COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE

**To:** Pennsylvania Milk Permitholder

**From:** Russell C. Redding, Pennsylvania Secretary of Agriculture

**CC:** Deputy Secretary Greg Hostetter
Dr. Lydia Johnson, Director, Bureau of Food Safety
Milk Sanitarians and Milk Program Specialists, Bureau of Food Safety

**Date:** October 4, 2017

**Re:** **Update on Implementation of Drug Residue Testing Requirements of FDA's Appendix N of the Pasteurized Milk Ordinance**

## INTRODUCTION

This letter[1] provides an update on issues relating to **Pennsylvania's *January 1, 2018* comprehensive implementation of the drug residue testing requirements required under Appendix N of the Food and Drug Administration's Pasteurized Milk Ordinance ("PMO").**

As many of you are aware, over the last several months, the Pennsylvania Department of Agriculture ("PDA") has been engaged in communications with the United States Food and Drug Administration ("FDA") about their drug residue testing requirements in the PMO's Appendix N.

Communications with FDA were focused on several areas where Appendix N requirements may differ from Pennsylvania's historical regulatory practices under the Milk Sanitation regulations. PDA identified several areas to discuss with the FDA during a March 17, 2017 meeting here at PDA with affected dairy producers.

PDA also recently met with representatives of dairy producer cooperative management on September 29, 2017 to review the FDA's position on the matters under discussion.

The dialogue with FDA was undertaken to clarify and seek to ease the burden of some Appendix N requirements on producers who process their own milk in certain scenarios. As part of this process, PDA delayed the comprehensive implementation date, as noted above, to January 1, 2018 to allow this dialogue to be completed.

[1] It is being sent to both impacted dairy producers with PDA permits and the milk plants and registered bulk tank units that may market milk from these producers.

Communications with FDA are now concluded and we are writing to report the results.

The scenarios discussed with FDA and the outcome of those discussions are addressed in this letter in the following order:

**(1) Retained milk from a farm bulk tank used for on-farm processing**
**(2) On-farm processing variances under PA regulations**
**(3) A new, potential production-based variance**

We have done our best to be helpful, knowing that the availability of markets for fluid milk and all value-added products is more critical than ever.

## 1. RETAINED MILK FROM A FARM BULK TANK

PDA asked FDA whether it would be necessary to conduct Appendix N drug residue testing on milk retained for on-farm processing / manufacturing after a tanker pick up and transport of the majority of the farm bulk tank's contents (which would include Appendix N drug residue testing of that transported milk).

a. FDA has confirmed that it is **not necessary to conduct Appendix N drug residue testing** on the retained portion of the farm's bulk tank after tanker pick-up and Appendix "N" drug residue testing **if**:

   (i) the Appendix N test results on the transported milk are received by the producer **before** any processing of the retained milk begins; and

   (ii) the test results are negative; and

   (iii) the retained milk is not commingled with any other milk or milking;

b. Since negative Appendix N drug residue test results are not typically reported to the source dairy farm, PDA asked FDA if the producer may consider the absence of a positive test result report within 24 hours of milk pick-up to be the equivalent of a negative test result report.

   (i) FDA responded that it would not accept this proposed approach if the producer participates in the National Conference of Interstate Milk Shippers' Interstate Milk Shippers Program ("IMS Program").[2]

[2] FDA states that if the Appendix N negative test results have not been received before processing retained milk, the producer will be found noncompliant during IMS Program rating inspections. The IMS-listed dairy farm, or bulk tank unit in which the producer is included, will also be found noncompliant. The bulk tank unit will be withdrawn from the IMS list.

PDA is sending a copy of this letter to milk plants and registered bulk tank units to provide them awareness of FDA's position. Individual producers are encouraged to contact their milk plant or registered bulk tank unit to seek an agreement to provide Appendix N test results, if necessary for your operation.

PDA has also learned of some producers or groups of producers engaged in establishing their own testing capabilities, individually or cooperatively, to satisfy FDA's requirements.

Please contact the Bureau of Food Safety and Laboratory Service at (717) 787-4315 with questions on available approved dairy laboratories, setting up your own testing capability or the requirements for testing.

You can also visit PDA's webpage at www.agriculture.pa.gov/Protect/FoodSafety/Laboratory for more information.

## 2. ON-FARM PROCESSING VARIANCES UNDER PA REGULATIONS

PDA's existing Milk Sanitation regulations contain two instances where processors or small "milk plants" (so-called "pasteurized jugger" operations) can apply to PDA to obtain a variance excusing compliance with Appendix N drug residue testing. PDA asked FDA the impact if such variances were applied for and granted in two scenarios.

a. ***Variance For Manufactured Dairy Products*** **- 59 Pa. Code §59a.111(a)(1)(i) -** A variance is available in PA for those who: (a) hold a manufactured dairy products permit; (b) process milk on the farm where it was produced; and (c) produce that milk in accordance with a PDA-approved written quality control program (eliminating the use of the drugs to be tested for under Appendix N).

   The question asked of FDA was whether possession of such a variance would eliminate the need for Appendix N testing results with regard to milk retained for on-farm manufacturing after a tanker pick up and transport of the majority of the farm bulk tank's contents.

   (i) FDA stated that all milk must meet Appendix N drug residue testing requirements if it originates from a farm permitted under a IMS-listed bulk tank unit. An IMS-listed bulk tank unit accepting milk from a farm with respect to which PDA has issued this variance will be found noncompliant during IMS Program rating inspections. The IMS-listed dairy farm, or bulk tank unit that the producer is included within, will be determined noncompliant and the bulk tank unit will be withdrawn from the IMS list.

   (ii) This means that applying for and accepting this variance will jeopardize a farm's or bulk tank unit's IMS listing and IMS program participation.

b. ***Variance For Non-IMS milk plants*** **- 59 Pa. Code §59a.18(c) -** A variance is available in PA for milk plants that are neither IMS-listed nor receive any Grade "A" milk, if all milk is produced in accordance with a PDA-approved written quality control program (eliminating the use of the drugs to be tested for under Appendix N).

   (i) FDA concurred that – *under these limited circumstances* – drug residue testing would be conducted entirely under Pennsylvania's laws and regulations for manufacturing grade milk plants and grade B (manufacturing) dairy farms, and need not comply with Appendix "N" drug residue testing requirements.

## 3. A NEW, POTENTIAL PRODUCTION-BASED VARIANCE

PDA proposed establishing a regulation to excuse small-volume dairy producers/processors from Appendix N drug residue testing requirements if producing less than $25,000 worth of milk and/or manufactured dairy products per year. The question asked of FDA was whether possession of such a variance would eliminate the need for Appendix N testing results with regard to milk retained for on-farm processing / manufacturing after a tanker pick up and transport of the majority of the farm bulk tank's contents.

a. FDA stated that there is no legal basis under the PMO to support such an exception to Appendix N drug residue testing and it would find any farm that fails to perform required testing "noncompliant" and will de-list any IMS-listed dairy farm or bulk tank unit that the on-farm producer/processor is included within.

b. PDA will not be pursuing establishing this proposed variance by regulation.

In conclusion, **the deadline for Pennsylvania's comprehensive implementation of the drug residue testing requirements under Appendix N of the FDA's PMO remains January 1, 2018.** However, producers should be aware that IMS Program rating inspections are on-going and some FDA rating officers have already noted deficiencies upon inspection. It remains vital to keep the channels of communications open with any IMS program-affiliated purchaser of your milk.

I hope this letter answers questions raised during this process and at the March 17, 2017 dairy producer meeting. If, for any reason, you have additional questions, please contact the Bureau of Food Safety at (717) 787-4315.

Thank you.