

Bureau of Food Safety, Milk Program
The PMO Appendix N Drug Residue Testing Variance

Pennsylvania's Title 7 PA Code Chapter 59a contains regulations found in both the Grade "A" Pasteurized Milk Ordinance and the USDA Recommended Requirements for Manufacturing Grade Milk regarding the drug residue testing of all fluid milk prior to processing. These provisions are contained in Chapter 59a.18(c) (Sampling and examination) and 59a.111 (Drug Residue Level), and they apply to processors of pasteurized fluid milk and milk products as well as manufactured dairy products such as raw milk cheeses that are aged 60 days or cheeses manufactured from pasteurized milk. Permit holders who purchase raw milk for pasteurization or raw milk for manufacturing will now be required to complete Beta lactam testing on representative samples of their commingled milk each processing day. Permit holders who utilize only milk that is produced on their own farm and do not purchase milk from other farms (or cooperatives) are eligible to request a variance from the testing requirements of these sections.

Important criteria regarding a variance request are listed below followed by additional guidance regarding a farm's Drug Residue Quality Control Program and the Application for a Variance Regarding Chapter 59a.18 and 59a.111.

Variance Request Criteria:

1. Permit holders who produce or receive Grade "A" certified milk are not eligible to apply for a variance from the drug residue testing requirements of Appendix N.
2. A variance request must include documentation of a written quality control program that details the production practices that are in place to minimize the possibilities for drug residue contamination of the plant's milk, milk products, and manufactured dairy products.
3. The on-farm procedures that are specified in the written quality control program will be verified during regular inspections by the Department's inspection staff.
4. A variance request must include a written recall program that specifies the procedures that the permit holder will follow to notify their customers if their finished product(s) are found to contain an illegal drug residue.
5. If approved, the variance must be renewed by the permit holder on an annual basis and the on-farm procedures will continue to be verified through regular inspections by the Department.
6. The variance may be revoked if violative drug residues are found in the finished product(s) or milk for pasteurization/ manufacturing. The variance may also be revoked if inspections determine that the on-farm practices specified in the variance request are not being followed.

Guidance Regarding a Drug Residue Quality Control Program:

The National Milk Producers Federation publishes an annual informational manual that summarizes production practices that, if followed, should significantly lower the risk for drug residues in meat and milk. Entitled the Milk and Dairy Beef Drug Residue Prevention Producer Manual of Best Management Practices 2018, this manual provides very current guidance regarding the safe and judicious use of animal drugs to prevent drug residues in milk products and manufactured dairy products. The manual is available as a link on the National Dairy FARM Program website at www.nationaldairyfarm.com. Permit holders who are requesting a drug residue testing variance should carefully review this manual and use it as a resource in evaluating their own production practices. The quality control program that is contained in a variance request should document that the farm is following a set of best management and records keeping practices that are consistent with those outlined in this manual. Listed below are the specific best management practices and record-keeping forms from the manual that should be referenced in a quality control program.

Best Management Check Lists to Avoid Antibiotic Residues:

1. Establish a Valid Veterinarian-Client-Patient Relationship (VCPR)
2. Use Only FDA Approved Over-the-Counter (OTC) or Prescription (Rx) Drugs with Veterinarian's Guidance
3. Administer All Drugs Properly and Identify All Treated Animals
4. Maintain and Use Proper Treatment Records on All treated Animals
5. Use Drug Residue Screening Tests and Maintain a Log for Testing Results
6. Implement Employee/ Family Awareness of Proper Drug Use to Avoid Marketing Adulterated Milk Products

Record-Keeping Forms:

1. Veterinarian-Client-Patient Relationship Validation Form
2. Recommended or Approved Drug List
3. Animal Treatment Plan
4. Beginning Drug Inventory
5. Record of Drug Purchases
6. Daily Treatment Record
7. Drug Disposal Record

With respect to item five of the best management practices listed above, the Department believes that basic drug residue screening kits should be part of the quality control program for every milk producer. When submitting a variance request, please include information regarding an appropriate drug residue screening test kit that will be used to document the farm's drug residue avoidance measures. Information regarding available milk screening test kits and the drug residues that they detect may be found on pages 48- 69 of the 2018 Milk and Dairy Beef Drug Residue Prevention Reference Manual.

Bureau of Food Safety and Laboratory Services, Milk Program

Application for Appendix N Variance

(Chapter 59a.18 and 59a.111)

Application year: 20__

1. Permit Name: _____
2. Permit Address: _____

3. Primary Telephone: _____ Fax Number: _____
4. Email Address: _____
5. Source of Raw Milk for Pasteurization or Raw Milk for Manufacturing:
 - Own Farm Only
 - Own Farm and other farms or Bulk Tank Units (Note: if this is checked variance will not be approved)
6. Average daily pounds of production of own milk supply: _____
7. Type of Operation:
 - Fluid Milk and/or Milk Products
 - Manufactured Milk Products (i.e. Aged or Pasteurized cheeses, etc.)
8. Average daily pounds of processed product: _____
9. List of all milk products processed: _____

10. Market Handler for Surplus Milk: (Note: A producer of "Grade A" Milk for Pasteurization is not eligible for variance)
 - Name of Market: _____
 - PA Approved Inspector (farm Inspector) Name: _____
 - Average daily pounds of surplus milk going to market: _____
11. Drug Residue Screening Test Kit Available for On Farm Testing: (**if sharing equipment with another facility, please submit signed copy of shared equipment agreement)
 - Model name of approved testing equipment: _____
12. Attach documentation of your drug residue quality control program including examples of record keeping forms as described in the guidance memorandum
13. Attach documentation of the recall program for your dairy products.
14. Attach an updated Veterinary-Client-Patient Relationship Form (signed and dated by veterinarian)
15. Attach Shared Equipment Agreement if sharing Drug Residue Screening Kit with another facility
16. Name of current Regional Regulatory Inspector: _____

Signature of Milk Supply Owner: _____

Printed Name: _____

Date: _____

Additional Information for Appendix N Application

- For more detailed information on items/forms required for this application please see the Appendix N Guidance Memorandum
- Grade A farms and/or dairy plants will not be approved for this variance.
- This variance is for individual producers making product at their own facility with their own milk supply. If milk from the supply is being sent to other facilities for production, that milk must be tested for Appendix N.*
- If a facility has additional milk supplies coming in for additional products, this variance does not apply.**
- The Shared Equipment form must be filled out if the facility is using a piece of antibiotic testing equipment at another farm or small dairy. If the source of testing equipment is an approved BFSLS 3rd party laboratory, the form does not need to be completed. If this form is necessary, it must be updated annually.
- The Veterinary-Client-Patient-Relationship form must be updated annually.
- Deviations in production from approved variance applications can result in removal from the variance program.
- This variance is only good for one calendar year. Each facility granted a variance must reapply each year for continued variance status. Failure to reapply will automatically remove you from the program. If your application is not received by January 1st of the coming year, you will be required to start testing your milk for antibiotics as required by Appendix N of the Pasteurized Milk Ordinance. It is strongly recommended your application is sent in by November 15th of the current year for proper review and approval time.

* The Appendix N variance is specifically for *one* milk supply going into *one* production facility. Not multiple production facilities.

** Products made for *personal use* for other individuals will not be held against facility as long as they are properly labeled as "Not for Sale".



Bureau of Food Safety, Milk Program Shared Equipment Agreement

A shared equipment agreement covers equipment primarily owned and/or stored by one facility or business, but which is made available to another facility on an as-needed basis.

Facility using the shared equipment:

FACILITY (Business) NAME: _____

OWNER(S) NAME: _____ PHONE NO: _____

Submit completed agreement along with other applications as necessary:

Type of Equipment Available to use under this agreement:

- Antibiotic Testing Equipment

Name/model of testing equipment available: _____

- Pasteurization Testing Equipment

- Type of Equipment available (circle each that apply):

- Water Bath

- Calibratable Thermometer

- Pressure board

- Salt Testing Equipment, Model: _____

- Salt canister

To Be Completed by Equipment Owner:

The facility listed above may use the above-indicated equipment, as needed, for compliance with state and federal regulations.

FACILITY NAME: _____

FACILITY OWNER/MANAGER: _____

FACILITY ADDRESS: _____

CITY/STATE: _____ ZIP: _____

PHONE NUMBER: _____ FAX NUMBER: _____

EMAIL ADDRESS: _____

SIGNATURE: _____ TITLE: _____ DATE: _____