HHS:PHS:FDA:CFSAN:OC:DCP:MSB

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-06-12

August 18, 2006

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Application And Standard Operating Procedure (SOP) For The Installation And Use Of An Acceptable Sample Septum For The Collection Of Dairy Farm Samples From Farm Vertical and/or Horizontal Tanks* For Acceptance Under Section 6 of the Grade "A" Pasteurized Milk Ordinance

Proposal 166 from the 2003 National Conference on Interstate Milk Shipments (NCIMS) addressed the collection of farm silo tank samples using a sample septum and a sterile needle to dispense the milk into a sterile sample container (i.e., vial) for acceptance under Section 6 of the *Grade "A" Pasteurized Milk Ordinance* (PMO). This Proposal did not make it mandatory that a syringe must be utilized, as cited in the *Standard Methods for the Examination of Dairy Products* for use in dairy plant sampling, for the collection of farm silo tank samples. It would allow the use of a sterile needle and the catching of the stream of milk in a sterile sample container (i.e., vial).

The Proposal modified FORM FDA 2399a-Bulk Milk Hauler/Sampler Evaluation Report, Item 10.-Sample Transfer Instrument by adding: "b. Sterile needle for aseptically dispensing milk sample from the bulk tank sample septum into a sample container (i.e., vial)". This Proposal passed with the provision that "the proposed solution will become effective upon the receipt of data and acceptance by FDA".

FDA's Laboratory Quality Assurance Team (LQAT) has received the required additional data from the completed farm silo tank septum sampling study. The data for the standard plate count (SPC), electronic somatic cell count (ESCC) and inhibitors as submitted were found to be acceptable to FDA based on the criteria established by the NCIMS Laboratory Committee for alternate methods. The procedures specified in Proposal 166 from the 2003 NCIMS and cited in the attached SOP need to be followed.

This data has been accepted by the FDA, the NCIMS Laboratory Committee and was presented to and accepted by the NCIMS Executive Board.

Included in this M-I is the SOP and application form for this acceptable farm vertical and/or horizontal tank* septum sampling procedure.
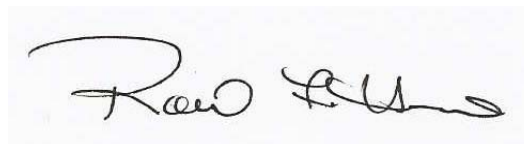
NOTE: *The type of farm vertical and horizontal tanks that are acceptable for utilizing the septum sampling procedure, as addressed in this M-I, are tanks that cannot have their manhole or door opened to be sampled in a similar manner as a traditional farm bulk tank.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies. State Laboratory Evaluations Officers and State 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@fda.hhs.gov.

Larry Maturin, PhD, Chief
Laboratory Quality Assurance Team

CAPT Robert F. Hennes, RS, MPH, Chief
Milk Safety Team

SOP for Farm Vertical and/or Horizontal Tank Sample Collection Using an Acceptable Sample Septum and a Sterile Needle to Dispense the Milk into a Sterile Container (i.e., Vial)*

General Requirements:

The application to install an acceptable sample septum utilizing a sterile needle should be filed with the operation installing the sample septum, the State Milk Regulatory Agency, the person responsible for the operation's regulatory oversight and the sample septum installer. (Refer to the application form)

Device Requirements:

1) An acceptable sample septum (i.e., QMI type as addressed in M-I-06-6) is to be installed in an appropriate location in the farm vertical or horizontal tank* to ensure accurate sampling and proper cleaning. (The installation must meet the approval of the State Milk Regulatory Agency and the equipment manufacturer.)
2) Use only acceptable sterile septum inserts; make sure the nut holding the insert in place is tight.
   NOTE: If a positive antibiotic result is obtained, manually clean, sanitize and replace the septum prior to the next milking.
3) If a protective septum cover has been provided with the septum, it should be in place at all times when the septum is not in use.
4) New, sterile, sealed needles must be used for each sample collection.
5) Single-service use containers (i.e., vials) must only be used for collecting the sample from one (1) farm silo tank.

Collecting the Representative Milk Sample:

1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.
2) The person(s) performing the following steps shall wash their hands before handling the equipment used to collect the milk sample.
3) The milk in the farm vertical or horizontal tank* must be adequately agitated for the required time (a minimum of 10 minutes or as recommended by the silo manufacturer) before the collection of the sample may begin.
4) At the desired sampling time, remove the protective cover, if provided with the septum, from the sampling septum and using alcohol or a sanitizer properly sanitize the cover over the septum surface. (Sanitize the septum surface with 200 ppm available chlorine solution, or equivalent, and expose the area for one (1) minute.)
5) Use a new sampling port each time you start collecting samples from a farm vertical or horizontal tank*. Replace the septum when all sampling ports have been used.
6) To begin the sampling of a farm vertical or horizontal tank*; aseptically remove the new, sterile, sealed needle by breaking the seal on the needle case and pulling the

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needle out using an alcohol swab. Insert the needle through one (1) of the unused sampling guide ports. (To correctly insert the needle, slant the needle slightly toward the center of the sample septum.)

7) Fill the sample container (i.e., vial) to the identified line, if present, with milk (without touching the container to the needle).

8) Immediately place the sample container (i.e., vial) into a properly constructed sample storage case, designed to maintain the sample at 0ºC – 4.4ºC (32ºF - 40ºF) and which protects the sample container from contamination.

9) Remove the needle from the sampling septum and dispose all single use items in the Sharpes container, or an appropriate container provided by the manufacturer.

10) Place the protective cover over the sample septum.

11) Transfer the sample(s) to the laboratory with the required sample information.

12) The sampling septum device may be cleaned-in-place (CIP). However, when replacing the septum after all sampling guide ports have been used, the opening that the septum sets in must be hand cleaned and sanitized.

Sample Handling:

1) The milk sample and temperature control (TC) sample containers and the weigh slip shall be identified with the following information:
   a. Producer identification or number;
   b. Date of sampling;
   c. Temperature of sample (Using the temperature of the TC sample);
   d. Time of sampling;
   e. Initials of the person taking the sample shall be recorded on the milk sample and TC sample; and
   f. Name and license or permit number of the person taking the sample shall be recorded on the weigh slip.
   NOTE: If the weigh slip accompanies the milk samples to the laboratory, only a. above is required to be on the milk sample container.

2) A TC sample shall be taken with each load of farm tank milk picked up and is identified with TC or by some other manner approved by the State Milk Regulatory Agency.

3) Duplicate samples may be taken for pick-up and testing by the producer's milk handling company or State Milk Regulatory Agency.

NOTE: *The type of farm vertical and horizontal tanks that are acceptable for utilizing the septum sampling procedure, as addressed in this M-I, are tanks that cannot have their manhole or door opened to be sampled in a similar manner as a traditional farm bulk tank.

FORM A
Application to Install an Acceptable Sample Septum and the use of a Sterile Needle to Dispense the Milk into a Sterile Container (i.e., Vial)

General Requirements:

Producer Name: _____, Date: _____
Producer Address: _____, State and Zip: _____
Producer Phone/Fax/E-mail: _____
Producer's Regulatory License or Permit Number: _____
Purchaser of Milk: _____
Producer's Regulatory Inspector: _____
Pounds of Milk/Day Shipped: _____
Sample Container of Approved Material: Yes _____ No _____
Sample Container of Approved Design: Yes _____ No _____
Material Type: _____
Sample Container Size: _____ (mls or ozs.)
Sample Septum SOP for the Sampler on File: Yes _____ No _____
Appropriate Sample Septum SOP Being Followed: Yes _____ No _____
Number of Milkings to Fill the Tanker_____

Sample Septum System Design:
(Meets State Milk Regulatory Agency and PMO Requirements)

Sample Septum Location: _____

System Operation:

Person(s) Operating the System Trained: Yes _____ No _____
Person(s) Operating the System Training Dates on File: Yes _____ No _____
Person(s) Operating the System Certification #'s on File: Yes _____ No _____
Person(s) who Performed the Training: _____
SOP for the Sample Septum Being Used on File and Being Followed: Yes ____ No _____
Cleaning/Sanitizing Sample Septum Approved by Regulatory Agency: Yes___ No___
Cleaning/Sanitizing Protocol Posted and Followed: Yes _____ No _____
All materials, approval for the installation plans, approval of the installation and all other relevant areas relating to the equipment construction of the sample septum and its usage must meet the requirements of Item 9r-Utensils and Equipment Construction of the most recent edition of the PMO.

8/2006 Revision