QUALITY MANAGEMENT INC.

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PRESS RELEASE

FDA and NCIMS APPROVE A SAFER, MORE ACCURATE METHOD OF TANK SAMPLING FOR MILK TANKER TRUCKS

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QMI® Aseptic Sampling Method Approved for Use by Milk Haulers and Dairy Plants

OAKDALE, MN SEPTEMBER 18, 2007 – Recent publication of FDA memo IMS-a-46 Actions of the 2007 National Conference on Interstate Milk Shippers, authorizes use of the QMI® Aseptic Sampling System for sampling milk tanker trucks.

Bob Gilchrist, Fluid Milk Marketing and Transportation Manager of Agri-Mark supports this innovative method of sampling. Agri-Mark of Lawrence, MA, is a leader in milk production and has used the QMI method for a long time.

"We have found the QMI Aseptic Sampling method to be a safe, convenient, accurate and economical method of sampling milk tanker trucks" said Gilchrist. "The QMI system is exactly what this industry needs to sample without having to open the top hatch of the milk tanker."

The QMI method of sampling from the side or rear of a locked compartment on a milk tanker truck has several advantages. First, the QMI method allows for a more accurate and representative sample. The sample is also collected aseptically, meaning it reduces the chance of contamination of the milk by bacterial, chemical or environmental contaminants. Second, it helps with receiving bay efficiency by allowing samples to be taken before trucks enter the receiving bay. This benefit is a particular advantage to milk processors facing a continual issue of congestion and delay in milk unloading. Third, this method helps the industry comply with the Bioterrorism Preparedness and Response Act by controlling access to the milk load. Finally, it improves sampling safety by allowing samples to be taken from the ground, meaning drivers and milk plant employees are no longer required to make the dangerous climb to the top of the milk tanker truck to collect samples.

Darrell Bigalke, President of QMI, stated, "This application of the QMI Aseptic Sampling method provides a significant benefit to the dairy industry. For the first time dairy processors and milk haulers will be able to collect clean, representative samples of their milk load, and do it efficiently and safely."

An FDA guided study was conducted, comparing the QMI method of sampling to the currently approved method of dip sampling. The FDA found that the data collected by the two methods were not statistically different and determined that the QMI Aseptic Sampling method is an equivalent and reasonable alternative to dip sampling. This is good news for the dairy industry.

# # #

Quality Management, Inc. (dba QMI®), based in Oakdale, MN has a 30-year history in the development and sales of high quality sampling products for dairy processing plants, dairy farms, pharmaceutical manufacturing and biotechnology. QMI markets the QMI Aseptic Sampling System, the QMI Aseptic Transfer System, the QMI Safe-Septum and the QMI Composite (Farm) Sampling System. More than 1,000 dairy processing plants around the world routinely use QMI sampling devices.

Utilizing the QMI Dairy Stress Test for Process Monitoring Line Sampling

Objectives: Identify and/or monitor sources of post-pasteurization contamination.

How the QMI Dairy Stress Test Works: Since gram-negative bacteria cannot survive proper pasteurization, these bacteria can be used as "indicator organisms". The Stress Test improves the sensitivity of line-sampling by allowing gram-negative bacteria (Post-Pasteurization Contamination) to be detected more effectively. Increased oxygen levels in the sample, along with room temperature incubation, optimizes the growth and recovery of gram-negative bacteria and improves the sensitivity and accuracy of line testing. (Table 1)

Rapid Results: 2-4 days.

Procedures:

1. Aseptically obtain a large sample (2-5 Liters) using the QMI Aseptic Line Sampling System and the QMI Composite Sampling Bag.
2. Research has shown that the QMI Composite Sampling Bag has sufficient oxygen permeability to allow effective growth of gram-negative bacteria (Table 2).
3. Incubate sample 24 hours at room temperature.
4. Plate using VRB Agar. No overlay should be used. **
5. Incubate 72 hours at room temperature, observing for growth every 24 hours.

Interpreting Results:

Positive or negative for contamination.

When identifying sources of contamination, any positive test result indicates contamination.

Contamination rates may be very low (for example, only 1 in 20 or more samples may be positive, indicating a source of contamination).

NOTE: For complete process monitoring, additional QMI Composite Bags samples should be held to end of code at 45ºF and plated for 7- 9 days (Keeping Quality Test) and at the end of code.

* If available, add 2.0 ml/50 ml of sample of sterile 12.5% sodium deoxycholate (Gram-positive inhibitor).

** Other Gram-negative selective media, such as CVT agar or dye-reduction methods may be used.

UNIQUE FEATURES OF THE QMI COMPOSITE BAG SAMPLING SYSTEM

- Large volume samples can be obtained
- Samples can be taken over a period of time
- QMI Composite Sampling Bags are oxygen permiable, promoting recovery and growth of gram-negative bacteria
- QMI bags are pre-sterilized

QMI Composite Sampling Bag (part number 2392)

INFLUENCE OF MILK AERATION ON GROWTH OF PSYCHROTROPHIC PSEUDOMONADS

Table 1: Effects of oxygen and temperature conditions on generation times[a] of Pseudomonas putida in *raw milk*

Oxygen (ppm)	Temperature (C°)	Generation Time (h)
1-3	3 +/- 1	31.0
9-12	3 +/- 1	16.0
1-3	9 +/- 1	9.4
9-12	9 +/- 1	5.4

[a] Means of two experiments

Journal of Food Protection. Vol 45, No. 2 Pages 132-134 (February 1982) M. J. Brandt and R. A. Ledford.

Table 1 points out the effect of temperature and oxygen concentration on generation times of pseudomonads in raw milk. The above chart shows the increased oxygen level from 1-3 ppm to 9-12 ppm which reduces the generation time in half., dramatically increasing the growth rate of the bacteria. *Pseudomonas* sp. are a common post-pasteurization contamination bacteria.

Table 2: Influence of Oxygen Permeability of Sample Container on Growth of *Pseudomonas*

	Day 1	Day 13
Control Bag 1	<1	<1
Control Bag 2	<1	<1
Bag 1	<1	$2.2x10^6$
Bag 2	<1	$1.0x10^6$
Bag 3	<1	$1.7x10^6$
Control Syr 1	<1	<1
Control Syr 2	<1	<1
Syringe 1	<1	3
Syringe 2	<1	<1
Syringe 3	<1	1

Table 2:
To illustrate the influence of oxygen permeability of the QMI Composite Sampling Bag, a study was conducted at the University of Minnesota's Biological Technology Institute. In this study, sterilized milk was inoculated with *Pseudomonas* bacteria at a population of about 60 organisms per liter. The inoculated milk was filled in the three composite bags and three 60cc syringes, and then incubated in the refrigerator at 7° C (45°F). Bags and syringes containing uninoculated milk served as controls.

RESOURCES AVAILABLE THROUGH QMI

QMI SOP's

- QMI Standard Operating Procedures for Farms
- QMI Standard Operating Procedures for In-Line Sampling (Direct Load Sampling)
- QMI Standard Operating Procedures for Dairy Plants
- QMI Standard Operating Procedures for the QMI Safe-Septum
- QMI Standard Operating Procedures in Spanish

Other Resources

- Various Articles on QMI Product Validation
- FDA Memos (M-I-06-6 and M-I-06-12)
- Safe-Septum Promotional Video
- Safe-Septum Training Video
- 3-A Certificate of Authorization

PowerPoint Presentations:

- QMI Monitoring Microbial Contamination of Dairy Products
- Effective Line & Tank Sampling on Dairy Farms
- QMI Installation Instructions for Dairy Farms
- QMI Raw Milk Sampling Update
- Heat Resistant Psychrotrophic Bacteria

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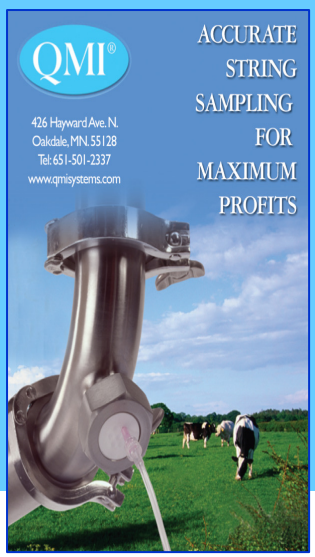

Summary of Regulatory Approvals for QMI Products

- QMI products are certified to display the 3-A Symbol
- QMI products are approved for line tank sampling as described in the Standard Methods for Examination of Dairy Products (section 3.005 and 3.4E4)
- The NCIMS and the FDA have approved QMI products for line sampling (direct load sampling) by FDA memo M-I-06-6
- The NCIMS and the FDA have approved the QMI method (QMI sampler and needle-only method) as published in FDA memo M-I-06-12
- The NCIMS and the FDA have approved QMI products for sampling tanker trucks (NCIMS Conference May 2007). Approval will be published in October 2007

Customer Address Here