

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-12-4

February 7, 2012

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Application And Standard Operating Procedure (SOP) For The Installation And Use Of An Acceptable Aseptic Sampler For The Collection Of "Universal" Dairy Farm Milk Samples From Farm Bulk Milk Tanks And/Or Silos For Acceptance Under Section 6 Of The Grade "A" Pasteurized Milk Ordinance

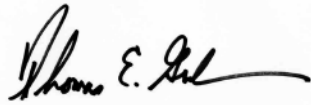
Proposal 208 from the 2011 National Conference on Interstate Milk Shipments (NCIMS) addressed the collection of "Universal" farm bulk milk tank and/or silo milk samples utilizing a sample septum, a sterile needle, a sterile single-service use sample collection bag with sanitary tubing, a septum sampling device attached to the outlet valve of the farm bulk milk tank or silo, and a peristaltic pump to dispense the milk into the sterile single-service use sample collection bag for acceptance under Section 6-The Examination of Milk and Milk Products of the *Grade "A" Pasteurized Milk Ordinance* (PMO). The Proposal also modified FORM FDA 2399a-Bulk Milk Hauler/Sampler Evaluation Report, Item 10.-Sample Transfer Instrument by adding: "d. Or an approved aseptic sampler".

FDA's Laboratory Proficiency Evaluation Team (LPET) has received the required data from the completed farm bulk milk tank and silo 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 sample collection methods. The procedures specified in Proposal 208 from the 2011 NCIMS and cited in the attached SOP shall be followed. This data and Proposal 208 have been accepted by the NCIMS Laboratory Committee, State voting delegates, FDA, and was presented to and accepted by the NCIMS Executive Board on October 4-5, 2011.

Included in this M-I is the SOP and application form for the use of this accepted QMI aseptic sampler for the collection of "Universal" farm bulk milk tank and/or silo samples for acceptance under Section 6 of PMO.

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



Thomas Graham, PhD, Chief
Laboratory Proficiency Evaluation Team



Robert F. Hennes, RS, MPH,
CAPT U.S. Public Health Service
Milk Safety Team

SOP for the QMI Aseptic Sampler for the Farm Bulk Milk Tank and/or Silo Sampling Septum System for the Collection of “Universal” Samples

General Requirements:

The application to install an acceptable QMI aseptic sampling septum system utilizing a sample septum, a sterile needle, a sterile single-service use sample collection bag with sanitary tubing, a septum sampling device attached to the outlet valve of the farm bulk milk tank or silo, and a peristaltic pump to dispense the milk into the sterile single-service use sample collection bag for the “Universal” farm bulk milk tank and/or silo samples shall be filed with the operation installing the QMI aseptic sampling septum system, the Regulatory Agency, the person responsible for the operation’s regulatory oversight and the QMI aseptic sample septum system installer. (Refer to the Application Form on page 9.)

Farm Bulk Milk Tank and/or Silo Requirements:

The farm bulk milk tank(s) and/or silo(s) shall have a properly working agitator equipped with a timer. This timer shall allow for the farm bulk milk tank and/or silo agitator to run the minimum amount of time as the farm bulk milk tank or silo manufacturer specifies.

Device Requirements:

- 1) The acceptable QMI supplied septum sampling device shall be attached to the outlet valve of the farm bulk milk tank or silo, as long as it does not create a dead end, so that it can be cleaned-in-place (CIP) when the farm bulk milk tank or silo is washed and sanitized, or alternatively, the QMI septum sampling device may be removed after each use and immediately hand cleaned and sanitized in the two (2) compartment wash and rinse vat, located in the milkhouse, and also prior to it’s next usage by the bulk milk hauler/sampler.

(NOTE: The installation shall be approved by the Regulatory Agency in conjunction with the sampling equipment manufacturer.)

- 2) The person(s) performing the following Steps shall wash his/her hands before carrying out any of the Steps that follow and whenever they become contaminated during the cleaning, sanitizing, handling and sampling procedure.
- 3) After the completion of the farm bulk milk tank or silo CIP wash and sanitizing cycle, remove the QMI septum sampling device from the farm bulk milk tank or silo outlet valve and place a cap or protective cover over each fitting end of the QMI septum sampling device. The QMI septum sampling device shall be stored in an appropriate manner to protect it from contamination (closed, clean single-service use plastic bag or multi-use plastic container) in a clean location in the milkhouse until its next usage.

If the QMI septum sampling device is traveling with the bulk milk pickup tanker, the QMI septum sampling device shall be removed from the farm bulk milk tank or silo outlet valve and immediately hand cleaned and sanitized in the two (2) compartment wash and rinse vat, located in the milkhouse, by the bulk milk hauler/sampler. Protective caps or a cover shall be placed over each fitting end of the QMI septum sampling device and the QMI septum sampling device shall be stored in an appropriate manner to protect it from contamination (closed, clean single-service use plastic bag or multi-use plastic container) in a clean compartment of the bulk milk pickup tanker or in the truck cab until its next usage.

(NOTE: The cleaning, sanitizing and storage of the QMI septum sampling device shall be approved by the Regulatory Agency.)

- 4) The protective caps or cover over each fitting end of the QMI septum sampling device shall be in place at all times when the septum sampling device is not being used.
- 5) Use only acceptable QMI sterile septum inserts.

Septum Use and Replacement Procedure:

- a. There are seven (7) septum insert sampling ports on each QMI septum. Use a new septum insert sampling port each time a farm bulk milk tank or silo is pumped out and the required "Universal" sample is collected. Replace the QMI septum when all seven (7) septum insert sampling ports have been used.
- b. Use each QMI septum insert sampling port **ONLY ONCE**. Pierced septum insert sampling ports can be readily seen. Once pierced, a septum insert sampling port cannot be used again.
- c. When all seven (7) QMI septum insert sampling ports have been used, the person replacing the septum shall properly wash their hands before removing the nut that holds the QMI septum in place and remove the used QMI septum insert and discard.
- d. **CLEAN** and **SANITIZE** the QMI septum insert holder area and install a new QMI septum insert, replace the nut, hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten. The protective cover shall be kept over the QMI septum insert at all times when not being used.

(NOTE: If a positive antibiotic result is obtained from the producer's milk supply, manually clean and sanitize the septum insert holder and replace the QMI septum insert before the next milking.)

- 6) The protective cover for the QMI septum insert shall be in place at all times when the septum is not being used.
- 7) New, sterile, sealed needles shall be used for each sample collection.
- 8) Use only acceptable QMI supplied sterile single-service use sample collection bags that are designed specifically for this QMI aseptic sampling septum system. These

QMI sterile single-service use sample collection bags shall only be used for collecting a sample from one (1) farm bulk milk tank or silo.

- 9) Use only the peristaltic pump recommended by QMI.
- 10) The volume of the milk sample collected cannot be more than three quarters ($\frac{3}{4}$) of the volume of the QMI sterile single-service use sample collection bag that is being used. The speed (RPM) of the specific type of peristaltic pump and the size of the QMI sterile single-service use sample collection bag being used shall be determined and recorded on the Application Form and on each farm weigh ticket.
- 11) The QMI sterile single-service use sample collection bag shall be placed in a properly designed portable hand carry type cooler, utilizing a water/ice mixture, to maintain the sample at 0°C – 4.4°C (32°F - 40°F) during the time when milk is being pumped out of the farm bulk milk tank or silo to maintain the temperature of the sample in accordance with the temperature requirements of the PMO.
- 12) No matter where supplies (septum inserts, sterile needles, sterile single-service sample collection bags, etc.) are stored, either in the milkhouse, or in a clean compartment of the bulk milk pickup tanker, or in the truck cab, they shall be stored in an appropriate manner to protect them from contamination (closed clean single-service use plastic bag or multi-use plastic container).

Sampling Procedures, Taking a Representative Sample, and Sample Handling Steps:

- 1) The person(s) performing the following Steps shall either be the milk producer who transports milk only from his/her own dairy farm or possess a valid bulk milk hauler/sampler's license/permit issued by the Regulatory Agency. Their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the Regulatory Agency.
- 2) Because of the design and the data obtained from the study there is not a need to run the bulk milk tank or silo agitator immediately prior to pumping all of the milk from the bulk milk tank or silo onto the bulk milk pickup tanker using this QMI aseptic sampling septum system.

(NOTE: If the milk in the farm bulk milk tank or silo will only be a partial pick-up, which shall be conducted in accordance with Item 10r-Utensils and Equipment - Cleaning of the PMO, the milk shall be adequately agitated for the required time, a minimum of five (5) minutes or as required by the farm bulk milk tank or silo manufacturer, before the pumping of the milk and the collection of the sample may begin. Following adequate agitation, perform the QMI aseptic sampling septum system procedures as cited below.)

- 3) The person(s) performing the following Steps shall wash their hands before carrying out any of the Steps and whenever they become contaminated during the sampling procedure.
- 4) If the QMI sampling septum device is stored either in the milkhouse, or in a clean compartment of the bulk milk pickup tanker, or in the truck cab, remove the protective caps or cover from each fitting end of the QMI septum sampling device

and properly hand **WASH** and **SANITIZE** the QMI sampling septum device in the two (2) compartment wash and rinse vat, located in the milkhouse. (Refer to Items 1 and 3, **Device Requirements**.)

- a. Use a spray bottle or other acceptable means with an approved sanitizer at the appropriate concentration to adequately sanitize the outlet valve of the farm bulk milk tank or silo.

(NOTE: Sanitize the farm bulk milk tank or silo outlet valve with 200 ppm available chlorine solution, or equivalent, and expose the area for a minimum of one (1) minute contact time.)

- b. Attach the QMI sampling septum device to the farm bulk milk tank or silo outlet valve.
- c. Perform the following Steps as cited below.

- 5) Remove the protective cover from the QMI sampling septum.
- 6) Adequately sanitize, using an approved sanitizer at the appropriate concentration, the white covering area over the QMI sampling septum.

(NOTE: Sanitize the sampling septum surface with 200 ppm available chlorine solution, or equivalent, and expose the area for a minimum of one (1) minute contact time.)

- 7) Position the QMI peristaltic pump close enough to the farm bulk milk tank or silo outlet valve so that the QMI single-service use sample collection bag can be connected to the needle that will be inserted into an unused septum insert sampling port on the QMI sampling septum.

(NOTE: The acceptable QMI single-service use sample collection bag shall be placed in a portable hand carry type cooler, containing a water/ice mixture, during sample collection.) (Refer to Item 11, **Device Requirements**.)

- 8) On the QMI peristaltic pump open the sampling head by lifting up on the lip on the upper part of the peristaltic pump head.

(NOTE: The Operator's Manual has pictures addressing this Step.)

- 9) Take out a QMI single-service use sample collection bag and locate the fatter section of the tubing. Place this fatter tubing section in the space created after opening the peristaltic pump head lid and close the peristaltic pump head lid when the tubing is positioned straight over the rollers in the peristaltic pump head.
- 10) Take the cover off the sterile needle attached to one (1) end of the QMI single-service use sample collection bag tubing and locating an unused QMI septum insert sampling port, insert and push the needle completely into the septum. For the perimeter needle channels, slant the needle toward the center of the channel following the angle of the channel.

(NOTE: Be careful not to bend the lumen tip of the needle.)

- 11) Use each QMI septum insert sampling port **ONLY ONCE!** Pierced QMI septum insert sampling ports can be readily seen. Once pierced, a QMI septum insert sampling port **CANNOT** be used again.
- 12) Smell the milk; observe the milk in a quiescent state; properly obtain the temperature of the milk; and properly measure the milk stored in the farm bulk milk tank or silo. Record the temperature and weight of the milk on the farm weigh ticket.
- 13) Open the farm bulk milk tank or silo outlet valve, lift the cover over the peristaltic pump just enough to press the start button on the control pad of the peristaltic pump, which turns on the peristaltic pump, and then lower the cover.
- 14) Make sure the RPM's of the peristaltic pump display match what has been determined to meet the requirements cited in Item 10, **Device Requirements**. Record the RPM reading on the farm weigh ticket.

(NOTE: One (1) RPM equals approximately one (1) ml per minute.)

- 15) If milk is not flowing toward the peristaltic pump and the QMI single-service use sample collection bag, press the clockwise-counterclockwise arrows on the peristaltic pump display until the milk starts flowing toward the QMI single-service use sample collection bag.
- 16) Place and maintain the QMI single-service use sample collection bag in a portable hand carry type cooler, containing a water/ice mixture, during sample collection to maintain the temperature of the sample in accordance with the temperature requirements of the PMO. (Refer to Item 11, **Device Requirements**.)
- 17) When the farm bulk milk tank or silo has been emptied or the completion of the collection of a partial pickup, which shall be conducted in accordance with Item 10- Utensils and Equipment - Cleaning of the PMO, turn off the peristaltic pump, remove the needle from the QMI septum insert sampling port, and replace the cover on the needle.
- 18) Replace the cover on the QMI septum insert.
- 19) Lift the peristaltic pump head lid to open it to allow the removal of the single-service use sample collection bag sample tubing. The reverse process as was used in Step 9 shall be used. Tie a knot in the QMI single-service use sample collection bag tubing close to where the tubing is attached to the QMI single-service use sample collection bag.
- 20) Take the QMI single-service use sample collection bag and invert rapidly twenty-five (25) times. This agitates the QMI single-service use sample collection bag so a representative sample can then be taken from the milk collected in the QMI single-service use sample collection bag.
- 21) Adequately sanitize a cutting device with an approved sanitizer at the appropriate concentration and cut the tubing from the QMI single-service use sample collection bag just above where the tubing attaches to the QMI single-service use sample collection bag.

(NOTE: Sanitize the cutting device with 200 ppm available chlorine solution, or equivalent, and expose the area for a minimum of one (1) minute contact time.)

Tip the QMI single-service use sample collection bag and allow some milk to flow before positioning a properly identified sample vial into the milk stream and fill the sample vial not more than $\frac{3}{4}$ full.

(NOTE: This sample vial shall comply with the same labeling identification requirements as would be required for a “universal” sample collected using a conventional sample dipper. When this sample collection is conducted at the first stop per load of milk, a temperature control (TC) sample shall also be collected and properly labeling in accordance with the PMO.)

- 22) Immediately transfer the sample vial(s), to a properly constructed sample storage case, designed to maintain the milk sample(s) at the required milk temperature (0°C-4.4°C (32°F-40°F)), using a water/ice mixture, and which protects the sample containers from contamination.
- 23) Handle the sample(s) from this point on in the same manner as a “universal” sample collected by the conventional sample dipper procedure.
- 24) All needles and QMI single-service use sample collection bags shall be properly disposed of in Sharpes containers or an appropriate container provided by the manufacturer.

FORM A
Application to Install an Acceptable QMI Aseptic Sampling Device
for the Collection of "Universal" Samples from
Farm Bulk Milk Tanks and/or Silos

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: _____
Model of Peristaltic Pump: _____
The speed (RPM) of Peristaltic Pump: _____
Sample Collection Bags of Approved Material: Yes _____ No _____
Sample Collection Bags of Approved Design: Yes _____ No _____
Material Type: _____
Sample Collection Bags Size: _____ (mls or ozs.)
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 Bulk Milk Pickup Tanker _____

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

Sample Septum Location: _____

QMI Aseptic Sampling Septum 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 shall meet the requirements of Item 9r-Utensils and Equipment Construction of the most recent edition of the PMO.

2/2012 Revision