The Food and Drug Administration has concurred with a proposal of the 1991 National Conference on Interstate Milk Shipments to add an Appendix N to the Pasteurized Milk Ordinance. Appendix N will help assure that milk suppliers are in compliance with safe levels or established tolerances for animal drug residues in milk. Section 17 of the West Virginia Grade "A" Pasteurized Milk Rules references the Grade "A" Pasteurized Milk Ordinance of the Food and Drug Administration and requires compliance with its appendices. The provisions of Appendix N to the PMO (copy attached) are therefore required to be enforced under the West Virginia Grade "A" Pasteurized Milk Rules. Food and Drug Administration interpretive memoranda regarding Appendix N are referenced as guidance in conducting required enforcement activities.

Appendix N is being implemented in two phases as follows:

**INDUSTRY RESPONSIBILITIES - EFFECTIVE JANUARY 1, 1992**

A. Screen all bulk milk pickup tankers for beta lactam drug residues.

- All farm bulk pickup tankers must be screened before the milk is processed. The tanker may be unloaded. However, if the test is unsafe the commingled milk in the silo, storage tank, etc., is considered adulterated regardless of the effect of the dilution or any subsequent test of the commingled milk.

- Grade "A" raw milk intended for "manufacture grade" uses (cheese, ice cream) must meet the requirements of Appendix N.

- Preferable methods for testing beta lactam residues at the present time are B. Stearothermophilus disc assay, Charm I or II (liquid) or Delvo P. Until further directed, industry may use other methods which have been evaluated by Virginia Polytechnic Institute and State University (Bishop et al, 1991) or equivalently evaluated methods which have been demonstrated to provide positive results for beta lactams and are acceptable to the Commissioner, WV Bureau of Public Health.

- At the option of industry a bulk tanker of milk may be discarded based on a screening test. A confirmation is required, however, to be conducted on the sample from the individual producer responsible for contaminating the load. If the results of a screening test are positive and the confirmation test is negative, the results of the confirmation test supersede the screening test results for either a bulk tanker load sample or an individual producer sample.
B. Screen for other drug residues (employing a random sampling program) as specified by FDA. Industry will be notified when drug residue screening other than beta lactams is required.

C. Report to the health department immediately (as practical) all positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, or finished milk or milk product samples.

- Initial notification under this requirement shall be done by telephone with hard copy follow-up of pertinent documents. Industry has been provided a list of persons who can be contacted regarding positive drug residue reports. Notification shall include information regarding the ultimate disposition of the raw or finished milk.

- The milk marketing or milk procurement organization serving the producer is responsible for notifying the health department immediately by telephone if the use of an "equivalent penalty" for suspension is desired as described under part B (page 3 - 4) of "Regulatory Responsibilities".

- Producer samples from a bulk milk pickup tanker found to be positive for drug residue must be individually tested to determine the farm of origin. Further pickups from the violative producer shall be discontinued until subsequent tests are no longer positive for drug residues.

D. Dispose of milk with unsafe drug residue in a manner that removes it from the human or animal food chain except where acceptably reconditioned under FDA guidelines.

- Bulk tanker loads of milk with drug residue levels above safe levels shall be disposed of at properly operated animal waste management facilities with adequate holding potential; at public or commercial sewage treatment facilities with prior approval of the health department and treatment authority; or through other disposal methods with prior health department approval.

- Additional information on the approval status of animal waste management facilities for disposal of tanker loads of milk will be forthcoming.

E. Record all drug residue sample results and retain the records for a period of at least six (6) months.

- West Virginia Bureau of Public Health issued or approved forms for recording drug residue tests are to be maintained at the raw milk receiving station or receiving plant. A copy of the record form must be submitted to the health department at the end of each month.
F. A "Quality Assurance Plan for Certification of Supervisors" (QAPCS) is being prepared for implementation whereby industry analysts will be qualified to perform screening tests under the supervision of a "certified supervisor" using FDA accepted screening tests.

- Once QAPCS is implemented and "certified supervisors" are in place at receiving stations, approved screening tests will be official for regulatory action under conditions approved by FDA, based on positive results.

- During the interim period, analysts who have not been officially recognized do not require "certification" to perform screening tests for beta lactams.

REGULATORY RESPONSIBILITIES - EFFECTIVE JULY 1, 1992

A. The WV Bureau of Public Health shall monitor industry drug residue surveillance activities by making unannounced on-site inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program.

- Inspections and sampling must be done at least quarterly and may be done as part of the routine plant inspection.

- Samples must be collected and analyzed from at least 10% of the bulk milk pickup tankers scheduled to arrive on the day of inspection.

B. Permit Suspension and Revocation - The WV Bureau of Public Health shall immediately suspend for a minimum of two (2) days or equivalent penalty the Grade "A" permit of a producer responsible for a drug residue violation at or above the actionable level. Drug residue violations are considered an imminent hazard to the public health and, as such, permit suspension shall be immediate with no proposed order to suspend required to be issued.

- The WV Bureau of Public Health will accept documentation from a producer or the producer's milk marketing or milk procurement organization that a monetary penalty or milk loss equivalent to two (2) full days (48 hours) of production has been assessed.

- Following initial notification (see part C of "Industry Responsibilities"), documentation must be submitted on a written verification form provided by the health department.

- The equivalent penalty will be equal to a formal suspension and will appear on the producer's permanent record as a two day drug residue violation suspension.
• Use of the equivalent penalty method for satisfying the penalty requirement of Appendix N will reduce the volume of non-violative milk which must be dumped thereby reducing waste milk disposal problems.

• For example: If a tanker is screened positive and disc assay confirmation tests reveal that both the tanker and individual farm sample of the responsible producer are violative, the tanker load must be dumped. Notification to the health department that the dumped tanker load contained two days production for which the producer will not be paid would serve as equivalent to two days suspension.

• In the case of an every day shipper the equivalent penalty may be:

  • One day monetary penalty due to a dumped tanker load plus one day monetary penalty due to milk loss (no pickup the day subsequent to causing a dumped tanker load), **OR**

  • A two day monetary penalty if the producer dairy is assessed the cost of the entire tanker of milk provided the assessment is greater than or equal to two days of the producer's production.

  • A suspension not using the equivalent penalty method will be for two (2) days effective from the time of notification of a confirmed violative drug residue.

• For example: If a tanker is screened positive and disc assay reveals a violative drug residue in an individual farm tank sample but the tanker load itself is not violative, the tanker load could be accepted by the processing plant and the producer compensated for his milk. In this case the health department would suspend the producer's permit for two days effective from the time of notification by the laboratory of the confirmed positive drug residue. The suspension would be carried out for the full two days even if subsequent tests before the end of the two day period revealed the milk was no longer violative for drug residue.

• On the second occurrence of violative drug residues in a twelve month period, the producer's permit shall be suspended for a minimum of four (4) days or equivalent penalty (with documentation as outlined above).
For a third occurrence of a violative drug residue in a twelve month period, the suspension shall be for a minimum of four (4) days or equivalent penalty (with documentation as outlined above). In addition, a proposed order to revoke the producer's permit shall be issued after the required four day suspension or equivalent penalty has been satisfied. The producer will be given an opportunity for a hearing on the proposed order to revoke the permit as provided for in the PMO and WV Grade "A" Pasteurized Milk Rules.

C. Permit Reinstatement - After the required permit suspension or equivalent penalty has been satisfied, and a sample taken from the producer's milk in the farm bulk tank is no longer positive for drug residue, the producer's Grade "A" permit may be restored to a temporary permit status pending completion of the "Milk and Dairy Beef Residue Prevention Protocol".

In no event shall the Grade "A" permit of the violative producer be fully reinstated until the producer and a licensed veterinarian have signed a quality assurance certificate for display in the milkhouse which states that the "Milk and Dairy Beef Residue Prevention Protocol" is in place and being implemented for the dairy herd(s) from which the adulterated milk containing violative drug residue was shipped.

- The "Milk and Dairy Beef Residue Prevention Protocol" is a quality assurance program designed to assist the producer in self-evaluation of production practices with the assistance of a veterinarian in the context of a valid veterinarian/client/patient relationship. Certification training, materials, etc., under the protocol are considered to be industry responsibilities. The WV Bureau of Public Health will assist with this program as resources permit.

- A maximum of thirty (30) days is considered adequate to have completed the "Milk and Dairy Beef Residue Prevention Protocol" although a greater time period may be allowed at the discretion of the health department on a case by case basis.

- A producer under temporary permit status who has not completed the "Milk and Dairy Beef Residue Prevention Protocol" within thirty (30) days will be issued a proposed order to suspend and afforded the opportunity for a hearing as provided for in the PMO and WV Grade "A" Pasteurized Milk Rules.

D. Certification of industry supervisors in the use of approved drug test methodology will be the responsibility of the WV Office of Laboratory Services' Laboratory Evaluation Officers. A flow chart of the sequence of events to obtain full certification of industry supervisors is attached.
References

64 CSR 34 – Grade “A” Pasteurized Milk Rule
Grade “A” Pasteurized Milk Ordinance

History

Attachments

Flow Chart
Appendix N
Penalty Verification Form