HHS:PHS:FDA:CFSAN:OC:DCP:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-07-3

January 29, 2007

TO: All Regional Food and Drug Directors

FROM: Milk Safety Team (HFS-626)

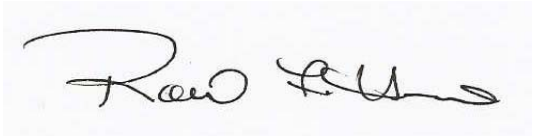
SUBJECT: Questions And Answers From FD-577 Special Problems In Milk Protection And FD-578 Advanced Milk Processing Courses And The Northeast Region Milk Seminar Held In FY'06

Following are questions and answers from FD-577 Special Problems in Milk Protection and FD-578 Advanced Milk Processing Courses and the Northeast Region Milk Seminar held in FY'06.

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.



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Milk Safety Team

QUESTIONS and ANSWERS
from the
FD-577-SPECIAL PROBLEMS IN MILK PROTECTION COURSES-BATON ROUGE (March 27-31, 2006) and ALBANY, NY (July 10-14, 2006);
FD-578-ADVANCED MILK PROCESSING COURSE-BOISE, ID (AUGUST 7-11, 2006); and the
NORTHEAST REGION MILK SEMINAR-PORTLAND, ME (APRIL 16-18, 2006)

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

   May hydrogen peroxide (H_2O_2) be added to milk?

   No. This is not allowed by the standard of identity for "milk".

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

   The 2005 NCIMS Conference modified the definition of "Food Allergens" in the PMO and added the following citation, Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) (FALCPA).

   The following question relates to a milk plant that processes "soy milk" and/or "soy products" on the same equipment as Grade "A" milk and milk product, such as, using the same High-Temperature-Short-Time (HTST) Pasteurization System, the same conveyances and the same fillers for both types of products:

   Does each milk product need to have advisory labeling that it was processed on equipment used to process soy, i.e., "This product was processed on machinery that was used to process products containing soy" or "May contain soy"?

   *FALCPA **does not require** advisory labeling. Manufacturers provide such labeling on a voluntary basis, but the information must be truthful and not misleading.*

   The issue of cross-contamination/cross-contact has been addressed in the Allergen Qs&As (#18) on CFSAN's website. The link for this information is http://www.cfsan.fda.gov/~dms/alrguid3.html. Below is Question #18 from that website for your information:

   18. [Added December, 2005] Is a major food allergen that has been unintentionally added to a food as the result of cross-contact subject to FALCPA's labeling requirements?

No. FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, "cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.

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

Please clarify the information regarding the use of the preservative natamycin in yogurt, sour cream, cottage cheese, and cottage cheese dressing.

By way of background, any substance intentionally added to a conventional food, such as the food products listed above, must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use, or is otherwise exempt from the food additive definition in section 201(s) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(s)).

To establish general recognition of safety, one must show that not only is the use of the substance safe, but that the technical evidence of safety is generally recognized and accepted. Such a determination can be made by qualified experts independent of FDA. However, FDA may challenge such a determination if it disagrees that such use is GRAS. If a firm believes that the use of a substance is GRAS, they may voluntarily notify FDA of their GRAS determination. The benefit of notifying FDA of a GRAS determination is that the notifier will receive a response from FDA that documents the agency's awareness of it.

In the case of natamycin, the substance is approved as a food additive for use as an antimycotic on the surface of cheese at levels up to 20 ppm, providing that if there is a standard of identity for the cheese, the standard permits such use (see 21 CFR 172.155). FDA has not evaluated the safety of any other uses of natamycin in food and has not received any notifications that other uses are GRAS. Therefore, if natamycin is being used as a preservative in other foods beside cheese, such uses are based on GRAS determinations independent of FDA.

The standards for cottage cheese (133.128) and sour cream (131.160) include provisions that permit the appropriate use of safe and suitable preservatives in the creaming mixture of cottage cheese and in sour cream.

However, the standard for dry curd cottage cheese (133.129) does not permit the use of preservatives, so substances such as natamycin cannot be used in dry curd cottage cheese. With respect to the use of preservatives in yogurt, the standards for yogurt, lowfat yogurt, and nonfat yogurt (131.200, 131.203, and 131.206, respectively) do not include provisions for the use of preservatives; however, FDA stayed those portions of 131.200(d), 131.203(d), and 131.206(d) insofar as they exclude the addition of preservatives (47 FR 41519 at 41522, September 21, 1982). Therefore, the appropriate use of safe and suitable preservatives in yogurt, lowfat yogurt, or nonfat yogurt will not be the basis for regulatory action by FDA.

Based on the information currently available to FDA, we are not prepared to challenge the use of natamycin as a preservative in yogurt, sour cream, cottage cheese, and cottage cheese creaming mixture at this time. However, the use of natamycin in dry curd cottage cheese is not permitted.

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

May a dairy product be labeled as “Cultured Real Butter Milk”?

No. Buttermilk is subject to the standard of identity in Title 21 Code of Federal Regulations (21 CFR) 131.112. The standard provides for identifying the product as “cultured milk” or “cultured buttermilk.” Therefore, the word “REAL” should be removed from the statement of identity. In addition, we advise that the use of the term “REAL” to describe this standardized food may mislead consumers to conclude that this product is different or superior to other standardized buttermilk products that comply with 21 CFR 131.112.

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

May nitrogen (N_2) or carbon dioxide (CO_2) gas be added to the head space of filled fluid milk (whole, 2%, 1%, etc.) containers?

We do not consider the N_2 or CO_2 gas that is introduced into the head space during packaging as an ingredient of the food; therefore, such introduction of the gas does not violate the standard of identity for "milk" and would not have to be labeled.

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

May N_2 or CO_2 gas be added directly (purged, injected, etc.) into fluid milk products (whole, 2%, 1%, etc.)?

We would consider the gas to be an ingredient and the product would not be in compliance with the standard for "milk" because the addition of N_2 or CO_2 is not permitted by the standard.

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

Grade “A” concentrated/condensed milk and milk products and whey permeate and retentate must meet the temperature and coliform requirements of Section 6 of the PMO.

Grade “A” concentrated/condensed milk and milk products and whey and products may be produced at varying percent levels, such as 45% Whey Protein Concentrate (WPC), 80% WPC, 90% WPC or 80% Milk Protein Concentrate (MPC), 85% MPC, etc. As long as it is a single specific product, such as WPC, MPC, Milk Protein Isolate or Whey Protein Isolate, only one (1) sample of each specific product would be required to be taken with a rotation of sampling and testing being done on the varying percentages of each specific product.

Would this same sampling requirement, addressed above, identified milk permeate(s) and retentate(s) as long as the product is the same, even with varying percentage levels, that only one (1) sample of each would be require to be sampled and tested at the required frequency as cited in Section 6 of the PMO?

Yes

8. **PMO-Sections 1 and 6; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Sections C and D**

In reference to the Grade “A” milk product, “Skim Deluxe”; is this milk product required to be sampled separately to satisfy Section 6 requirements of the PMO or could this milk product be sampled in rotation with the plant’s Skim Milk? Since the “Skim Deluxe” is made from Skim Milk that has been modified by adding stabilizers to enhance the "mouth feel", without added milkfat, should the “Skim Deluxe” be considered a new separate milk product and be subject to Section 6 requirements of the PMO in addition to the Skim Milk?

“Skim Deluxe” would be considered a separate Grade “A” milk product and would be required to be individually sampled in accordance to Section 6 of the PMO. This would be in addition to Skim Milk, if it is also being processed in the plant.

9. **PMO-Section 4**

Would the following descriptive labeling term used in conjunction with the name of the milk product, “Decadent Chocolate Milk”, be considered in violation of Section 4-Labeling of the PMO?

Yes; however, the term "decadent" may be used on a product label in a manner not associated with the product name or grade, i.e., "made from decadent chocolate", or "decadent smooth milk chocolate", etc., if the statement is factual.

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

The PMO states that "Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or mislabeling".

a. Would the term "Trim Lowfat" be allowed to describe the fat content of a product such as 2% cottage cheese (this term is on the principle panel)?

No. Because cottage cheese is a standardized food any modification to lower the fat content must be in accordance with the provisions in 21 CFR 130.10. Therefore, a cottage cheese that has been modified to meet the definition of lowfat (i.e., 3 g or less per serving) ***must*** *bear the term "lowfat" as part of its name, i.e., lowfat cottage cheese". If the fat content does not meet the lowfat definition, but has been reduced by at least 25% the product name must include "reduced fat." The term "Trim" would not be an appropriate part of the name of the food. The proper name for this product is "reduced fat cottage cheese".*

b. Would this be considered a "descriptive label" and is there any additional labeling allowed for the labeling of the fat content of the product on the principle display panel?

Yes. (Refer to the answer provided in a. above.)

11. **PMO-Section 6**

May the sample collected from an approved in-line sampler from direct load tankers, as cited in M-I-06-6, be split in order for an independent sample to be tested by another laboratory?

Yes, this split must be conducted by an approved licensed/permitted bulk milk hauler/sampler at the farm while collecting the sample or in a laboratory by a certified analyst.

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

What is required for tanker loads of milk, which have been held for an extended period of time, prior to sampling and off-loading at a receiving facility?

The samples collected must be representative of the milk in the tanker and; therefore, the tanker must be adequately agitated prior to taking these samples. An appropriate means to properly agitate the tanker must be provided to obtain a representative sample.

Standard Methods, Chapter 3, 3.3(B) states: "The time required to agitate a tanker truck of milk, until it is homogeneous, is determined by the size and shape of the tank; volume of the product held; type, location and number of agitators on the tank; force of the agitator; and time allowed for creaming before starting agitation. Therefore, it is necessary to determine for an individual tanker how much agitation time is needed to ensure homogeneity of its content.

Agitation time may be determined by taking a series of milkfat samples at specified intervals during agitation, until at least five (5) milkfat tests stabilize at a definite value…. Adequate agitation is that degree of agitation which, at full tank, will result in the milkfat content of the product in the tank varying by not more than two (2) standard deviations from the mean."

The Regulatory Agency must review and verify the procedure a receiving facility is proposing to utilize, based on data they have generated, to address the adequate agitation of tankers that are stored for an extended period of time after filling, either at the farm, plant, receiving station, transfer station, or other appropriate location. ***NOTE****: The definition of an "extended period of time" is to be determined by the receiving facility and must be acceptable to the Regulatory Agency.*

The Regulatory Agency in cooperation with the receiving facility must determine what is required to provide adequate agitation to provide a representative sample for Section 6 and Appendix N testing.

13. **PMO-Section 7**

May milk be clarified for the specific purpose of the removal of microorganisms under the PMO and the Grade "A" Milk Safety Program?

The use of a clarifier, historically found in a typical U.S. milk plant, which is intended for the removal of extraneous materials, such as straw, dirt, etc., and not specifically for the removal of bacteria is acceptable.

The use of a clarifier that specifically proclaims to remove microorganisms from milk, as recently being marketed in the U.S., has not been acceptable.

14. **PMO-Section 7, Item 13r and 11r**

Bulk milk haulers are conducting partial pickups on dairy farms and are not following Administrative Procedure #3, Item 10r of the PMO. Would this be considered a violation of both Items 10r and 11r?

Yes.

15. **PMO-Section 7, Item 13r**

May a teat dip sanitizer, used only during udder prep, be conducted through a PVC pipe?

Yes

16. **PMO-Section 7, Item 13r; and Appendix Q, Item 13r**

Is concentrated strength hydrogen peroxide (H_2O_2) approved as an udder wash?

No. The over-the-counter (OTC) H_2O_2 product anyone can purchase is a 3% solution. Concentrated solutions can be purchased at most any solution. The Material Safety Data Sheet (MSDS) on the concentrated solutions of 25% and higher are rife with human warnings about skin and eye damage and damage if ingested or inhaled.

There are some 30 products drug listed with FDA's CVM as teat dips that contain H_2O_2 in concentrations less than 1.25%. They are marketed under regulatory discretion without FDA approval. The firms must drug list, label properly and manufacture these products under cGMPs. This still does not make them FDA approved products but they do comply with our Compliance Policy Guide (CPG) on teat dips and udder washes.

BOTTOM LINE: *It is not OK for the producer to make (dilute) and use* concentrated strength *H_2O_2 as a teat dip or udder wash. H_2O_2 could not be used as a "stand-alone" sanitizer since it does not have an EPA registration number and H_2O_2 by itself is not recognized as a sanitizing agent under CFR 178.1010.*

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

Below is a treatment that is called Organicwash, which is being distributed and is touted as being 100% natural and drug free. It is distributed in 30 mL infusion tubes. Would this be considered an approved treatment and be allowed for use on dairy animals?

ORGANICWASH

100% Natural and Drug Free

Ingredients: Purified seaweed and distilled water
Packing: 30 mL tube
Benefits: Improved teat hygiene
Purpose: Dislodge abnormal milk from teats
Removes: Clotty milk
Stringy milk
Watery milk
Usage:
A. After milking, clean the abnormal teat end with the alcohol swab provided.
B. Apply liquid wash into the teat.
C. Check at the next milking to see whether another wash is needed.
D. Repeat cleaning if necessary.

***** Always discard abnormal milk not fit for use*****

New Decade Investments (Pty) Ltd.
81 Villers Road, Walmer 6070
South Africa

No. This product is not an FDA approved drug for its intended use and it is not acceptable for use on dairy animals. M-I-06-5 speaks to the use of such products.

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

May a licensed veterinarian extra label Doramectin (Dectomax®) and generic Ivermectin in accordance with 21CFR 530 (AMDUCA)?

There are two (2) pour-on products, Cydectin pour-on (moxidectin) and Eprinex pour-on (eprinomectin), for use in lactating dairy cattle with a zero (0) discard time. Using the AMDUCA regulations, one could make the argument that since there are approved avermectin products for lactating dairy cattle there is generally no need to use doramectin or ivermectin off label.

Technically under AMDUCA, a licensed vet can extra-label doramectin or ivermectin for use in lactating cattle. AMDUCA allows vets to extra-label FDA approved human and animal drugs, provided they follow the specified AMDUCA regulations. Some of the extra-label use (ELU) stipulations include the vet's responsibility for determining the approved products are clinically ineffective or not available, and establishing a milk discard time - slaughter withhold sufficiently long enough to prevent violative residues in milk or meat.

It is known from past experiences that doramectin and ivermectin milk residues can be sixty (60) and forty (40) plus days, respectively. Any ELU from these drugs would be violative if detectable levels are found in milk.

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

How should ECP (estradiol cypionate an estrogen compound) be handled on state ratings and check ratings?

It would be considered a violation of Item 15r of the PMO and debited under Item 15(e) on FORM FDA 2359a-Dairy Farm Inspection Report (5 point debit).

M-I-06-5 states: "Products may contain estrogen compounds such as ECP (estradiol cypionate). Such products may bear an Rx legend. None have ever been approved by FDA for use in animals. ECP is no longer marketed in the U.S. It should not be used or stored on dairy operations."

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

A 5 gallon bucket, which is labeled for Quartermaster (dry cow medication) and identifies the appropriate prescribing veterinarian, has Orbeseal tubes (determined to be a medical device) mixed in with the Quartermaster tubes. Would this be considered an Item 15r violation, due to the improper storage of the medical device tubes?

No. Orbeseal is considered a medical device and is exempt from Item 15r (labeling and storage) requirements of the PMO.

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

What is the status of the new animal generic drug sodium sulfadimethoxine (brand name "SULFAMED-G Soluble Powder")?

This is an over-the-counter (OTC) product and is approved for use in chickens, turkeys, dairy calves, dairy heifers and beef cattle, with a seven (7) day withdrawal time for cattle. This product is not approved for lactating cows and vets cannot extra label it for dairy cattle twenty (20) months of age and older, even dry cows, as per AMDUCA. If it is observed on the dairy farm as being extra labeled for use in cattle twenty (20) months of age or older or for dry cows it would be considered a violation of Item 15r and be debited under Item 15(e)-FORM FDA 2359a-Dairy Farm Inspection Report (5 point debit).

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

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.

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

The following questions relate to steam block CIP/Product separation controls and the testing of temperature sensors described in Section 7, Item 15p(B) of the PMO. The criteria in Item 15p(B), 1., c., Sub-items one (1) through five (5) are clearly stated; however, these questions relate to the criteria in Sub-item six (6) that are not so clearly stated.

a. The temperature sensor is required to detect a drop in temperature that may indicate the presence of liquid (either product or cleaning solutions) in the steam block. What would be an appropriate temperature to meet this criterion?

Evaporation of even very small amounts of liquid within the steam block will result in a relatively large drop in the temperature of the steam in the steam trace. It is that temperature drop that must trigger the alarm. In setting the alarm it is important to determine what temperature drop indicates liquid being evaporated in the steam block.

If the alarm is set to detect a temperature drop that is too small, the cleaning system will alarm and shut down when the steam block has not been compromised. If the alarm is set to detect a temperature drop that is too large, liquid may be leaking into the steam block undetected. This alarm set temperature will be determined by the industry and must be verified and documented to the satisfaction of the Regulatory Agency.

b. The practice commonly used by industry is to set the steam trace temperature sensor at 250°F (121ºC), which is considered to be commercially sterile. Would this be considered an appropriate temperature for a steam trace alarm used to separate cleaning solutions from product?

This would need to be determined on a case-by-case basis based on the documentation provided by industry and the Regulatory Agency's verification of that documentation.

c. Are there standard test procedures that are to be used to verify the temperature sensor and operation of the control system?

No

d. Are the means to verify the accuracy of the temperature sensor and the automatic controls system operation required to be provided to the Regulatory Agency by the manufacturer of the control system?

No. Sub-item six (6) requires that a means to verify the accuracy of the temperature sensor and control system be provided. It does not specify who is responsible to provide them, only that they be provided. They may be developed and provided by the equipment supplier, the system designer, the installer, the plant engineer, etc.

e. What is the verification frequency?

Currently, the PMO does not specify a verification frequency; however, the temperature sensors must be accurate and the control system must function as required when tested

f. What records are required?

There are none specified; however, the Regulatory Agency may require documentation of the verification of the accuracy of the temperature sensors and the control system's operation.

24. **PMO-Section 7, Items 15p(B) and 17p**

The following scenario involves milk and milk products that are stored in the cooler and have never left the milk plant.

May a milk plant reprocess undamaged/unopened containers of milk that may have milk spillage on the outside of the containers from adjacent or overhead damaged or punctured containers?

Yes, provided that the undamaged milk containers and milk and milk products are handled in a sanitary manner and maintained at 7ºC (45ºF) or less.

25. **PMO-Section 7, Item 16p(A)**

May a cone-shaped vat pasteurizer's outlet pipeline be disconnected at the manifold or must they be broken at the outlet valve?

The outlet pipeline must be disconnected at the outlet valve.

26. **PMO-Section 7, Item 16p(B) and (C)**

The following questions concern pressure controls for a holding tube on an HHST unit, utilizing Indirect Heating. This is for an HHST unit that is capable of operating in forward flow with a holding tube pressure less than 518 kPa (75 psig).

a. Is there a specific location in the holding tube where the pressure control sensor needs to be located?

No. However it is recommended that the most appropriate location is at the end of the holding tube. In this location, any lowering of the pressure in the holding tube, based on side wall friction, will have already taken place.

b. Does the PMO require that the pressure in the holding tube need to be recorded on a chart recorder?

No.

27. **PMO-Section 7, Item 16p(B) and (C)**

a. Is there a requirement that only micro-switches may be used as the position indication device within a legal Flow Diversion Device (FDD)?

No; *however, all FDDs evaluated and accepted by FDA and/or State Regional Equipment Review Committees to date have used micro-switches to detect valve position.*

b. Are other position indication technologies, i.e., proximity switches, hall-effect devices, etc. acceptable?

To date, none of these have been evaluated by FDA and/or a State Regional Equipment Review Committee for this purpose.

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

Is it a violation of the PMO if a Programmable Logic Controller (PLC) controlled pasteurizer has output(s) to a computer used for monitoring or trouble shooting purposes?

No, outputs can be repeated out of the PLC and be provided as inputs to another PLC for any purpose including information or control of peripheral devices, which are not used to manage the functions of public health controls. These outputs shall be hardwired and may not be done through a communication link.

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

May an AC variable speed pump be used as a booster pump in an HTST system with a homogenizer that serves as the timing pump?

Yes. However, the differential pressure controller must meet the minimum requirement of at least 6.9 kPa (1 psi) greater pressure on the pasteurized side than the raw side of the regenerator ***at all times*** *as cited in Item 16p(D) of the PMO.*

The system must be timed with the AC variable speed booster pump at the maximum operating speed that will allow the booster pump to run, based on pressure controls.

30. **PMO, Section 7, Items 16p(E); and Appendix I**

In a pasteurization system that utilizes an AC variable frequency drive stuffing pump to feed a separator, located prior to a gear driven timing pump, required to be tested for holding time in both forward and diverted flow?

Yes.

31. **PMO, Section 7, Items 16p(E); and Appendix I**

The following questions relate to APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS II. TEST PROCEDURES – Test 15 of the PMO.

a. Are digital reference thermometers required to be tested?

No. Test 15 only applies "To all electronic **controls** *(emphasis added) used to assure compliance with public health safeguards on continuous flow pasteurization and aseptic processing equipment that are installed in milk plants where hand-held communication devices are used."*

b. It has been suggested that Test 15 is to be conducted in "diverted flow" only; is this correct?

No. The criterion for Test 15 is: "The use of hand-held devices shall have no adverse effect on the public health safeguards."

The example provided in Test 15 only describes one method of testing for the effect of a hand-held communication device on the recorder/controller operating in diverted flow.

c. What electronic controls are required to be tested under Test 15? What is considered an adverse effect for each and what is the rationale?

Refer to the Following Table:

Electronic Controls	***Adverse Effect?***	***Rationale***
HTST Recorder/ Controller (temperature pen)	*Forward-flow or any false upward movemer of the temperature pen*	*May result in forward-flow below the sealed cut-in temperature set point(s).*
HHST and Aseptic Recorder/Controller or Auxiliary Controller (temperature pens or digital displays)	*Forward-flow or any false upward movement of the temperature pen or in the case of controllers, without a recorder, an increase in temperature on a digital display*	*May result in falsely satisfying the cut-in requirements of the specific controller(s) causing the system to go into forward-flow without meeting thermal-limit-controller-sequence logic.*
HTST Flow Rate Recorder/Controller (Flow rate indicating pen)	*Any false downward movement of the flow rate pen*	*If the device is in send mode for longer than the required time delay, it may result in forward-flow while still above the high flow alarm set point.*
Regenerator Pressure Switches (Milk or Milk Product-to-Milk or Milk Product; or Milk or Milk Product-to-Water-to- Milk or Milk Product)	*Any false upward movement of the "pasteurized" side or false downward movement of the "raw" side pressure digital read outs*	*May result in the continued operation of the booster pump (HTST) or continued forward-flow (HHST or aseptic) during a loss of differential pressure.*

Steam Injector Pressure Controllers	*A false increase in the pressure drop across the injector (Any rise in the milk or milk product pressure before, and/or drop in the milk or milk product pressure after the steam injector)*	*May result in continued forward-flow with less than the required pressure drop across the injector.*
Pressure Controller in the Holding Tube, for Those Systems Capable of Operating with less that 75 psig (518 kPa) in the Holding Tube	*Any false increase in the pressure*	*May result in continued forward-flow with less than the minimum required holding tube pressure.*

32. **PMO-Appendix B**

What are the requirements for the person that only transports official samples to a laboratory?

If the sample case is sealed as required by the Regulatory Agency, then a common carrier (driver) may transport the samples to a laboratory for testing. This driver would not be required to possess a valid permit or be evaluated biennially for the collection of samples for official laboratory analysis. However, if the sample case is not sealed and a sample chain-of-custody must be established, then the driver may be required to carry a valid permit or shall be evaluated for the collection of samples for official laboratory analysis.

33. **PMO-Appendix B**

May a dairy plant reject a tanker of milk if the tanker has not been inspected within the last 12 months?

Yes

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

Under what “Material Code” should a component part made of silicone, utilized in a single-service article, be listed under on the REPORT OF CERTIFICATION-FORM FDA 2359d?

MATERIAL CODE - 3. Plastic

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

A single-service article is composed of a three (3) layer film. Each layer is produced at a different facility. Plant A produces the outer layer, Plant B produces the middle layer and is responsible for the final assembly, and Plant C produces the inner food contact layer.

a. Do all three (3) firms need to be IMS listed or only Plant B (final assembly) and Plant C (food contact)?

Section A. Purpose and Scope, Appendix J of the PMO clearly states that these Standards apply to Plant B (final assembly) and Plant C (inner food contact layer). Both of these plants would be required to be IMS Listed.

*As for Plant A (outer layer), if this outer layer make**s** direct contact with the inner food contact layer during storage, handling, assembly, etc., then this Plant would also fall under the Scope of Appendix J and be required to be IMS Listed.*

b. Which facilities are required to comply with the sampling and testing requirements of Section C. Bacterial Standards and Examination of Single-Service Containers and Closures, Appendix J of the PMO?

*Section C. 4. requires that only the final assembled products that may have product contact surface(s) must be sampled and tested for compliance with this Section. Therefore, only Plant B**,** point of final assembly of the single-service article, would be required to be sampled.*

c. If the film is sent to an outside printer is the printer required to be IMS listed?

Yes, in accordance with Section A. Purpose and Scope, Appendix J of the PMO.

d. Does the PMO require that sampling also be conducted at the printer?

No.

36. **PMO-Appendix J, Sections A and D**

If a single service plant receives their resin from a distributor that utilizes a secondary rail car delivery location, which is not located at the plant, to transfer resin to an over-the-road tanker that provides the resin directly to the plant or to another facility under the control of the plant, would this secondary rail car delivery location need to be inspected as part of the plant's routine inspection and rating process?

No.

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

Definition 15 “Sample Set” refers to a sample consisting of 4 sub-samples (containers/closures). Can the sample (4 sub-samples) consist of different sized containers? For example, in the Month of May, one sample was collected for bacteriological testing, the sample consists of two (2) 1/2 gallon sized container and two (2) quart sized containers.

No. Each size of containers must be sampled at the required frequency and the sample set consists of four (4) containers and closures of each different size of containers. The example that was given above would not be acceptable for either 1/2 gallon or quart sized containers.

38. **PMO-Appendix N**

Must an industry plant sampler or licensed bulk milk hauler/sampler collect a representative sample at a transfer station from the individual bulk milk pick-up tankers that are received and commingled in an over-the-road tanker?

Yes.

39. **PMO-Appendix N**

A transfer station collects an Appendix N sample from the individual bulk milk pickup tankers that deliver milk to the transfer station and chooses to not test these samples. They provide these individual bulk milk pickup tanker samples that they collected, which make up the load in the over-the-road tanker, with the over-the-road tanker of milk that is shipped to a milk plant for the milk plant to test along with a sample that the milk plant collects upon receipt of the commingled milk in the over-the-road tanker. The individual bulk milk pickup tanker(s), whose previous load has not been tested, is dispatched to collect an additional load(s) of milk that same day without being washed and sanitized between loads. If the receiving milk plant’s Appendix N testing is completed upon receipt of the over-the-road tanker, this receipt may occur later that day or even the next day. If the testing indicates a positive result from an individual bulk milk pickup tanker load, would the additional load(s) of milk collected prior to the next washing/sanitizing of the bulk milk pickup tanker be considered saleable milk? (**NOTE:** This scenario is based on the assumption that neither the bulk milk hauler nor the transfer station operator were aware of the positive results of the initial load prior to collecting an additional load(s) that same day.)

Yes, if the additional bulk milk pickup tanker load(s) tested negative for drug residues.

40. **PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS**

Is it permissible for a State Rating Officer to conduct a State Rating at the same time a Check Rating is going on?

No. It has been a long standing practice that this not occur. One of the issues with doing them at the same time, is Industry's fear that we are now teaming up and using more than one set of eyes to evaluate Industry during State Ratings and Check Ratings. Also, State Ratings and Check Ratings have two different purposes and scoring levels and where the Check Rating would be acceptable, the State Rating may not, and this seems that it would only lead to a great deal of confusion for everybody. The system of check and balances that has been used in the NCIMS Grade "A" Milk Safety Program would seem that they are now overlapping and the distinct separate activities would loose their importance and meaning. The objective of a State Rating is to provide an assessment of State and Local sanitation activities regarding public health protection and milk quality control. The objective of a Check Rating is to ensure that the published State Rating is valid and maintained during the interval between State Ratings.

For these reasons, even though it is not specifically cited in any of the NCIMS documents, historically this practice has never been acceptable and is not acceptable under the current system.

41. **MMSR, Section A**

Within the MMSR document it defines “Certified Milk Sanitation Rating Officers (SRO)” as State employees. Are employees of a state political subdivision, such as a local health department, which are under contract with the State Regulatory Agency to be their agents as defined in State statute considered as State Employees?

Yes, if they are legally identified as agents of the State, they would be considered State employees within the MMSR definition for SROs. They are under contract with the State Regulatory Agency to perform their assigned work and; therefore, would be considered agents of the State. As identified agents of the State, they could be certified by FDA as SROs.

42. **MMSR, Section E; and FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT**

a. Does Product Code #18-Eggnog cover ultra-pasteurized eggnog or is it covered under Product Code #5-Ultra-pasteurized milk and milk products?

Product Code #5

b. What Product Code is to be used for ultra-pasteurized half & half? Product Code #4 mentions pasteurized half & half or would ultra-pasteurized half & half be covered under Product Code #5 also?

Product Code #5

NOTE: *Historically, all ultra-pasteurized products have been coded under Product Code #5. The other Products Codes, i.e., 2, 4, 8, 18, 19, 20, 21, 25, etc. were assigned based on HTST or vat pasteurization.*

43. **FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT-DAIRY PLANT SAMPLING – RAW AND PASTEURIZED MILK**

Why does this Form cite a metal dipper, with a long handle, and a capacity of at least 100 ml (4 oz.)?

The metal dipper, with a long handle, and a capacity of at least 100 ml (4 oz.) is cited because it is an example of one of the traditional sample collection devices.