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M-I-06-12  
(Supplement 1)

April 16, 2020

TO: Director, Office of State Cooperative Programs  
Attn: Office of State Cooperative Programs, Division of Milk Safety  
Management and Staff

FROM: Milk and Milk Products Branch (HFS-316)

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 Proficiency & Evaluation Team (LPET) 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.

With this Supplement, the septum sampling procedure outlined in M-I-06-12 no longer applies only to tanks that cannot have their manhole or door opened to be sampled.

Please note that upon issuance of M-I-06-12 (Supplement 1), M-I-06-12, issued August 17, 2006, will be classified as **“INACTIVE”**.

An electronic version of this memorandum is available for distribution to Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluations Officers and State Rating Officers. 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.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to [monica.metz@fda.hhs.gov](mailto:monica.metz@fda.hhs.gov).

A handwritten signature in blue ink that reads "Monica Metz". The signature is written in a cursive style.

Monica Metz, Chief  
Milk and Milk Products Branch

**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 (QualiTru™) type as addressed in M-I-06-6, Supplement 1) 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 needle out using an alcohol wipe. 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 0°C – 4.5°C (32°F - 40°F) 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.

**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.