

**New York State Department of Agriculture and Markets**  
**Division of Milk Control and Dairy Services**

**Memorandum**

**To:** Dairy industry and Regulatory Personnel  
**From:** Charles Lindberg, Dairy Products Specialist 2  
**Date:** February 5, 2010  
**Subject:** Appendix N Drug Residue Program

In 2008 FDA's Milk Safety Branch conducted a State Program Evaluation of the Department's Grade A milk and dairy product inspection program during which they concluded that the animal drug residue surveillance program of bulk milk in New York State did not comply with Appendix N of the Pasteurized Milk Ordinance. This program, which has been in effect since 1995, requires drug residue testing of a sample taken from the tanker's top manhole as well as agitating the load, sampling, and testing milk taken from the tanker's outlet valve after obtaining an initial positive test. FDA no longer accepts this drug residue testing protocol as compliant in meeting the intent of the PMO's Appendix N. Therefore, after consultation with FDA's Laboratory Proficiency Evaluation Team (LPET), the Department has decided to change the required drug residue testing protocol for all plants, receiving stations, and transfer stations which receive loads of prepasteurized milk. This new protocol or standard operating procedure (SOP) is outlined below.

**Positive Drug Residue Confirmation Procedure**

- 1) Initial sample from a truck tests positive which triggers in-plant procedures for holding and or tagging the load.
- 2) Two (2) additional tests using the same test kit are run on the initial sample along with a control set. All testing done in accordance with the appropriate FDA 2400 series forms.
  - a) If two (2) out of three (3) of the truck's test results are positive; the truck is considered Positive.
  - b) If the second two (2) test results are Not Found (NF) then the sample is considered NF.
- 3) If there is a Positive test result:
  - a) The DMC 1639 Tracking Report is started at this time.
  - b) The owner of the milk is notified to determine the disposition of the load and confirm who shall test the producer samples.

- 4) Producer samples are tested along with a control set using the same or an equivalent test method as the initial load test; the positive producer(s) are retested in duplicate. Two (2) out of three (3) positive results yields a confirmed positive producer sample.
- 5) Contact producer's cooperative, handler and/or field representative with producer test results for appropriate producer follow up. Producer reinstatement samples are tested by the same or an equivalent test method used to determine the producer sample was positive.
- 6) Notify the appropriate NYSDAM Regional Supervisor to start our follow-up and NYSDAM's Central Office to receive a tracking number (see DMC 1639 and instructions)

This procedure has been determined to comply with the PMO's Appendix N **Bulk Milk Pickup Tanker Screening Test** "Option 2".

As you will note, there is no provision in the procedure outlined above to agitate the milk or obtain another sample after the initial test has been found positive. Therefore, it is incumbent on the receiving plant's milk receiver/sampler or the farm pickup milk receiver/sampler to ensure that the sample taken for Appendix N drug residue screening is representative of the load of milk **prior** to taking or testing the sample.

Re-sampling a load of milk for Appendix N testing will only be permitted under extraordinary circumstances and only with the permission of the Department. If a situation occurs which draws the validity of the sample or test into question, the receiving plant must contact the Division of Milk Control and Dairy Services at 518-457-1772 to receive permission to resample a load. Objective evidence must be presented to the Department as to why the original sample and/or analysis did not adhere to accepted practices as stated in 1NYCRR Part 6, Appendix N, Standard Methods for the Examination of Dairy Products, and the FDA 2400 series forms. If permission to resample is granted, it is understood that the reasons which made re-sampling or retesting necessary will be clearly documented and these records, along with the test records, will be maintained by the laboratory and copies provided to the Department with the DMC-1639 tracking form. The Department will follow-up a request to re-sample with an investigation of the milk receivers, analysts, and/or laboratories involved to identify the problem and ensure that corrective action has been initiated to prevent the problem from occurring in the future.

These changes to the drug residue surveillance program will be implemented by May 1, 2010 after a reasonable amount of time is spent in notification and education of all concerned parties. The Department will review the program at Processing Plant Superintendents updates and Laboratory Workshops held throughout the state. Questions are encouraged but in an effort to maintain uniformity throughout the state, all questions about the program must be addressed in writing to Casey McCue, Dairy Products Specialist 3, New York State Dept. of Agriculture and Markets, Division of Milk Control and Dairy Services, 10B Airline Drive, Albany, NY 12235 or [casey.mccue@agmkt.state.ny.us](mailto:casey.mccue@agmkt.state.ny.us)

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