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M-I-04-6

August 27, 2004

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Questions and Answers from FY'04 Regional Milk Seminars and an
Advanced Milk Processing Course

Following are questions and answers from Regional Milk Seminars and an Advanced Milk Processing Course held during the first half of FY 2004.

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 a 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 will also be available on the FDA 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@cfsan.fda.gov.

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QUESTIONS and ANSWERS
from the
SOUTHEAST REGION MILK SEMINAR-OCTOBER 6-9, 2003,
WILMINGTON, NC,
CENTRAL REGION MILK SEMINAR-OCTOBER 20-23, 2003,
WHEELING, WV,
COMBINED SOUTHWEST AND PACIFIC REGION MILK SEMINAR-NOVEMBER 18-
20, 2003, RENO, NV,
and the
FD 5108 COURSE-JANUARY 5-9, 2004, STURBRIDGE, MA

NOTE: All references to the *Grade "A" Pasteurized Milk Ordinance* (PMO) refer to the 2003 Grade "A" PMO.

1. PMO-Sections 1 and 4 and Appendix L

Are vitamins A and D the only nutrients required to be added back to reduced fat milk products, or are other vitamins; such as, C, E and K, required to be added back?

Vitamins A and D are the only nutrients required to be added back to reduced fat, low fat, and skim or non-fat milk and/or milk products by the PMO. 21 CFR 130.10 specifies that standardized foods that are modified to make nutrient content claims must not be nutritionally inferior to the standardized food. Nutritional inferiority means any reduction of an essential nutrient present in a measurable amount, i.e., at least 2% of the Daily Reference Value (DRV) per Reference Amount Customarily Consumed (RACC). Vitamin C is not a fat-soluble vitamin and; therefore, will not be lost in the separation process. Vitamins E and K are fat-soluble; however, they are present in such small and variable amounts that they do not meet the 2% DRV specified within 21 CFR 101.3(e)(4). Milk modified in accordance with 21 CFR 130.10 would not be required to have vitamins E and K added. However, there also is no prohibition on the addition of these vitamins under 21 CFR 130.10; provided, the addition is in accordance with the nutrient content claim provisions for fortified/enriched, and the name of the modified milk is in accordance with the provisions of 21 CFR 130.10. The nutrient content claim provisions for "fortified" or "enriched" can be found in 21 CFR 101.54.

2. PMO-Sections 1, 4 and 7, Item 16p and Appendix L

a. May dimethylpolysiloxane, an anti-foaming/de-foaming agent, be added to skim milk to be pasteurized, which is used for the production of dry curd cottage cheese and/or to the creaming mixture for cottage cheese?

Yes. The use of dimethylpolysiloxane in standardized foods must be in accordance with the provisions of the relevant standards of identity. Ingredients that are not permitted by the standard may be used under the provisions of 21 CFR 130.8, which allows a food to conform to the standard of identity for that

particular food even if it contains an ingredient not provided for in the standard of identity, provided that: 1) The ingredient qualifies as an incidental additive in non-standardized foods in accordance with 21 CFR 101.100; and 2) The ingredient is introduced in the standardized food as a result of its addition to another ingredient permitted by the standard of identity for that food.

The standard of identity for dry curd cottage cheese does not list “anti-foaming/de-foaming agents” or “dimethylpolysiloxane” as permitted ingredients. However, dimethylpolysiloxane may be used, provided it meets the requirements of 21 CFR 130.8. It may be added to skim milk to be pasteurized and used to make the dry curd cottage cheese; provided, it does not have a technical or functional effect in the finished food, and it is present in insignificant amounts in the finished cottage cheese.

The standard for cottage cheese permits the use of “safe and suitable ingredients” other than milk that have a useful function (other than building the total solids content of cottage cheese) in the preparation of the creaming mixture used in cottage cheese.

b. If so, what amount can be added to the skim milk to be pasteurized?

21 CFR 173.340 limits the presence of dimethylpolysiloxane in a finished food to no more than 10 ppm. (Please refer to 21 CFR 173.340 for certain exceptions to this limitation.)

c. May dimethylpolysiloxane be added after pasteurization?

M-I-86-16, Question #22 provides criteria for the addition of ingredients after pasteurization to a Grade “A” product, provided such addition is made in a sanitary manner that prevents product contamination. The addition of dimethylpolysiloxane after pasteurization, as a powder or liquefied with safe water, may be allowable if it meets one or more of the criteria cited in Question #22. If a firm can provide scientific evidence acceptable to FDA’s Milk Safety Team that indicates that they can safely add “dimethylpolysiloxane” to a pasteurized product, and if the standard of identity for that product allows for the addition of “anti-foaming/de-foaming agents”, they may be allowed to add an “anti-foaming/de-foaming agent” after pasteurization.

3. PMO-Sections 1, 4 and 7, Item 18p

a. A firm adds flavoring and/or spices to Grade “A” sour cream and labels it as “Chip Dip”; for example “French Onion Dip”. Should it be labeled as a Grade “A” product?

Yes. As described, this product would be considered a Grade “A” flavored sour cream.

b. Is this flavored sour cream required to be sampled under Section 6 of the PMO?

Yes. It must be sampled at the same frequency as other flavored milk and milk products.

c. Under the PMO, may a firm ship pasteurized Grade "A" sour cream in bulk (55 gallon containers) to another plant where flavoring and/or spices are added, and it is packaged and labeled as a Grade "A" chip dip.

No. This product, as described, is a Grade "A" milk product. Section 7, Item 18p of the PMO states: "All milk and milk products, including concentrated (condensed) milk and milk products, are bottled and packaged at the milk plant where final pasteurization is performed." Thus, the PMO does not allow the transport of sour cream to a second plant for the purpose of processing and/or packaging of a Grade "A" milk product.

4. **PMO-Sections 1 and 6**

a. Are required coliform tests on blended dry Grade "A" dairy products official tests?

Yes.

b. M-I-02-8 states that bacterial counts are not to be taken on "cultured products, acidified products, condensed products, UF milk, whey and powdered whey". Are Grade "A" powdered dairy blends, which are included in the definition of "Milk Products" in the PMO and referenced under M-I-03-13 (Question 85) included in this list for which the required bacterial counts are now exempt?

Yes. Grade "A" powdered dairy blends that contain dry whey and whey products are included in this list.

5. **PMO-Sections 3, 5 and 7, Item 15r**

a. If a dairy producer keeps his dairy drugs in the horse barn office, which is located on the dairy farm, would we inspect this area?

Yes. M-I-01-03 states: "With regard to drug storage, labeling and use, the scope of a dairy farm operation/inspection extends beyond the milkhouse, milking barn or parlor, including any area reasonably expected to contain drugs used to treat lactating cattle, cattle that may soon be placed in or returned to a milking herd, or other cattle intended for milk production (replacement heifers). Private residences and vehicles are not included without the permission of the owner or their authorized agent."

b. If, during a routine inspection, State Rating or FDA Check Rating, the drug storage cabinet/room is locked and the Regulatory Agency does not have access to the content; or the producer is not available; or the producer refuses to unlock the cabinet, what happens?

The producer must make arrangements with the State Regulatory Agency that will ensure that the Regulatory Agency, Rating Agency and FDA have ready access to the animal drug storage cabinet/room (not located within a private residence or vehicle) for routine inspections, Grade "A" Ratings and FDA Check Ratings, when applicable.

When animal drugs are stored in a locked animal drug storage cabinet/room, access shall be provided to the Regulatory Agency upon request to determine compliance. Denial of access on a regulatory inspection shall be grounds for willful refusal to permit authorized inspection and in conformance with Section 3 of the PMO shall call for the immediate suspension of the permit. When the willful refusal to permit authorized inspection occurs during a State Rating or FDA Check Rating, the farm shall be given -0- credit.

When there is not a person immediately available to unlock the animal drug storage cabinet/room; or when the Regulatory Agency has not been provided a means to readily have access to the animal drug storage cabinet/room through a pre-arranged agreement; or when there is otherwise failure to act in accordance with the pre-arranged agreement, a reasonable effort should be made to seek access to the animal drug storage cabinet/room before debiting Item 15r (seven (7) points) on Form FDA 2359a, Dairy Farm Inspection Report.

6. **PMO-Section 4**

Does the PMO require "Bills of Lading" or "Manifests" for dry milk or dry milk products packaged in bags?

No. Packaged Grade "A" milk and milk products are evaluated by the package labeling criteria cited in Section 4 of the PMO.

7. **PMO-Sections 4 and 7**

An Interstate Milk Shipper (IMS) Listed Grade "A" dry milk plant also has USDA status for dry milk power. All milk received by the plant is from IMS listed sources. The plant had coliform counts not acceptable under USDA Standards. Could the plant change from the USDA Grade and package the product as Grade "A" Dry Milk, since it would meet the Grade "A" requirements for coliform, but not the USDA standard?

Yes. If all applicable criteria of Sections 4 and 7 of the Grade "A" PMO are met. This product must be packaged in bags that are permanently labeled "Grade "A"".

8. **PMO-Sections 4 and 11; and METHODS OF MAKING SANITATION RATINGS OF MILK SUPPLIES (MMSR)**

While conducting a condensed whey (DMO) check rating, it was discovered that the plant is bulk shipping Grade "A" pasteurized cream. The plant is a cheddar cheese plant that ships excess cream. The State is collecting samples, testing the HTST, and inspecting the relevant plant operations. Can this Grade "A" pasteurized cream be included in the DMO Listing?

No. Under the current system, we cannot combine pasteurized or heat-treated PMO products with a DMO listing. There must be separate PMO and DMO listings.

9. **PMO-Section 6**

Is the Regulatory Agency required to sample both plain and flavored yogurt per fat level, i.e., full fat, low fat and nonfat, as specific types of yogurt in accordance with Section 6 of the PMO, or can the Regulatory Agency just sample the categories (full fat, low fat and nonfat) with no regard to whether the product is plain or flavored?

Both plain and flavored yogurt at each fat level: full fat (3.25% or greater, inclusive) reduced fat and low fat (0.5%, 1.0%, 1.5% and 2.0%) and non-fat (less than 0.5 %) are required to be sampled. Section 6 of the PMO does not specify that each different flavored milk product must be sampled separately. It is recommended that each different flavor of yogurt at each fat level be sampled on a rotational basis.

10. **PMO-Section 6**

If a Grade "A" plant is producing and shipping out raw ultra-filtered (UF) milk product(s), are they required to sample and test the raw UF milk product(s) or just the raw milk that the raw UF milk product(s) are made from?

Only the raw milk that the raw UF milk product(s) are made from must be sampled and tested.

11. **PMO-Sections 6 and 7, Item 18r, and Appendix B; and EVALUATION OF MILK LABORATORIES (EML)**

The following Scenario is provided: 1) A bulk milk tank on a farm is not working properly, and the temperature of the milk in the bulk milk tank is 55°F, three hours after the completion of milking; 2) The hauler/sampler collects a milk sample and picks up the milk; 3) The hauler/sampler labels the sample container properly and properly cools the sample; 4) The milk sample is delivered by a state inspector to the laboratory at 33°F; 5) The sample container indicates the temperature of the milk in the bulk milk tank at the farm was 55°F; and 6) This sample was properly cared for from the moment it was collected and was

accompanied by a proper temperature control (TC) sample and delivered to a certified laboratory 10 hours after being collected from the bulk milk tank at the farm.

a. May this sample be analyzed?

Yes. LQAT has always contended that the sample should be marked as a “temperature violation” sample, and, if the State Regulatory Agency desires the sample to be analyzed, then the sample report sheet submitted should be stamped “Unofficial – Does not meet National Conference on Interstate Milk Shipments (NCIMS) Requirements”.

NOTE: *If a bulk milk tank is known or determined to not be working properly, the bulk milk hauler/sampler should immediately notify the Regulatory Agency and should not pick-up the milk. The Regulatory Agency may direct the bulk milk hauler/sampler to collect an official temperature sample for regulatory purposes.*

b. For this question, change only #1 in the above scenario, as follows: 1) The temperature of the milk in the bulk tank was 50°F upon sampling. The sample was collected within 2 hours of the completion of milking. May the sample that is collected be analyzed?

Yes. Such a sample is considered “Official”; however, it must be noted on the collection report or written information accompanying the sample to the lab that the temperature of the milk was 50°F and that the sample was collected within 2 hours of the completion of milking.

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

If an IMS listed plant manufactures whey protein concentrate (WPC) to be used only as an ingredient in a Grade “A” listed product that they process in the plant, i.e., yogurt, must this WPC also be listed?

Yes. This plant will have two listings. The WPC will be listed under the DMO listing and the yogurt will be listed under the PMO listing.

13. **PMO-Section 6 and Appendix B**

The following scenario is concerning a regulatory sample of milk from a farm bulk tank: 1) The milk sample is properly taken at a farm by a licensed hauler/sampler; 2) The sample container is labeled with the date, time of collection, temperature, producer number, and sampler ID; 3) A temperature control sample is taken at the first stop and stored in the sample ice chest; 4) The samples are delivered to a locked refrigerator, which is properly maintained, temperature recorded at least twice a day on each storage shelf and are accessible by only licensed hauler/samplers, at a processing facility; and 5) The samples are picked up from the processing facility by a licensed hauler/sampler and transported to a certified laboratory.

Is the scenario acceptable for a regulatory sample under the IMS program?

Yes. The scenario must also be acceptable to the Regulatory Agency.

14. PMO-Section 6 and Appendix B

The following questions pertain to the producer "Sample Chain-of-Custody" citation in Appendix B of the PMO.

a. Do individuals who package raw producer samples in coolers with ice need to be permitted and evaluated if they are not employees of the dairy plant, or would they only need to be evaluated once each two years?

Appendix B states: "When samples for official laboratory analysis are transported by any individual where the sample chain-of-custody must be established, the driver may be required to carry a valid permit or shall be evaluated biennially for the collection of samples for official laboratory analysis." In the case of individuals who package raw producer samples, as cited above, and sample chain-of-custody must be established, the Regulatory Agency may require a permit; however, the individual repacking the samples is required to be evaluated biennially for the collection of samples for official laboratory analysis.

b. Can certified laboratory analysts repackage samples and transport them to their off-site laboratory from the plant, transfer station, or receiving station?

Yes. It must be acceptable to the Regulatory Agency. The same criteria cited in a. would apply.

15. PMO-Section 6 and Appendix N

Appendix N states: "Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers." What additional testing is required?

At the current time, no additional testing besides the required Section 6 and Appendix N Beta lactam testing is mandated. A State may choose to test for additional drugs under their State Laws or Regulations.

*The PMO states: "**Note:** When the Commissioner of the Food and Drug Administration (FDA) determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will continue until such time that the Commissioner of the Food and Drug Administration is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon:*

- Sample survey results,
- USDA tissue residue data from cull and veal dairy animals,
- Animal drug disappearances and sales data,
- State feed back, and
- Other relevant information.”

16. **PMO-Section 6; and MMSR**

When reviewing vitamin testing records, during Ratings and Check Ratings, for the required annual vitamin A and/or D assays of fortified milk and milk products, which products should be evaluated for purposes of the Enforcement Rating?

Until further notice, for purposes of calculating the Enforcement Rating, evaluate only those milk and milk products that have a validated vitamin testing methodology. Currently, the only pasteurized milk or milk products that have a validated vitamin testing methodology are white milk and milk products (whole, reduced fat, lowfat and nonfat).

NOTE: *Sour cream, yogurt, half-and-half, cottage cheese, and flavored milk and milk products, etc., do not have validated test methodologies.*

17. **PMO-Section 6; and EML**

Are delegated Regulatory Sampling Surveillance Officers (SSO) required to be evaluated on their sampling procedures every two years by a State SSO or another Regulatory SSO?

Yes, if they are responsible for the collection of official regulatory samples.

18. **PMO-Section 7, Item 2r**

With the increase of barns with basements, which house milk lines, receivers, etc., if the basement opens into a room other than the parlor, does it need a door to the basement to separate the rooms?

A door would only be necessary if there are milkhouse operations conducted in the basement.

19. **PMO-Section 7, Item 3r**

May sand be used as a bedding material in the milking area of a stanchion or tie-stall barn?

Yes. In a milking area where milking animals may be housed, sand may be used; provided, the milking area complies with Item 3r. However, the bedding material, if used, must not contain more manure than has accumulated since the previous milking.

20. PMO-Section 7, Item 7r

Assume the toilet on a dairy farm is clean and in good functioning order. Is it a violation of 7r if there is no toilet paper in the toilet room on the farm?

Yes.

21. PMO-Section 7, Items 8r and 18r and Appendixes D and G

a. Who can sample the potable water supply providing water to a Grade "A" dairy farm facility and a re-circulating cooling water system that may be in use?

Water samples must be collected by a person acceptable to the State Regulatory Agency.

b. Is this person required to be a licensed/permitted/evaluated sampler?

No.

22. PMO-Section 7, Items 8r and 7p

Have there been or do you know of any portable high-pressure washers which come with a factory installed low-pressure cut-off switch?

None that we are aware of; however, some models have built-in reservoirs with an appropriate air gap provided that would not require a low-pressure cut-off switch.

23. PMO-Section 7, Item 8r and Appendix D

How is a drilled well, located directly outside the milking barn and within a few feet of a concrete manure gutter in a stable type milking area evaluated?

This would be considered a violation of Item 8r (5 point debit) of the PMO, unless it can be shown that the construction of the concrete floors and gutters is acceptable, i.e., free of cracks, crevices, holes, etc., and will prevent the leaching of animal waste into the surrounding ground or directly into the well.

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

Is it considered a violation if the end of a water hose is below the flood rim of a 2 compartment wash vat in the milkhouse and the vat is not plugged and there is no standing water?

No.

25. **PMO-Section 7, Items 11r and 12p and Appendix F**

Why have applications of hydrogen peroxide applied to a milk product contact surface and then driven off by high heat been accepted for sterilizing aseptic product packaging and product contact surfaces in the sterile zone of aseptic packaging equipment when there are currently not any applications for hydrogen peroxide that are acceptable for use as hard surface sanitizers?

The use of hydrogen peroxide alone, as a sterilizing agent or sanitizer, has not been accepted. Hydrogen peroxide must be in combination with other processes, i.e., heat, as specified in 21 CFR 178.1005, and/or in solution with other acceptable ingredients, as specified in 21 CFR 178.1010, respectively, in order to be used as a sterilizing agent or sanitizer on packaging and dairy equipment.

26. **PMO-Section 7, Item 14r**

Regarding the protection of the re-circulation line on a farm bulk tank that is disconnected from the tank outlet after the tank is cleaned, and the other end remains connected to and is open to the inside of the tank through the spray device; does a brush inserted into the opening of this line provide acceptable protection for the milk in the tank?

No. The re-circulation line must be properly capped with a solid cap.

27. **PMO-Section 7, Item 18r and Appendix Q**

Appendix Q, dealing with Automatic Milking Installations, makes the following statement in Item 18r, Raw Milk Cooling: "Bulk milk tank recording thermometers are recommended", does this mean that recording thermometers are recommended on new bulk tanks?

No. Item 18r, Administrative Procedure #3 of the PMO states: "All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature recording device."

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

What protection is required when separating a water line that is directly connected to a product line?

An approved back flow prevention device is required on the water line. A sanitary check valve and sanitary piping down stream from the check valve on the water line is also required to protect the water system from the product.

If the product conducted through the product pipeline will not be condensed or dried, additional safeguards to prevent adulteration with added water must be provided. Connections to milk lines or valve clusters need to provide a similar

level of protection against adulteration with water.

Following are examples of additional safeguards, which are application specific:

- 1. Swing elbows are used to create a physical break when product is in the line.*
- 2. In HHST systems, with both a product and a water tank feeding the system, non-pasteurized water is often separated from non-pasteurized product, using a block-and-bleed valve arrangement.*
- 3. In the case of a water line that is permanently installed in a line that feeds a balance tank, we have accepted valve arrangements that will assure that water leaking past the water valve will go to the floor and not into the balance tank.*

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

A plant plans to reuse cow water for various purposes in the plant. After coming off the evaporator at 140°F and through piping to a hot collection or storage tank, with a turbidity or conductivity meter prior to the hot storage tank, one use will be into a pre-heater section of the HTST press to pre-heat raw milk going to the regenerator. The plant plans to then collect the cow water exiting from the HTST press in a cold storage tank for additional use in the plant.

a. In the scenario above, does the plant need a turbidity/conductivity meter after the HTST pre-heater and prior to the cold storage tank?

*Yes. This water may be used for Category II, provided all Category II requirements are met, and for Category III purposes. However, this additional turbidity/conductivity meter located after the plate type pre-heater and before the cold storage tank is **NOT ADEQUATE** protection from raw milk that may leak into the reclaimed water through a defect in one or more plates. Therefore, this reclaimed water may not be used for Category I purposes.*

b. With the addition of a second meter after the plate type pre-heater and before the cold storage tank, does the plant still need the turbidity/conductivity meter before the hot cow water storage tank?

Yes.

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

May potable water utilized for a plate heat exchanger in a Grade "A" dairy plant be reclaimed for potable water purposes if the water meets the same basic requirements as for reclaimed water on farms?

No. Provisions for the use of reclaimed water from plate heat exchangers in plants are not addressed in the PMO.

31. **PMO-Section 7, Item 7p and Appendixes D and G**

A dairy plant uses city water. The city gives notice to all customers that the water supply is unsatisfactory. What should the State Regulatory Agency have the plant do?

If the water supply does not meet the PMO requirements, the State Regulatory Agency needs to verify that the plant adheres to the regulatory requirements and refrains from using the unsatisfactory water supply, unless the dairy plant can demonstrate to the satisfaction of the Regulatory Agency that the problem causing the unsatisfactory water supply has been addressed by the plant's water treatment program.

32. **PMO-Section 7, Item 7p and Appendixes D and G**

a. Do the same plumbing codes apply to “cow” water (reclaimed water meeting the requirements to be used as potable) as they do to city water?

Water reclaimed from milk or milk products (from condensing or reverse osmosis (RO) processes, i.e., cow water) may be reused when all necessary means of protection are afforded, and it complies with the procedures outlined in Appendix D., Part V of the PMO. All necessary means of protection does not necessarily mean all the same plumbing code requirements, but may include many of the same protections afforded potable water systems; such as, preventing cross connections with unsafe water and/or other possible contaminants. The PMO requires that systems used for reclaimed water from milk and milk products must be completely separated from the potable water supply.

b. What if a plant mechanically cleans the “cow” water distribution system on a regular basis?

“Cow” water must still comply with Item 7p, Administrative Procedure #5 and the provisions of Appendix D of the PMO.

33. **PMO-Section 7, Items 10p, 11p, 16p(B), 16p(C) and 16p(E) and Appendixes H and I**

If you observe, on a Rating or Check Rating, a magnetic flow meter or flow diversion valve that has not been reviewed by FDA or accepted by the State Regulatory Agency for usage in the manner being used, is this a violation or can you utilize the equipment tests run by the Regulatory Agency to validate the proper functioning of these pieces of equipment?

This would not be an automatic debit on a Rating or Check Rating. Appendix H of the PMO, under Components of the Magnetic Flow Meter Based Timing Systems for HTST Pasteurizers, states: “Magnetic flow meter based timing systems shall consist of the following components: 1. A sanitary magnetic flow meter which has been reviewed by FDA or one (1) which is equally accurate,

reliable and will produce six (6) consecutive measurements of holding time within 0.5 seconds of each other.” Therefore, a magnetic flow meter must have been reviewed by FDA or the Regulatory Agency to determine that it is equally accurate and reliable to ones that have been reviewed by FDA or the plant must be able to demonstrate to the satisfaction of the Regulatory Agency that the magnetic flow meter is equally accurate and reliable to ones evaluated by FDA. This technical information regarding accuracy and reliability of the system must include information from the manufacturer that addresses specific methods of testing, recommended methods of installation and operation, results of any field tests performed by the manufacturer, rate of updating the meter, the flow direction, susceptibility to electromagnetic interference and sealing instructions.

The PMO does not require that a flow diversion device be reviewed and accepted by FDA prior to use. If this equipment is found not to meet the design, construction, installation requirements and operational procedures of the PMO, the violations shall be debited in the appropriate location on Form FDA 2359, Milk Plant Inspection Report, and points shall be taken off of the Enforcement Rating for the Regulatory Agency's failure to interpret the PMO properly.

34. PMO-Section 7, Item 11p

Is it allowable to have a mild steel exhaust fan in a dryer system or would it need to be stainless steel to comply with the PMO?

We have not objected to the presence of mild steel dryer system exhaust fans. The flexibility of mild steel may be needed in this application. Under Section 7, Item 11p, of the PMO, a dryer system exhaust fan of mild steel would be considered a violation during a Rating or Check Rating if it is rusted or in poor condition.

35. PMO-Section 7, Item 12p

Is a Grade “A” RO or UF milk processor that runs for longer than 24 hours required to have an extended run approval?

Yes.

36. PMO-Section 7, Item 12p

a. Will a quick wash on an HHST pasteurizer, that is done with the equipment remaining in forward flow, satisfy the requirement that the HHST equipment be cleaned every 24 hours?

No.

b. What if it has been evaluated and accepted for longer operation under the extended run provision?

The Regulatory Agency should have scientific and inspectional data that supports their decision and that the criteria for regulatory evaluation identified in Item 12p, Administrative Procedure #1, of the PMO is followed.

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

Due to the sanitization and washing requirements for milk storage tanks, may cooled pasteurized cultured products be held in a storage tank or vessel longer than 72 hours?

The tank or vessel is required to be emptied and cleaned every 72 hours, unless the State Regulatory Agency, in consultation with FDA, has reviewed an extended run protocol and has granted acceptance for this specific tank or vessel.

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

An evaporator has a built-in HTST system as part of the evaporator. This evaporator can only be operated if the HTST system runs product through it.

a. May the entire system run for 44 hours prior to clean up?

Yes. The HTST must be an integral part of the evaporator and the product is being fed directly to the evaporator.

b. May all components used to feed the evaporator; such as, pre-heat press units, etc., run for the 44 hours with the evaporator?

Yes.

NOTE: *The separator(s) in the systems used to verify the safety of operating an evaporator for a continuous period not to exceed 44 hours did not operate continuously during the 44-hour evaluation period. Currently, there is not an exemption for the operation of separators in excess of 24 hours.*

c. The heater section, balance tank, etc., of the HTST system is built into the evaporator. Does this proposal only limit the 44-hour run to the evaporator from the FDD downstream?

No.

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

Is an electronic signature required for computer stored mechanical cleaning records?

No. An electronic signature is one option. Refer to Section 7, Item 12p, Administrative Procedure #2 for additional information.

40. **PMO-Section 7, Item 12p(a) and (c)**

M-I-01-5 stated that Tetra Pak's response to the cleaning and construction problems with the vacuum vessels included a commitment to inspect each older unit with a boroscope. This was to be completed by May 2002. Was this a one-time deal by Tetra Pak or was it to be an on-going process to be done every six (6) months or yearly?

In May 2002, Tetra Pak completed their examinations on all of their VTIS vacuum chambers that are of the older designs (1989 and 1998). Followup inspections were made to verify the cleaning of equipment found dirty, and equipment found with internal construction problems (mostly the 1989 design) have been or are being repaired.

Vacuum chambers of the 1989 and 1998 designs cannot be visually inspected and will need to be examined as described in M-I-01-5 for as long as they remain in service. The frequency mentioned in M-I-01-5 is six (6) months, with followups for unclean equipment, until the State Regulatory Agency decides that a greater interval between examinations is warranted.

At the present time, Tetra Pak has agreed to examine these vacuum chambers at least one more time to be sure that there is an opportunity for regulatory and plant personnel, if they choose to be present, to learn to make these examinations accurately. After that, they have committed to make information available regarding where milk plants can rent equipment to make these evaluations.

We strongly suggest that State Regulatory Officials and industry personnel that will be conducting these examinations in the future use this next set of examinations to be sure that they know how to perform these examinations and interpret the video recordings produced during these examinations.

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

a. What is the minimum time and temperature for steam sanitization of a processing vessel?

Steam flow must be maintained at the outlet of the vessel for at least five (5) minutes after the temperature of the discharge at the outlet has reached 94°C (200°F).

b. When tanks are being automatically steam sanitized, is a temperature-recording device required to show that the minimum time and temperature for steam sanitization has occurred?

No. If the sanitizing process is not performed as a continuous part of the cleaning cycle, then a separate record must be made of the sanitizing process.

A means acceptable to the Regulatory Agency to verify that this minimum required sanitization time and temperature is being met must be provided.

c. A firm has charts covering cleaned-in-place (CIP) cleaning of the tanks, but not the steam sanitizing of the tanks. The firm wants to know if they can just set the computer control system for steam sanitization without having to have a temperature-recording device.

Refer to the answer in b. above.

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

Does a computer password suffice for securing computer controls of a single-bodied, double-seated valve used for separating cleaning solution from milk or milk product as required by Item 15p(B) of the PMO?

Yes. It must be acceptable to the Regulatory Agency.

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

Item 15p(B) of the 2001 PMO does not allow for steam blocks to separate product and CIP solution. Until the effective date of IMS-a-44, Proposal 131, are no steam blocks allowed or are all steam blocks acceptable regardless of design?

If a Regulatory Agency can legally enforce the provisions of the PMO, related to steam blocks, prior to the established effective date for steam blocks cited within Proposal 131 (one year from the date on which the remainder of the proposals passed at the 2003 Conference become effective in each State), steam block(s) will be acceptable, if the alarmed steam block(s), located between the product and cleaning and/or chemical sanitizing solution, comply with the requirements of the PMO and are acceptable to the Regulatory Agency and FDA. Steam block(s) that do not meet Proposal 131 are not acceptable.

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

May computers (Programmable Logic Controllers) be networked that are used for separating cleaning solution from product, as required by Item 15p(B) of the PMO?

Yes. It must be acceptable to the Regulatory Agency.

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

Is it a violation to connect several vat pasteurizers by a common outlet line during processing? If so, would this be a violation of Item 15p or 16p of the PMO?

The use of a common line between pasteurization vats would not automatically be considered a violation. However, during a routine inspection or equipment test, Rating or Check Rating, the following areas of concern involving vat pasteurizers must be thoroughly evaluated:

- The operator should be asked to carefully (aseptically) disconnect the outlet line or cap from the outlet valve, and an inspection for leakage of product past the forward seat of the valve shall be conducted. If milk product is observed leaking past the forward valve seat, either in the outlet cap (Item 16a(2)(h) debited) or common line connected to the outlet valve, Items 16a(2)(h) or 15(b)(a) on Form FDA 2359i-Milk Plant Inspection Report should be debited.

NOTE: If the milk plant is regulated and listed under the voluntary HACCP alternative, utilize the same criteria outlined in the paragraph above. In addition, review the plant's written HACCP program to determine whether the potential problems of a common outlet line have been addressed and whether the plant is complying with their own written HACCP requirements. If milk product is observed leaking past the forward valve seat either in the outlet cap (Section 10 G. debited) or common line connected to the outlet valve, Sections 9. A. 3. and/or 10 G. on the Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report, should be debited. The milk plant must also take corrective action to deal with product not meeting the critical limit for vat pasteurization as described in Appendix H. MILK AND MILK PRODUCT VAT (BATCH) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY of the PMO.

Regardless of how the milk plant is regulated and listed, the State Regulatory Agency may take immediate action, as provided by Section 5 of the PMO. The determination whether this issue rises to the level of a critical processing element must be done on a case-by-case bases, based on a thorough evaluation of the circumstances.

Other areas to consider when conducting an evaluation of a vat pasteurizer:

- The excessive use of lubricant on the outlet valves and the method used to apply this lubricant (manually, spray, etc.) could result in the blockage of the leak protect grooves or the contamination of the outlet valve.
- Failure to hold the product for the minimum holding time, if the product is being pre-heated prior to entering the vat pasteurizer or is being cooled after opening the outlet valve.

46. **PMO-Section 7, Item 15pB and Appendix L**

- a. May a Grade "A" dairy plant perform a water flush in order to flush raw milk from bulk milk tankers to the raw milk silos?

Yes. The water-milk mixture may be flushed directly to the raw milk silo if the milk plant condenses, concentrates or dries the milk or milk product, or if the milk plant takes other appropriate actions to prevent the dilution or adulteration of milk with the added water. An example of an appropriate method to accomplish this is to flush the bulk milk tanker with potable water to a separate tank or vessel and capture this raw milk slurry for further processing. Other examples might include the use of a system or process designed, constructed and controlled that manually or automatically prevents the addition of water. The efficacy of this system should be verifiable if challenged.

b. How may this recovered water-milk mixture be used in Grade "A" milk products?

This recovered milk mixture may be used in cultured milk, 21 CFR 131.112 (d), and eggnog, 21 CFR 131.170 (e), as an "other optional ingredient", to reconstitute dried milk and condensed ingredients. Additionally, it may be used in yogurt and in cottage cheese creaming mixtures.

47. PMO-Section 7, Item 16p

a. Does bulk Grade "A", 40% solids, acid whey being shipped in interstate commerce have to be re-pasteurized, if all the requirements of the PMO are met for the exemption for whey with 40% solids?

No. If the whey complies with the requirements in Item 16p of the PMO, it does not have to be re-pasteurized following transport to another plant.

b. Is whey with 40% solids exempt from temperature requirements if the correct pH is met?

No. The PMO does not provide for an exemption from the requirement that condensed (to at least 40% total solids), acid and partially crystallized whey be cooled and maintained at = 45°F (7°C) for transporting from one plant to another.

48. PMO-Section 7, Item 16p

Is it acceptable to adjust the pH of pasteurized condensed, partially crystallized whey to a pH in the range of the mid-6's, using a solution of hydrated lime and un-pasteurized potable water at a pH of 11 to 12, without re-pasteurization of the pH adjusted whey product?

Yes.

49. PMO-Section 7, Item 16p

IMS-a-44, Proposal 136 adds the words, "if required," in front of the requirement to seal the STLR on HHST systems. Under what conditions would an STLR on an HHST system, used for legal pasteurization, not be required to be sealed?

The cut-in and cut-out set points for all continuous flow pasteurizers, including HHST pasteurizers, must be sealed. Proposal 136 acknowledges that some systems may be used to process previously pasteurized milk or milk products for the purpose of labeling them ultra-pasteurized. Equipment used strictly for this purpose is located after the legal pasteurization equipment and does not need to be sealed. The words, "if required", in Proposal 136 refer to these systems.

50. **PMO-Section 7, Item 16p and Appendix K**

a. If a HACCP plant breaks a public health control seal, is the plant required to notify the Regulatory Agency?

Yes. In all cases the Regulatory Agency must be notified of a broken seal.

b. May the HAACP plant re-seal the public health controls?

Yes, if acceptable to the Regulatory Agency.

51. **PMO-Section 7, Item 16p(A) and Appendix H**

What are acceptable digital indicating thermometers for vat pasteurizers?

Digital indicating thermometers that meet the requirements of Appendix H, INDICATING THERMOMETERS FOR BATCH PASTEURIZERS and AIR SPACE INDICATING THERMOMETERS FOR BATCH PASTEURIZERS of the PMO and found acceptable may be used.

52. **PMO-Section 7, Items 16p(A), 16p(B) and 16p(C) and Appendixes H and I**

In addition to the read out panel door, is the probe (cap) of a digital indicating thermometer used for pasteurization systems required to be sealed?

Yes.

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

Where does the holding tube begin and end in an HHST pasteurizer?

The holding tube begins at the point after the product exits the final heater where the piping begins a continuous upward rise of at least 1/4 inch per foot and ends where this rise ends.

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

Are all HHST pasteurizers that utilize steam infusion technology required to have a timing pump?

No. However, older versions of DASI HHST pasteurizers may need a pump installed between the infuser and the holding tube in order for the equipment to be capable of safely complying with the requirement that "the pasteurizer or aseptic processor shall not operate in forward flow, unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product".

55. **PMO-Section 7, Items 16p(B) and 16p(C)**

Why are STLRs allowed that require breaking the seal before the pen arm can be adjusted?

Design features are the manufacturer's purview, as long as they do not violate PMO requirements they are acceptable.

56. **PMO-Section 7, Items 16p(B), 16p(C), and 16p(E) and Appendix I; and MMSR**

Scenario: If the Regulatory Agency states that a particular (required) test could not be conducted on a pasteurizer, due to the fact that the information requested by the Regulatory Agency, which is necessary to conduct the required test, has not been provided, is the omission of a required pasteurization equipment test a Regulatory Agency enforcement violation during a Rating or Check Rating?

Yes.

NOTE: *Under the HACCP alternative, Section 7. D. on the Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report would be marked. Because this is a critical listing element (CLE), the State Listing Agency must immediately remove the milk plant's listing.*

57. **PMO-Section 7, Items 16p(B) and 16p(E)**

How much time does a Rating Officer give the Regulatory Agency to test and seal a newly installed HHST or HTST pasteurization system, before the failure to time and seal the system becomes a violation.

None. A pasteurization system must be tested and sealed upon installation and before the system is used to process milk and milk products.

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

May air lines on separator isolation valves have a quick disconnect?

Yes. Separators must be automatically valved-out of the system. This is accomplished using valves that are spring-loaded to the separator valved-out position; therefore, quick disconnects on these air lines are a non-issue.

59. **PMO-Section 7, Item 16p(B) and Appendixes H and I**

If HTST systems have multiple cut-in and cut-out set points, do you need to check each set point each day?

*No. Provided that, the **same minimum pasteurization time setting** is used for each of the temperature settings on a particular pasteurization system, i.e., eggnog at 180°F/15 sec. and chocolate milk at 166°F/15 sec.*

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

a. Is the ten (10) minute CIP time delay relay required on HHST systems?

Yes. The ten (10) minute CIP time delay relay is required on HHST systems with a Flow Diversion Device (FDD) located after the cooler section, when it is desired to run the timing pump and/or other flow promoting devices during the CIP cycle without the controls required during “product” processing.

b. If so, what pumps are permitted to run while in CIP mode?

During the ten (10) minute time delay relay, the FDD must remain in the diverted flow position, and pumps that are permitted to run in diverted flow may run.

61. **PMO-Section 7, Item 16p(C) and Appendix L**

In a Grade “A” IMS listed plant that produces aseptic milk or milk products, is the plant required to comply with the requirements of the PMO, as well as, the filed process?

Yes.

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

If captive water, on the raw side of an HHST milk-to-water-to-milk regenerative heat exchange system, is not protected by using pressure controls, but the same captive water system, on the pasteurized side of the regenerator, is protected, is this a concern?

No.

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

If a CIP-able vacuum breaker’s vent line is directly attached to a tygon drain that releases to the floor, does the tube at its release point effectively lower the atmospheric break?

Yes. The vacuum breaker must be installed according to M-b-322 and the Instruction Manual # IM881-35779. During pasteurization, there may not be a hose or piping attached to the CIP fitting, which would negate its affect. If found during a routine inspection, Rating or Check Rating, this would be considered a violation of Item 16p(D)(a) on Form FDA 2359-Milk Plant Inspection Report.

If found during a routine audit under the HACCP alternative, Section 10. G. on the Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report would be marked

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

Is the PMO Pasteurization Equipment and Controls Test #15 for Electro-Magnetic Interference (EMI) required to be applied to mix-proof valves at the stated frequency? If these valves are not appropriately tested, is there a violation?

No to both questions.

65. PMO-Section 7, Item 16p(E) and Appendix K

During a State Regulatory Audit, if a HACCP plant fails to ensure that all pasteurizer tests are performed by industry at the prescribed frequency, is there a permit action?

If this practice is not corrected in a plant, which industry has been authorize to conduct the equipment testing, after a written notice by the Regulatory Agency, the Regulatory Agency should begin action to suspend the permit as required by Section 5, Inspection of Dairy Farms and Milk Plants, of the PMO.

66. PMO-Section 7, Item 17p

Is the water in a milk-to-water-to-milk regenerative heating system required to be sampled under Item 17p, Recirculated Cooling Water, of the PMO?

No.

67. PMO-Section 7, Item 17p

Acidified sour cream (pH 4.5) is being filled into four (4) gallon buckets (33 lbs.) at 80°F and higher, is this a violation of Item 17p of the PMO?

The PMO does not provide for a cooling exemption for acidified products, including acidified sour cream; however, FDA does not consider the conditions represented in this example to be a food safety hazard and recommends that regulatory discretion should be used until such time as this issue is addressed at the 2005 NCIMS Conference. FDA will look at other time/temperature/pH conditions and make recommendations based on available models on a case-by-

case basis.

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

Item 17p, Administrative Procedure #10, of the PMO, allows recirculated cooling water in continuous pipes to be cooled with non-potable water in open evaporative cooling towers. These pipes may have welds, which meet applicable ASME or equivalent standards. When this is done:

a. Is the open evaporative cooling tower water required to be sampled and tested semi-annually?

No.

b. Is the recirculated cooling water enclosed in continuous pipes required to be sampled and tested semi-annually?

Yes.

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

What are the temperature requirements for the packaging of cultured products and/or cottage cheese?

The PMO states: "All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 7°C (45°F) or less. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less."

A product that has been previously cultured; such as cottage cheese, must meet the temperature requirements cited above.

FDA recommends that regulatory discretion should be used until such time as this issue is addressed at the 2005 NCIMS Conference.

Products to be cultured are different: Products in containers to be cultured in the container include sour cream and various yogurts. These products may be packaged in a liquid form and "set" in the container, using a starter that is added just prior to packaging. In this case, when culturing is stopped, normally by moving the product from a warm incubator or culturing room to the product cooler, the packaged product must be stored in a cooler that is maintained at 7°C (45°F) or less.

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

Is it a violation if the product contact surface of roll stock that is used on a Tetra Pak aseptic packaging filler is not shielded from the point that it leaves the roll to the point it enters the machine to be hydrogen peroxide sterilized?

No. This equipment was originally reviewed and accepted with the understanding that the packaging material is moving rapidly toward the hydrogen peroxide application point and will be sterilized within a few seconds.

71. PMO-Section 7, Item 18p

a. What overhead protection is required on a filler after applying the foil seal to the plastic bottle with product in it and the addition of the protected plastic cap?

None.

b. Does the cap and foil seal have to be from an IMS listed source?

Yes.

72. PMO-Section 7, Item 21p

What may be hauled in Grade "A" milk tank trucks prior to them hauling Grade "A" milk or milk products?

Item 21p of the PMO states: "Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans." Food grade ingredients, food additives, GRAS substances, etc., are acceptable as long as there is adequate and documented washing and sanitizing of the milk tank truck prior to their use for milk or milk products. This may include the visual inspection of the milk tank trucks.

73. PMO-Appendix I

What components of the Taylor Magnetic Flow Meter System, as described in M-b-238, are required to be sealed?

The high-flow and low-flow/loss-of-signal alarms and the required time delay relay, following a diversion based on excessive flow, are required to be sealed.

74. PMO-Appendix I

Is there an approved/compliant test procedure for testing Tri Clover Flo-Diversion Valves, Models 762-227 and 762-227 MRAL, by only removing the air line and capping the vent?

No. The accepted test procedures for these models must be used, as specified in the M-b for these models. The tests described in the manual, that are referenced in M-b-330 for these valves, describe the disassembly of the valve and the use of a spacer provided with the valve. These are the test procedures that were reviewed and accepted and are the ones that must be followed. The spacer is only used with the newer Tri Clover Flo-Diversion Valves. Older Tri Clover Flo-Diversion Valves are disconnected, using the quick release sleeve.

75. **PMO-Appendix J**

Is PVC an acceptable material for moving resin from the resin silo(s) to the blow-mold machines?

Yes. It must be food grade. An example is a polyurethane-lined PVC food grade material handling hose with embedded static wire for dry applications. Such hoses have been identified for use with polymer (resin) pellet transfer.

76. **PMO-Appendix N**

Milk tankers may be constructed with two (2) compartments that are filled and emptied through a common manifold that connects to valve controlled pipelines from each compartment. When Appendix N testing at the receiving plant indicates that one (1) of the compartments is adulterated, is the single valve seat separation adequate protection when the negative compartment is pumped off?

Yes.

77. **PMO-Appendix N**

According to Appendix N, Part B (Enforcement), of the PMO, an accepted protocol for reconditioning antibiotic milk is required in order for this milk to be fed to animals, which may be entering the human food chain.

a. If a State does not have an accepted protocol for reconditioning, what authority does the State have if an antibiotic load goes to animal feed without their knowledge, and they find out about it later? (Would CVM or USDA want to know?)

A State has the responsibility to protect the public health. It is recommended that the State work together with FDA-CVM to develop legal or regulatory action against the individual(s) or party (parties) in violation of the reconditioning requirements of Appendix N and FDA Compliance Policy Guide (CPG 7126.20).

b. If the State informs their industry about this and industry goes ahead and feeds the adulterated milk to animals anyway, what would the State do then?

The appropriate action to be taken by the State would be based upon the State's legal regulatory authority.

78. **PMO-Appendix N**

If antibiotic positive milk was taken to a facility for animal feed and the protocol was not approved by the State and acceptable to FDA, what recourse would a State have on a routine inspection and Rating against the plant sending the milk to be dumped?

The State should inform FDA-CVM and USDA and they may ask for assistance in making a legal case against those that violate the reconditioning requirements of Appendix N of the PMO and their State Laws and Regulations.

States should take appropriate legal action as indicated in their State Statutes, Laws, or Regulations, i.e., seizure and hold orders (detention of product) for any product that is adulterated and not suitable for human food.

79. **PMO-Appendix N**

May a bulk milk tanker found to be presumptive positive, using IDEXX New Snap test kit, be load confirmed, using the old SNAP test kit?

No, not after July 7, 2004.

80. **PMO-Appendix N**

Is the IDEXX New Snap test kit approved to test raw goat milk?

No.

81. **PMO-Appendix N**

Of the 17 test kits cited in M-a-85 (Revision #11), Beta lactam Test Methods for Use Under Appendix N and Section 6 of the Pasteurized Milk Ordinance (PMO), which test kits are approved for use on raw goat milk?

CHARM SL; CHARM II Sequential; Penzyme Milk Test; Delvo 5 PAK; and BSDA + Bacillus subtilus.

82. **MMSR**

A number of forms were added to the MMSR to be used with the Voluntary HACCP Program. One of them was a "Permission to Publish" that addresses both the HACCP Program and the traditional rating system with the implementation of the 2003 MMSR. Will this form now be the required form to be submitted with the FDA Form 2359i to the FDA RMS?

Either this form or a State form with similar wording would be acceptable.

83. **MMSR**

a. What should happen, if during a Check Rating or FDA HAACP Audit, the RMS suspects the shipper has been pre-notified of the Check Rating or HACCP Audit?

If prior to, or when conducting the field work (farm or plant inspections/audits) for an IMS Listing, the FDA RMS determines that the dairy farm(s) and/or milk plant have been pre-notified (i.e., specifically prepared for this Check Rating or HACCP Audit), the RMS shall immediately terminate all Rating/Auditing activities. At this time, the RMS may select an alternate BTU or milk plant. Following the termination of a Check Rating/Audit, a written notification shall be sent from the FDA Regional Office (RFDD or designee) to the State Rating and/or Regulatory Agency Program Director and the State Commissioner of Agriculture or State Health Officer, as applicable, with a copy to the FDA CFSAN/Milk Safety Team. This letter shall provide the circumstances relative to the rating/audit termination. Should this situation continue to persist within the State, this concern shall be included in the next State Program Evaluation and shall be reported to the NCIMS Executive Board.

b. What should happen, if during a State Rating or HACCP Listing Audit, the State Rating Officer (SRO) suspects the shipper has been pre-notified of the Rating or HACCP Listing Audit?

If prior to, or when conducting the field work (farm or plant inspections/audits) for an IMS Listing, the SRO determines that the dairy farm(s) and/or milk plant have been pre-notified (i.e., specifically prepared for this Rating or HACCP Audit), the SRO shall immediately terminate all rating activities.

NOTE: *This response is not intended to prohibit the notification that is traditionally associated with an original listing, a re-inspection, a re-rating or a re-audit conducted at FDA's request following a Check Rating or FDA Audit. It is recommended that State Rating Agencies do not routinely conduct Ratings/Listings at or near their expiration date. It is suggested not to use any set interval for conducting IMS Listings prior to the expiration date, so as not to provide potential pre-notification.*

84. **PROCEDURES-Section IV.B.6.c.**

What is considered the official formal notification/written recommendation to the State Rating Agency of the results of an FDA Check Rating or HACCP Audit?

A completed Form FDA 2359h (Interstate Milk Shipper Check Rating Report) signed by the RMS conducting the Check Rating (with or without the signature of the State Rating Agency representative) constitutes the required formal notification and/or written recommendations of PHS/FDA of their Check Rating/Audit results at the time it is provided to the representative of the State Rating Agency. This may be accomplished via hand delivery, FAX, E-mail or mail. The RMS is encouraged to have the State sign Form FDA 2359h. States are encouraged to sign Form FDA 2359h, when provided with the opportunity. If a State Rating Agency representative declines to sign the Form, the RMS shall provide the Form to the State Rating Agency representative and make a notation on the Form in regards to whom and when the Form was provided.

85. **IMS LIST (FORM FDA 2359i)**

When should the following product codes: #19, 39, 40, be used on Form FDA 2359i for inclusion in the IMS list?

Lactose reduced milk (i.e., Lactaid) is code 19. UF raw milk is code 39. UF pasteurized milk is code 40.