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M-I-16-17

December 13, 2016

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 Aseptic Sample Septum For The Collection Of  
Samples From Milk Tank Trucks Under Appendix N of the Grade "A"  
Pasteurized Milk Ordinance

Appendix B-Milk Sampling, Hauling and Transportation of the *Grade "A" Pasteurized Milk Ordinance* (PMO) provides for the use of an approved aseptic sampler for milk tank trucks.

### **III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS**

A protocol specific to each milk plant in which industry plant samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk plant and FDA. As a minimum, the protocol should include the following:

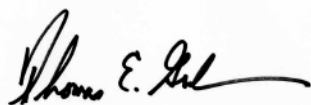
1. A description of how the milk sample is to be collected, identified, handled and stored.
  - a. The aseptic sampler fitting shall be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
  - b. The aseptic sampler septum shall be installed according to the manufacturer's instructions.
  - c. Transfer of milk is achieved using a SOP specific to the aseptic sampler.
  - d. An appropriate device, i.e., a syringe, shall be used to transfer the milk.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the industry plant samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampler as well as to collect, identify, handle and store the milk sample.

This PMO text does 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 milk tank truck sampling for Appendix N of the PMO. It would allow for the use of a sterile needle and the catching of the stream of milk in a sterile sample container (i.e., vial).

Included in this M-I is the SOP and application form for this acceptable milk tank truck aseptic sampler septum sampling procedure for the collection of samples required within Appendix N of the PMO.

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



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**SOP for Milk Tank Truck Sample Collection for Appendix N of the PMO Using an Acceptable Sample Septum and a Syringe or 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 syringe or sterile needle should be filed with the operation installing the sample septum, the 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 milk tank truck to ensure accurate sampling and proper cleaning. (The installation must meet the approval of the Milk Regulatory Agency and the equipment manufacturer.)
- 2) If the milk tank truck has multiple compartments, an acceptable sample septum shall be installed in an appropriate location in each compartment.
- 3) A protective septum cover shall be provided with the septum and shall be in place at all times when the septum is not in use.
- 4) Use only acceptable sterile septum inserts; make sure the nut holding the insert is installed in accordance to the manufacturer's instructions.

**NOTE:** If a positive antibiotic result is obtained, manually clean, sanitize and replace the septum prior to the next load of milk.

- 5) New, sterile, sealed needles shall be used for each sample collection.
- 6) Single-service use containers (i.e., vials) shall only be used for collecting the sample from one (1) milk tank truck or from one (1) compartment of a multiple compartment milk tank truck.

**Collecting the Representative Milk Sample:**

- 1) The person(s) performing the following steps shall be identified as an Industry Plant Sampler and their sampling techniques shall be evaluated at least once every twenty-four (24) months by a FDA certified Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Official (dSSO) for plant sampling.
- 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 milk tank truck shall be adequately agitated 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 milk tank truck. Replace the septum when all sampling ports have been used.
- 6) To begin the sampling of a milk tank truck; aseptically remove the new, sterile, sealed needle by breaking the seal on the needle case and pulling the 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, which protects the sample container from contamination or other means to protect the sample container from contamination.
- 9) Remove the needle from the sampling septum and dispose all single use items in the Sharps 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 shall be hand cleaned and sanitized.

### **Sample Handling:**

- 1) The milk sample container shall be identified with the following information:
  - a. Milk tank truck identification or permit number;
  - b. Date of sampling;
  - c. Time of sampling; and
  - d. Initials of the person taking the sample.

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

**General Requirements:**

Plant Name: \_\_\_\_\_, Date: \_\_\_\_\_  
Plant Address: \_\_\_\_\_, State and Zip: \_\_\_\_\_  
Plant Phone/Fax/E-mail: \_\_\_\_\_  
Plant's License/Permit Number or Plant Code: \_\_\_\_\_  
Plant's Regulatory Inspector: \_\_\_\_\_  
Average Pounds of Milk/Day Received: \_\_\_\_\_  
Average Number of Milk Tank Trucks Received/Day: \_\_\_\_\_  
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 \_\_\_\_\_

**Sample Septum System Design:**

(Meets 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 Items 10p-Sanitary Piping and 11p-Construction and Repair of Containers and Equipment of the most recent edition of the PMO.

12/2016 Revision