901:11-2-05 **Drug residue level.**

(A) Dairy plant responsibilities.

(1) Sampling and testing program:

(a) All raw milk shipped for processing or intended to be processed on the farm where it was produced shall be sampled and tested, prior to processing, and all individual producer raw milk samples submitted to an approved laboratory for examination to determine bacteria and somatic cell counts shall also be tested for beta lactam drug residue. Collecting, handling and testing of samples shall be done according to procedures approved by the director, and the laboratory results shall be transmitted to the department as requested by the director;

(b) When so specified by the director, all raw milk shipped for processing, or intended to be processed on the farm where it was produced, shall be sampled and tested, prior to processing, and all individual producer raw milk samples submitted to an approved laboratory for examination to determine bacteria and somatic cell counts shall also be tested for other drug residues. Collecting, handling and testing of samples shall be done according to procedures approved by the director, and the laboratory results shall be transmitted to the department as requested by the director;

(c) When the director determines that a potential problem exists with an animal drug residue or other contaminant in the milk supply, additional sampling and additional testing shall be conducted, as ordered by the director. The testing shall continue until such time that the director determines with reasonable assurance that the potential problem has been remedied; and

(d) The dairy plant shall analyze samples for beta lactams and other drug residues by methods evaluated by the association of official analytical chemists (AOAC) and accepted by the director as effective in determining compliance with established "safe levels" or tolerances as established and amended by the United States food and drug administration. The dairy plant may employ on a temporary basis other test methods determined to demonstrate accurate compliance results. These test methods may be used until they are evaluated by the AOAC and accepted or rejected by the director.

(2) Individual producer sampling:

(a) For bulk milk a milk sample for beta lactam drug residue testing shall be taken at each farm and shall include milk from each farm bulk tank;

(b) For can milk a milk sample for beta lactam drug residue testing shall be formed separately at the receiving plant for each can milk producer included in a delivery, and shall be representative of all milk received from the producer; or

(c) For producer/processor a milk sample for beta lactam drug residue testing shall be formed separately according to paragraphs (A)(2)(a) and (A)(2)(b) of this rule for milk produced or received by a producer/processor.

(3) Load sampling and testing:

(a) For bulk milk a load sample shall be taken from the bulk milk pickup tanker after its arrival at the plant and prior to further commingling;

(b) For can milk a load sample representing all of the milk received on a shipment shall be formed at the plant, using a sampling procedure that includes milk from every can on the vehicle; or

(c) For producer/processor a load sample shall be formed at the plant using a sampling procedure that includes all milk produced and received.

(4) Sample and record retention. A load sample that tests positive for drug residue shall be retained according to guidelines established by the appropriate state regulatory agency. The records of all sample test results shall be retained for a period of not less than twelve months.

(5) Dairy plant follow-up:

(a) When a load sample tests positive for drug residue, dairy plant personnel shall notify the director immediately, in accordance with state policy, of the positive test result and of the intended disposition of the shipment of milk containing the drug residue. All milk testing positive for drug residue shall be disposed of in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under United States food and drug administration compliance policy guidelines;

(b) Each individual producer sample represented in the positive-testing load sample shall be individually tested in a laboratory approved by the director to determine the producer of the milk sample testing positive for drug residue. Identification of the producer responsible for producing the milk testing positive for drug residue, and details of the final disposition of the shipment of milk containing the drug residue, shall be reported immediately to the director, according to state policy; and

(c) Milk shipment from the producer identified as the source of milk testing positive for drug residue shall cease immediately and may resume only after a sample from a subsequent milking does not test positive for drug residue.

(B) Regulatory agency responsibilities.

(1) Monitoring and surveillance. The director shall monitor the milk industry's drug residue program by conducting unannounced on-site inspections to observe testing and sampling procedures and to collect samples for comparison drug residue testing. In addition, the director shall review industry records for compliance with state policy. The review shall seek to determine that:

(a) Each producer is included in an effective routine drug residue milk monitoring program utilizing the official methods and federal drug administration approved methods to test samples for the presence of drug residue;

(b) The director receives prompt notification from industry personnel of each occurrence of a sample testing positive for drug residue, and of the identity of each producer identified as a source of milk testing positive for drug residue;

(c) The director receives prompt notification from industry personnel of the intended and final disposition of milk testing positive for drug residue, and that disposal of the load is conducted in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under federal drug administration compliance policy guidelines; and,

(d) Milk shipment from a producer identified as a source of milk testing positive for drug residue completely and immediately ceases until a milk sample taken from the dairy herd does not test positive for drug

residue.

(2) Enforcement:

(a) The director may deny, suspend or revoke the producer's license or registration for violation of this rule~~.~~;

(b) ~~The producer shall review the "Milk and Dairy Beef Quality Assurance Program" with a licensed veterinarian within thirty days after each occurrence of shipping milk testing positive for drug residue. A certificate confirming that the "Quality Assurance Program" has been reviewed shall be signed by the responsible producer and a licensed veterinarian. The director shall be notified after the program has been reviewed~~The producer shall review the "Milk and Dairy Beef Drug Residue Prevention" manual with a licensed veterinarian within thirty (30) days after each occurrence of shipped milk testing positive for drug residue. A validation form confirming that the "Milk and Dairy Beef Drug Residue Prevention" manual has been reviewed and that a valid Veterinary Client Patient Relationship (VCPR) exists shall be signed by the responsible producer and a licensed veterinarian. The validation form shall be submitted to the director after the manual has been reviewed; and,

(c) If a producer ships milk testing positive for drug residue three times within a twelve month period, the director may revoke the producer's license or registration.

Effective:

R.C. 119.032 review dates: 09/19/2012

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	917.02
Rule Amplifies:	917.05, 917.22
Prior Effective Dates:	6/1801, 6/06/05, 9/19/07, 8/9/2009, 4/22/2010