milk plant must work with the Regulatory Agency and submit data supporting the cooling profile(s) that they propose to use. This submitted data must support the temperature exception and be acceptable to the Regulatory Agency prior to initiating the program. Within this profile or process, the Regulatory Agency should cite a frequency of the monitoring of the profile to continue to utilize the specific temperature exception.*

b) Should each size container be monitored or would the largest container be satisfactory?

The cooling rates for all types of containers to be cooled, whether they are large bulk items or small containers tightly packed and palletized, should be monitored.

NOTE: *Within this profile or process cited above, the milk plant should cite which size containers are to be included and the Regulatory Agency should cite a frequency of the monitoring of such sized containers included within the profile to continue to utilize the specific temperature exception.*

c) In what form should the data or records (chart recording, laboratory check list, etc.) be kept?

Whatever form or means that is acceptable to the Regulatory Agency.

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

The following questions relate to M-I-06-11 (Uniform Protocol For Determining Plastic Fluid Milk Container Closure Removal Without Detection (Tamper Detectability) To Evaluate The Requirements Of Item 19p Of The PMO:

a) Item b. states: “During the State Rating or FDA Check Rating, randomly select plastic containers filled with milk and/or milk products that have been capped from the following locations:

(1) If a packaging machine(s) is operating, randomly select up to five (5) filled and capped containers directly off the line..."

If the milk plant is operating more than one line (same container size/type/cap) at the time of the rating or check-rating, are you required to select up to five (5) containers from each line, from one (1) randomly selected line or a combination of the lines?

If the containers and caps are the same size and type on all of the lines, then it is recommended that a total of five (5) filled and capped containers from a combination of lines be selected. The important point to remember is that the containers and caps must all be the same size and type. If different lines are using different containers and different caps then up to five (5) filled and capped containers from each different combination must be collected and tested.

For example, one (1) line uses containers from SS plant A and caps from manufacturer C and another line uses containers from SS plant B and caps from manufacturer D, then up to five (5) filled and capped containers from ***EACH*** *of these lines would need to be collected and tested. With this scenario, a total of ten (10) filled and capped containers should be collected and tested. Each set of five (5) similar filled and capped containers will stand on their own for meeting the requirement of either three (3) not demonstrating detection (signs/evidence) of removal (non-compliance) or three (3) demonstrating detection (signs/evidence) of removal (compliance). A result of not demonstrating detection (signs/evidence) of removal (non-compliance) from three (3) of the five (5) similar filled and capped containers would be prorated based on the volume of products for that specific packaging machine or similar packaging lines.*

b) Sub-items "d", "e", and "f" specify that compliance/non-compliance is based on evidence obtained from three (3) containers. May you select less than five (5) containers and do you have to find sufficient evidence from three (3) containers before determining compliance or non-compliance?

Yes, you continue to select containers until you determine either three (3) not demonstrating detection (signs/evidence) of removal (non-compliance) or three (3) demonstrating detection (signs/evidence) of removal (compliance). This may be a total of three (3), four (4) or five (5) filled and capped containers selected and tested.

c) May the bottleneck be distorted in order to remove the cap?

In some situations this may be done to see if the closure can be removed or not.

d) Protocol describes using the hand, can you use the fingernail?

Yes.

e) If contents of the bottle are spilled or fill level reduced because of removal of the cap does this constitute tamper evidence?

If the closure can be removed and replaced without detection, and during the process of testing the closure and container the fill level is reduced, yes it would still be considered as being able to be removed without detection.

f) Is there a time limit for this process?

No. An unreasonable amount of time is not going to be put forward on trying to remove the closure. It will either be able to be removed or it will not. State Rating Officers and FDA Regional Milk Specialists will use their professional judgment.

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

a) A milk tank truck was rejected because the producer samples were stored in a portable refrigerator found in the cab of the truck, instead of being stored in an ice bath. The PMO specifically states samples are to be stored in an ice bath, not just kept cold. Does a milk plant have the right to reject this milk tank truck because of how the samples were being stored?

Yes, the receiving milk plant's choice to reject the milk tank truck is completely within their right and authority.

b) Is the intent to keep the samples cold by any means or specifically by an ice bath?

As NCIMS documents are currently written, the samples must be cooled in an ice bath. While being a little nebulous, the current wording cannot be extended to allow for the use of a refrigerator as described above. The

NCIMS requirements must be followed. In order for another means to store and transport samples to be used, it would first have to be adopted by the NCIMS and subsequently included in the PMO and other necessary NCIMS documents.

c) Will we need guidelines for the use of portable refrigeration units, if this is an acceptable practice?

Not until such time as these units are approved by the NCIMS for use.

d) If portable refrigeration unit are to be acceptable for use in the storage of producer samples as a substitution for an ice bath, will this require a change to the PMO?

Yes.

51. **PMO-Appendix B, Section I; and MMSR-Section D**

Where would you debit on a State Rating or Check Rating if you observed that the weigh tickets/slips left at the dairy farm do not have the name and permit or license number of the bulk milk hauler/sampler(s) recorded on them as required in Appendix B-Milk Sampling Hauling and Transportation of the PMO?

If a bulk milk hauler/sampler evaluation is being conducted this would be considered a violation of Appendix B, I. Milk Sampling and Hauling Procedures, Evaluation of Bulk Milk Hauler/Sampler Procedures, Item 3.c. and would be debited under Bulk Tank Sampling Procedures, Item #14.I. on FORM FDA 2399a-Bulk Milk Hauler/Sampler Evaluation Report.

If there is a history of this non-compliance over the preceding thirty (30) days of the State Rating or Check Rating and it may be creating a problem as to the proper identification of the bulk milk hauler/sampler(s) that are collecting samples from the farm for use in the calculation of Item #9-Sampling Procedures Approved by PHS/FDA Evaluation Methods, Part I-Dairy Farms on Form FDA 2359j-Report of Enforcement Methods, then it could be considered evidence that the bulk milk hauler/sampler's sampling procedures are not in substantial compliance with Appendix B of the PMO. Therefore, if it is determined to be significant, then Item #6-Sampling Procedures in Substantial Compliance on the "Evaluation of Sampling Procedures" would be prorated based on the "Number Comply" with this specific Item. This observation should be addressed in the State Rating Report or Check Rating cover letter provided to the State Rating Agency. If this is continuing to occur across the State or in a specific Region of the State then it should also be identified in the State Program Evaluation Report.

52. **PMO-Appendix B, Section III**

What is to happen when a milk tank truck, that does not have a state inspection sticker or inspection sheet available, delivers to a milk plant? This is not as clearly defined as an antibiotic load of milk.

- *Milk Plant: The receiving milk plant has the right to accept or reject the receipt of the milk contained within the milk tank truck.*

- *State Regulatory Inspection: If the tanker is permitted in the State, a State employee should conduct an inspection of the milk tank truck at the milk plant or make arrangements for the inspection of the milk tank truck. If it is not permitted in the receiving State, or any other State, and it is operating within the State, then arrangements should be made for the milk tank truck to be permitted and inspected in that State.*

  ***NOTE**: A milk tank truck may be inspected at any time when deemed appropriate by the Regulatory Agency. A Regulatory Agency may have the option of inspecting any milk tank truck at any time when milk and milk products are transported in or out of a particular jurisdiction. If a milk tank truck does not have proof of a current permit and inspection, then a Regulatory Agency, other than the permitting Agency, may charge an inspection fee to the owner or operator of the milk tank truck. Inspection reports completed by Regulatory Agencies, other than the permitting Agency, shall be forwarded to the permitting Agency for verification of an annual inspection. The permitting Agency may use these reports to satisfy permit requirements.*

- *State Ratings or FDA Check Ratings: During the course of conducting a State Rating or FDA Check Rating, the State Rating Officer (SRO) or Regional Milk Specialist (RMS) will check the milk tank truck(s) in the receiving bay and/or on the plant's premises to see if an inspection sticker (label), which identifies the Regulatory Agency with the month and year of the inspection, is affixed near the tank outlet valve, or a current inspection report is accompanying the milk tank truck and the milk tank truck is currently permitted. If it is observed that a current inspection sticker (label) is not properly attached, or a current inspection report is not accompanying the milk tank truck, or the milk tank truck is not currently permitted, then the SRO should cite the observation on Form FDA 2359j-Milk Sanitation Rating Report, Section A. Report of the Milk Sanitation Rating or similar report utilized by the SRO. A RMS would note this deficiency in their check rating report and would utilize this type of information when they are conducting the State Program Evaluation. If it is determined to be a trend within the State, then it would be addressed in the triennial State Program Evaluation Report. In any of the cases cited above, appropriate follow-up should be considered to make sure the*

Regulatory Agency is aware of the milk tank truck(s) that has not been permitted or inspected.

***NOTE**: The lack of a current milk tank truck permit, inspection sticker (label) or inspection report is not considered a violation against the receiving milk plant and; therefore, would not be debited against the milk plant on State Ratings or FDA Check Ratings.*

53. **PMO-Appendix J, Section A**

If a single service facility has additional off-site warehouse storage that is inspected by the Regulatory Agency, does this off-site storage also have to be inspected during a State IMS Certification and FDA Audit?

Yes.

54. **PMO-Appendix J, Section C**

a) If two (2) blow mold machines each produced a different size container (A = ½ gallon; B = gallon) would each blow mold be required to be sampled so that there would be four sample sets from each blow mold machine (4-½ gallon and 4-gallon containers) in a consecutive six (6) month period or would it be acceptable to have three (3) sample sets of gallons and one (1) sample set of ½ gallons in the consecutive six (6) month period?

In the example cited above, three (3) sample sets (four (4) containers with caps/sample set) of gallons and one (1) sample set of ½ gallons in the consecutive six (6) month period would be acceptable as would any other combination of sampling sets to meet the four (4) sample sets in any consecutive six (6) month period as long as each size container is sampled at least once during the consecutive six (6) month period.

b) Do we want to know if each individual machine is clean or do we want to know if the raw materials are tainted? I'm trying to find out the theory behind the sampling.

The sampling requirement for single service containers and closures is to determine the sanitary quality under which the containers and closures were produced, handled and stored so that they do not present a potential source of contamination to the milk or milk products that are packaged in them.

55. **PMO-Appendix N**

What Appendix N drug residue test kits are approved for use with goat milk?

The following drug residue test kits are approved for use with goat's milk: CHARM BsDA, CHARM SL, CHARM II-Sequential and Delvotest.

56. **PMO-Appendix N**

May the Appendix N sample from a single producer load be used as the producer trace back sample?

Yes.

57. **PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS (PROCEDURES)-Section IV; and MMSR-Appendix G**

Is the State Rating Agency required to submit a properly completed FORM FDA 2359i-Interstate Milk Shipper's Report on all ratings when the shipper has not signed a FORM FDA 2359o-Permission for Publication or equivalent Form?

Yes, this is FDA's official notification from the Rating Agency that this listed shipper is not authorizing the listing of their shipper in the IMS List.

NOTE:

- *For all BTU ratings, no matter what the Sanitation Compliance or Enforcement Ratings are, the State Rating Agency is required to submit a properly completed Form FDA 2359i and a "Permission for Publication", with the applicable rating scores recorded on both forms, to the shipper for the shipper to have the opportunity to make the decision if they are going to sign the "Permission for Publication" and be listed in the IMS List. This is strictly a shipper's decision and not the State's decision to deny or accept such a listing. In either case, the State Rating Agency is required to submit a properly completed FORM FDA 2359i to FDA.*

- *Plants, receiving stations, and transfer stations must achieve a sanitation compliance rating of ninety percent (90%) or higher in order to be eligible for a listing in the IMS List. For plants, receiving stations and transfer stations that have not received a Sanitation Compliance Rating of ninety percent (90%) or higher, the plant cannot sign a "Permission for Publication" to have this facility and rating listed in the IMS List. The Rating Agency is required to officially notify the shipper of the results of this rating, either by submitting FORM FDA 2359i or an official letter to the shipper. FORM FDA 2359i is required to be submitted to FDA following this rating. The Enforcement Rating would not have to be recorded and the "No" box for Permission to Publish must be checked.*

However, the State must remember that with a rating with a Sanitation Compliance Rating of ninety percent (90%) or higher and an Enforcement Rating below ninety percent (90%), they still are required to submit a properly completed FORM FDA 2359i and a "Permission for Publication", with the applicable rating scores recorded on both Forms, to the shipper for the shipper to have the opportunity to make the decision if they are going to sign the "Permission for Publication" and be listed in the IMS List. This is strictly a listed shipper's decision and not the State's to deny or accept such a listing. In either case, the State Rating Agency is required to submit a properly completed FORM FDA 2359i to FDA.

58. **PROCEDURES-Section IV**

When evaluating the following statement from the *Procedures* document, does it also apply to a significant change in the volume of milk shipped from the IMS Listed BTU?

Section IV-Oversight and Responsibilities, B-State Responsibilities, 1. d.: "When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, **significant change in number of producers**, or change in the sanitation compliance or enforcement rating to less than ninety (90), the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Office."

No. It specifically addresses a significant change in the number of producers and does not address a significant change in the volume of milk shipped from the IMS Listed BTU.

M-I-00-8 (Question 31) provided the following answer in relationship to what would be considered a "**significant change in number of producers"**:

FDA considers that a significant change has occurred when a 25% or higher (increase or decrease) in the total number of producers within a BTU has occurred.

59. **PROCEDURES-Section IV**

The following questions relate to M-I-03-12 (Supplement 1)-Updated State Program Evaluation Report General Guidelines And Format And The Addition Of Minimum State Program Evaluation Requirements And Criteria and State Program Evaluation Resolution Process, issued 3/6/2007, and FDA's Compliance Program 18003-Grade "A" Milk Safety Program.

a) When it lists the number of files to be reviewed are we assuming that each farm, plant, etc., has to have an individual file?

This question is in reference to the following documents: “CHECK LIST-Regional Milk Specialist’s Visit to the State for the Gathering of Information for the State Program Evaluation” and “Sample Size Estimates for the Number of Files to be Reviewed by the Total Number of Files and 95% Confidence Level-(Farms, Receiving Stations, Transfer Stations, Milk Plants, Bulk Milk Hauler/Samplers, Industry Plant Samplers, Dairy Plant Samplers, Milk Tank Trucks, etc.)”.

Yes. When RMSs review records/files during a check rating or State Program Evaluation (SPE) we can utilize ledgers; however, we should also be reviewing the individual files to follow up on any issues that we may have with their ledgers. Make sure that during the course of the time period that the SPE is covering that the minimum number of files per groups, i.e., farms, plants, receiving stations, bulk milk hauler/samplers, milk tank trucks, etc. have been reviewed. This minimum number of files that are required to be reviewed may be accomplished during the check ratings that were conducted during the time frame of the SPE. If not, then additional randomly selected files are going to have to be reviewed to meet the minimum numbers as cited in the Table on page 13 of M-I-03-12 (Supplement 1).

b) Are the Asterisk Items the only ones that **DIRECTLY** trigger a “Strategic Action Plan” as designated at the bottom of the document titled, “National Conference on Interstate Milk Shipments Minimum State Program Evaluation Requirements and Criteria”?

Yes. The NCIMS Liaison Committee has identified the "Minimum State Program Evaluation Requirements and Criteria". Within this document they have identified the Critical Evaluation Requirements and the percentage that must be met, which would not trigger a "Strategic Action Plan". If a State does not meet the percentage cited of the Asterisked Items, then this would automatically trigger a "Strategic Action Plan". They did not determine or specifically provide when a State would be classified as not being in "Substantial Compliance" with the Program requirements. This was very difficult to determine and quantify; therefore, they agreed to the document "State Program Evaluation Resolution Process", which was developed by the RMSs and supported by DCP, to be utilized when a State fails to meet a jointly State/FDA Region developed "Strategic Action Plan". That document cites the action that may be taken against a State that is not in "Substantial Compliance" with the Program.

c) The percentages associated with each reviewed Asterisked Item on the document titled, “National Conference on Interstate Milk Shipments Minimum State Program Evaluation Requirements and Criteria”, are they to be strictly adhered to, i.e., 89% completed when 90% is required?

For the Asterisked Items that is true so as to be consistent across the country and to treat all States in a similar manner. This is the level that the NCIMS Liaison Committee determined and FDA agreed to which would trigger the development of a "Strategic Action Plan".

d) Under IV. Attachments cited on the "State Program Evaluation Report/General Format", page 10, it cites that copies of State laws, regulations, policies and procedures, regulatory forms, sampler/hauler materials, Appendix N forms and SOPs are to be included as needed to support conclusions and recommendation. Are these documents and forms required to be submitted with every State Program Evaluation (SPE)?

No. However, if there is something that has significantly changed in State's laws or regulations, since the last SPE, then it may be worthwhile to include it in the SPE. Also, if there is a concern with a specific section of the State's laws or regulations; or a form; or other practice, etc. then it would be worthwhile to include it in the report to support your conclusions and recommendations.

60. **PROCEDURES-Section IV**

When conducting a review of the milk tank truck inspection program during a State Program Evaluation do you utilize the designated period, plus the remaining days of the month in which the inspection is due when determining compliance with the inspection frequency for milk tank trucks?

Yes.

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

How should the issuance and expiration dates be recorded on the certificates issued to State Rating Officers (SROs) and State Sampling Surveillance Officers (SSOs)?

On all SRO and SSO certificates, the actual issuance date and expiration date shall be recorded, i.e. February 1, 2007 and expiration date January 31, 2010, and not just the month and year, i.e., January 2007 and January 2010. The certificates are valid for three (3) years and expire on a specific date. If we cite January 2007, it may have been actually issued on the 12th for example and by listing an expiration date of January 2010, we do not know if it is the 1st or the last day of the month that it actually expires, when in essence it will expire on January 11, 2010.

62. **MMSR-Section D**

EVALUATION OF SAMPLING PROCEDURES-Used with the calculation of Item #9-(Sampling Procedures Approved by PHS/FDA Evaluation Methods) from FORM FDA 2359j-Milk Sanitation Rating Report, Section B. Report of Enforcement Methods, (Page 2).

On a farm rating, none of the samplers identified in #5-(Samplers Evaluated Every Two (2) Years and Reports Properly Filed) were evaluated; therefore, how is #6-(Sampling Procedures in Substantial Compliance) to be handled and filled out?

In this scenario, even though they have not been evaluated in the last two (2) years, they would get 100% Credit for #6 under the current procedures. Under #6, it is recommended that zero (0) and zero (0) be recorded for the "Number Inspected" and "Number Complying", respectively, and 100% Complying with a Credit of fifteen (15) being granted, unless the computer program that you are using does not allow you to input zeros (0s) and still obtain 100% Complying and a Credit of fifteen (15). If this is the case, it is recommended that one (1) and one (1) be recorded for the "Number Inspected" and "Number Complying", respectively, to obtain the 100% Complying and a Credit of fifteen (15) for Item #6.

63. **MMSR-Section D; and Appendix A**

a) Do you utilize the designated period, plus the remaining days of the month in which the inspection is due when determining compliance with the sampling collection procedures inspection frequency for bulk milk hauler/samplers, dairy plant samplers and industry plant samplers when calculating Item #5-Samplers Evaluated Every Two (2) Years and Reports Properly Filed (DAIRY FARMS and MILK PLANT) from **Section C. Evaluation of Sampling Procedures** (FORM FDA 2359j (10/06) (Page 3)) for Part I-DAIRY FARMS, Item #9-Sampling Procedures Approved by PHS/FDA Evaluation Methods and Part II-MILK PLANT, Item #8-Sampling Procedures Approved by PHS/FDA Evaluation Methods from **Section B. Report of Enforcement Methods** (FORM FDA 2359j (10/06) (Page 2))?

Yes.

b) FDA certificates for State Rating Officers (SROs) and State Sampling Surveillance Officers (SSOs) and State delegated Sampling Surveillance Regulatory Officials are valid for three (3) years. Do these FDA certifications and State delegations, respectively, expire on a given date or do they extend to the remaining days of the month in which the FDA certification or State delegation is due?

They expire on a certain date, three (3) years after the FDA certification or State delegation has been granted. The FDA certificate or State delegation shall be issue citing a specific Date of Issuance and a specific Date of Expiration, e.g., Issuance Date of June 1, 2007 and an Expiration Date of May 31, 2010.

Wording from the FDA "Guide to Inspections of Dairy Product Manufacturers"- April 1995, which was incorporated into Proposal 308 passed at the 2007 NCIMS Conference, cited that the FDA certification or State delegation will be valid for three (3) years.

c) If a SRO's or SSO's FDA certification or a Sampling Surveillance Regulatory Official's State delegation has expired, are ratings, sampler/hauler inspections, sampling surveillance delegations or sampler/hauler inspections conducted after the expiration date, without a completed recertification or re-delegation, valid and acceptable to FDA?

They would not be considered valid and; therefore, would not be acceptable to FDA.

*When calculating Item #5-Samplers Evaluated Every Two (2) Years and Reports Properly Filed (DAIRY FARMS and MILK PLANT) from **Section C. Evaluation of Sampling Procedures** (FORM FDA 2359j (10/06) (Page 3)) for Part I-DAIRY FARMS, Item #9-Sampling Procedures Approved by PHS/FDA Evaluation Methods and Part II-MILK PLANT, Item #8-Sampling Procedures Approved by PHS/FDA Evaluation Methods from **Section B. Report of Enforcement Methods** (FORM FDA 2359j (10/06) (Page 2)) credit would not be given for these inspections.*

*Also, credit would not be given for Item #1- Sampling Surveillance Officers Properly Certified and Item #4-Sampling Surveillance Authority Properly Delegated (DAIRY FARMS and MILK PLANT), respectively, from **Section C. Evaluation of Sampling Procedures** (FORM FDA 2359j (10/06) (Page 3)) for Part I-DAIRY FARMS, Item #9-Sampling Procedures Approved by PHS/FDA Evaluation Methods and Part II-MILK PLANT, Item #8-Sampling Procedures Approved by PHS/FDA Evaluation Methods from **Section B. Report of Enforcement Methods** (FORM FDA 2359j (10/06) (Page 2)).*

64. **MMSR-Section F; and FORM FDA 2359i-Interstate Milk Shipper's Report**

What is the correct Product Code for "Kefir" in the IMS Listing?

Product Code #8-Cultured or Acidified Milk and Milk Products (Cow's Milk)
Product Code #33-Cultured Goat Milk and Milk Products
Product Code #38-Cultured Sheep Milk and Milk Products

65. **MMSR-Section F; and FORM FDA 2359i-Interstate Milk Shipper's Report**

a) Is an EPA Certified water laboratory acceptable for water testing under the IMS Program?

Yes.

b) How should an EPA Certified water laboratory be identified on Form FDA-2359i?

The name and address of the EPA Certified Laboratory and the date of EPA Certification shall be recorded under Item #8-Laboratory Control, "Approved Water Laboratory and Date". Also, under Item #8-Laboratory Control, "Water Tests Approved", Laboratory Procedure Code #24-Dairy Water shall be recorded.

66. **EVALUATION OF MILK LABORATORIES (EML); and FDA 2400 SERIES FORMS**

A plant is processing and shipping frozen Grade "A" cream. Under what condition should this frozen Grade "A" cream be delivered to the NCIMS laboratory that will be conducting the analysis?

Samples should be maintained and delivered to the lab frozen. Allowing a change in state (frozen to liquid or visa versa) may cause changes to the sample.

67. **EML; and FDA 2400 SERIES FORMS**

When would the "flat lid method" be used to meet the requirements of Section C. Bacterial Standard and Examination of Single-Service Containers, Appendix J of the PMO for the testing of single service container and closures?

The "flat lid method' is performed on milk container lids that are manufactured separately. The test is to be performed in an IMS listed laboratory approved to perform this test. The sample of lids should be delivered to the laboratory the way they are normally sent to the plants or alternatively, a sub-sample may be sent if aseptically collected.

68. **EML; and FDA 2400 SERIES FORMS**

On containers of less than 100 mL, the microbial count shall not exceed ten (10) as stated in Section C, Appendix J of the PMO. Is this by the rinse test or the swab test? How much rinse solution or swab solution is used?

For 100 mL (about 4 ounces) or smaller containers the swab test must be performed. The swab test uses tubes with 5 mL of solution (Form 2400i, Item 20).

69. **EML; and FDA 2400 SERIES FORMS**

Is the disintegration test addressed in Section C, Appendix J of the PMO on paper stock, required to be conducted in an IMS Listed lab approved for the disintegration test? If not, are there any disintegration tests required to be conducted in an IMS Listed laboratory?

The laboratory conducting the test must be IMS listed and approved to do the disintegration test. The disintegration test described in Form 2400L is the only method currently recognized by the NCIMS.