Follow Up to Hydrogen Peroxide as a Sanitizer Article

In the June 2009 issue of the CMI Newsletter I had mentioned the requirement for an EPA registration number for a sanitizer to be approved. The comment which stated “To the best of our knowledge we are not aware of any approved Hydrogen Peroxide Sanitizer currently on the market” created some confusion and I received a couple of inquiries. To clarify we are aware that there are many approved sanitizers which have Hydrogen Peroxide as an ingredient, but we still are not familiar with any EPA registered Hydrogen Peroxide, only sanitizer. Should anyone have knowledge of such product, please contact this Division at your convenience.

Farms with Multiple Pickups in a 24 hour period

Currently the Division of Milk Control and Dairy Services is conducting an investigation into sampling and component testing of producers who have more than one pickup of milk in a 24 hour period. The purpose of this fact finding mission is to verify that milk companies and cooperatives are meeting the requirements outlined in 1NYCRR Part 6. Specifically we are interested in 6.7(b) which reads ensure that universal sample is properly taken from each dairy farm from which milk is picked up and such sample is properly maintained. 6.7(h) addresses the event that milk is picked up from a dairy farm more than once a day (multiple pick-ups) ensure that a universal sample is properly taken on each occasion when milk is picked up and that such samples are tested and that the weighted average of the milk component content of all such samples is calculated.

Such weighted average shall constitute the milk component content of all of the milk picked up on a particular day. As per 1NYCRR Part 2.7(b)(2) the sample taken as the official sample of the month to be analyzed for the requirements outlined in 2.8 of the regulations (Temperature, Bacterial Limits, Drugs, Somatic Cells) shall be made in compliance with Part 6 Standard Methods for the examination of Dairy Products and the PMO.

On page 23 of the 2007 PMO, Section 6 under the section labeled Note: When multiple samples of the same milk or milk products are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the regulatory agency and recorded as the official results for that day. This is applicable for bacterial (Standard Plate Count and Coliform), Somatic cell count and temperature determinations only.

In short, the regulation references state that all of the samples representing all of the milk shipped on that particular day are to be used in the component calculations as well as on the day chosen for the official sample which the Temperature, Bacterial Limits, Drug and Somatic Cell analysis are run.

Please take a moment to review your employers practices to be sure the sampling and component programs meet all of the requirements listed above. We will be following up with all of the companies that are found not to be complying with the applicable regulations. Should anyone have any questions relating to the information provided, please feel free to contact this Division.

2009 Annual CMI Seminars
The program for the above seminars is as follows:

Rob Ralyea – Milk Quality around the world and how to improve quality in our milk supply (comparison of where we are at in the US to other countries)

Brad Houck – Observations from farm ratings and questions and answers on farm related issues (water supplies, drugs, etc.) If you have questions please bring them to the seminar.

QMPS Representative – What’s happening at QMPS?

If you are unable to attend one of the listed seminars, you may attend any applicable seminar or course as noted on DMC 284 Continuing Education Registration Form. (available on our web page at – http://www.agmkt.state.ny.us/DI/DInews.html)

Please remember any seminar or course not listed must be submitted for prior approval to receive credit for attending.

24. PMO-Section 5; and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Section D

a) How should industry inspectors, certified under the Certified Industry Inspection Program, within Section 5-Inspection of Dairy Farms and Milk Plants of the PMO be evaluated on State ratings and FDA check ratings? During State ratings or FDA check ratings, State Sampling Surveillance Officers (SSO) and Delegated Sampling Surveillance Officers (DSSO) certifications are evaluated to measure sampling compliance; similarly would it be appropriate to determine the certification status of Certified Industry Inspectors (CIIs) when evaluating PART I-Dairy Farms, Item 2-All dairy farms inspected at least once every six (6) months or as required in Appendix "P" of FORM FDA 2359j-Section B-Report of Enforcement Methods?

Yes.

b) For example, if the CII’s certification has expired would inspections performed by that person after the expiration date of his/her certification be accepted?

No.

c) A worse case scenario would be that a BTU’s CII has not been certified in accordance with Section 5 of the PMO. With this scenario, would inspection credit be given for PART I-Dairy Farms, Item 2-All dairy farms inspected at least once every six (6) months or as required in Appendix "P" (15 points) on FORM FDA 2359j-Section B-Report of Enforcement Methods?

No.

d) Should this situation be evaluated during the State Program Evaluation (SPE) or just on each individual BTU State ratings or FDA check ratings?

For State Rating Officers they should evaluate this on all BTU State ratings. For FDA Regional Milk Specialists, this should be evaluated on both the SPE and on all BTU check ratings.

25. PMO-Section 6

If the two (2) bulk tanks/silos on a multiple tank/silo farm are not picked up and subsequently sampled and tested on the same date, what action should be taken by the Regulatory Agency if the sample result collected from tank/silo #1, on a given day, is acceptable and the sample result from tank/silo #2, which is collected the next day, is in violation?

The Regulatory Agency is responsible to identify which day or days results are to be considered official, i.e. the first day of the month or the first Monday of the month. If both of the samples are considered official regulatory samples by the Regulatory Agency, then both results would be recorded individually on the official regulatory producer ledger and if any appropriate enforcement action is warranted (two (2) out of the last four (4) or three (3) out of the last five (5) samples exceeding the standard) then such action would be required to be taken.

However if only one (1) of the samples results is considered official by the Regulatory Agency, then the results for that sample would be recorded on the official regulatory producer ledger and appropriate action taken
as warranted.

NOTE: Section 6 of the PMO requires that when multiple samples of the same milk are collected from the same producer from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count), somatic cell count and temperature determinations only.

27. PMO-Section 6 and Section 7, Item 5r

a) Is it acceptable to use a Ziploc bag as the sample collection container for the Anderson in-line sampler used on direct load farms, with or without a suitable shelter? No.

b) Is anything other than the single-service bottle designed for the Anderson in-line sampling device acceptable at this time for this sampling device? No.

c) If an unacceptable sample collection container, used with an approved in-line sampler, is observed on a State rating or FDA check rating, besides a sampling procedure issue, would it be considered a violation of the PMO?

Yes. It would be considered a violation of Item 5r-Milkhouse – Construction and Facilities, under a transportation tank that is used for the cooling and/or storage of milk on a dairy farm with or without a suitable shelter.

32. PMO-Section 7, Items 8r and 7p; and Appendix D; and MMSR-Appendix B

What would be considered the minimum acceptable distance/location (fifty (50) or one-hundred (100) feet) for a well to be located from a septic system drain field used for handling human waste?

Appendix D-Standards for Water Sources of the PMO provides criteria which is to be used in determining compliance with Items 8r-Water Supply (Dairy Farms) and 7p-Water Supply (Milk Plant). These guidelines specify the minimum distances allowable based upon general or basic soil formations for specific areas. Since human or animal excreta is considered to be a "point source" of contamination and a serious health hazard, individual wells serving milkhouses on Grade "A" dairy farms and for use in Grade "A" milk plants, which are inspected during a State Rating or PHS/FDA Check Ratings and are located within fifty (50) feet of contaminating sources such as cowyards, manure piles, septic systems, including drain fields, pit privies, sewage lagoons, cattle housing areas, feed lots, calf pens, etc., will be considered to be in violation of Item 8r or 7p, respectively.

Fifty (50) feet is not a concrete distance, it is a guideline. Any consideration of distances must take into account the soil structure, geologic conditions and other aspects, to determine acceptable minimum safe distances. Rather than rely strictly upon feet and distances, the only exceptions that will be made must be supported by qualifying documentation from the State Water Control Authority, which support a lesser distances for wells located in favorable (unconsolidated) soil formations. If the State has accepted the water supply on the basis of a sanitary survey, then that would be sufficient evidence for its acceptance on a State Rating or PHS/FDA Check Rating. (Refer to Table 10-Distance of a Well from Sources of Contamination in Appendix D and Appendix B-Table of Farm Water Supply Violation (Major-5 point debit) of the MMSR.)

34. PMO-Section 7, Items 12r, 12p and 13p

Is a plate heat exchanger (cooler), installed in a horizontal position, on a dairy farm or in a milk plant, automatically considered a violation of the PMO and debited against the dairy farm or milk plant?

No. Each installation must be evaluated on a case-by-case basis to determine if the plate heat exchanger is self-draining or drainable. Individual manufacturers of plate heat exchangers have provided installation service bulletin guidelines to their installers instructing them how to properly install their plate heat exchangers in a horizontal position to provide an adequate means for the plate heat exchanger to properly drain.

36. PMO-Section 7, Item 15r

a) What is FDA’s position on the labeling of homeopathic nutritional supplements used on dairy animals?

FDA cannot find any justification for regulating veterinary homeopathic drugs any differently from other animal drugs subject to the FFD&CA. M-I-06-5 (Current Information Addressing Item 15r-Drug and Chemical Control Of The Grade “A” Pasteurized Milk Ordinance) requires that homeopathic drugs found on dairy operations must comply with the drug labeling and storage requirements of Item 15r of the PMO.

b) Do they need to be properly labeled with adequate
directions for use, withholding times, etc.?

Yes, if animal health claims are stated on the label.

37. PMO-Section 7, Item 15r

A firm is selling a dietary supplement with the words homeostasis and homeotherapeutic on the label. Does a homeopathic medicine have to say “homeopathic” on the label to be a homeopathic medicine?

No. A homeopathic medicine does not need to say homeopathic on the label to be considered an unapproved animal drug. With any animal health claims made, the labeling and storage requirements of Item 15r of the PMO must be complied with. The term “Homeotherapeutic” is a drug claim.

39. PMO-Section 7, Item 15r

The following question and answer is provided for guidance in relationship to M-I-08-6 (FDA Approval For The Use Of Baytril® 100 (Enrofloxacin) Injectable Solution For The Treatment Of Bovine Respiratory Disease (BRD) In Dairy Cattle Replacement Heifers Less Than Twenty (20) Months Of Age), which was issued March 28, 2008.

Baytril® 100 has recently been approved and labeled for dairy replacement heifers less than twenty (20) months of age (M-I-08-6). How will this new approved animal drug be evaluated during farm inspections, State ratings and FDA check ratings concerning the animal drug labeling and storage requirements of Item 15r-Drug and Chemical Control of the PMO?

Baytril® 100 cannot be extra-labeled for use in female dairy cattle twenty (20) months of age and older by anyone, including veterinarians.

This new approved and labeled animal drug product can be stored with the non-lactating drugs to comply with Item 15r of the PMO, which requires that drugs intended for the treatment of non-lactating dairy animals are segregated from those drugs used for lactating animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item.

Baytril® 100 is a prescription (Rx) product. To comply with Item 15r labeling requirements of the PMO it shall be properly labeled to include the name and address of the veterinary practitioner dispensing the product or if the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian. The label shall also include:

a. Directions for use and prescribed withholding times;

b. Cautionary statements, if needed; and

c. Active ingredient(s) in the drug product.

Unapproved and/or improperly labeled drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of containers, utensils or equipment.

NOTE: Old labeled product will be in the field for a period of time until existing stocks are depleted. The old label states that the drug is specifically prohibited for use in cattle intended for dairy production or calves to be processed for veal. This included all classes of cattle on a dairy operation, including calves reared as dairy cow replacements, heifers, lactating and non-lactating (dry) cows, and bulls maintained for breeding purposes. The old label restricted the use of Baytril® 100 to treat BRD only in cattle maintained for beef production, i.e., beef or dairy breed feedlot steers, bulls, and heifers.

If old label product, labeled as not to be used to treat cattle intended for milk production, is found stored on the non-lactating shelf it is not to be debited under Item 15 on FORM FDA 2359a-Dairy Farm Inspection Report during farm inspections, State ratings and FDA check ratings, provided the name and address of the prescribing vet are identified on the label.

40. PMO-Section 7, Item 15r

Baytril® 100 (enrofloxacin) has received FDA approval for the treatment of Bovine Respiratory Disease (BRD) in dairy replacement heifers less than 20 months of age and per M-I-08-6 it cannot be extra-labeled for lactating cows. What about Baytril® A-180 (danofloxacin) that is currently labeled for beef cattle only? Is there any change for this product?

M-I-06-5 states: "Baytril® 100 and A-180 are specifically prohibited for use in cattle intended for dairy production or calves to be processed for veal. This includes all classes of cattle on a dairy operation, including calves reared as dairy cow replacements, heifers, lactating and non-lactating (dry) cows, and bulls maintained for breeding purposes."

Now that Baytril® 100 is approved for replacement
heifers it can be stored on the non-lactating shelf; however it cannot be extra-labeled for cattle 20 months and older. Baytril® A180 is not approved for replacement heifers so the language in M-I-06-3, cited above, still applies to this product.

41. PMO-Section 7, Item 15r

What are the PMO labeling requirements for Lidocaine (Rx), which is a local anesthetic?

Lidocaine is an Rx drug so to be in compliance with Item 15r of the PMO the drug shall be properly labeled to include the name and address of the veterinary practitioner dispensing the product or if the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian. In fact to comply with their own State veterinary licensing and practice acts, veterinarians are supposed to label all Rx drugs.

42. PMO-Section 7, Item 15r

If medications approved for dairy cattle are used on other species of dairy animals, are the extra labeling requirements required?

Yes.

44. PMO-Section 7, Item 15r

May a dairy producer use an udder and teat topical ointment that contains colloidal silver on dairy animals? The topical ointment contains a minimal amount of colloidal silver as a preservative.

No. Using such a topical ointment on dairy animals may cause some of the silver to end up in the milk.

91. PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS (PROCEDURES)-Section III; and MMSR-Section B

How many IMS listed BTUs may a single dairy farm be included in?

One (1). Provided, that with a single dairy farm where there are two separate owners with separate permits, two separate herds, and two separate bulk milk tanks the individual owners/permits may be listed in separate BTUs.

93. MMSR-Section B

Industry field staff has requested that they drive for ratings and check ratings. Industry field staff would like to have an advanced notice (3 to 4 days) to prepare dairy producers for ratings and check ratings. Is this an acceptable practice for a safe milk supply? Would this be considered prenotification?

This is not an acceptable practice and it would be considered prenotification.