

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amendment)

902 KAR 50:090. Milk adulteration.

RELATES TO: KRS Chapter 13B, 211.090, 217.025, 217C.060, 217C.100~~[217.005-217.215, 217.992, 217C.010-217C.990]~~

STATUTORY AUTHORITY: KRS 194A.050(1), 211.180(1)(c), 217C.040~~[194.050, 211.090]~~

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Cabinet for Health and Family Service to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.180(1)(c) authorizes the cabinet to promulgate administrative regulations for the safe handling of food and food products.~~[The Cabinet for Human Resources is directed by]~~ KRS 217C.040 authorizes the cabinet to promulgate regulations for the ~~[to regulate]~~ the production, transportation, processing, handling, sampling, examination, grading, sale, and other matters relating to Grade A and manufactured~~[manufacturing]~~ milk and milk products as may be necessary to protect the public health. This administrative regulation establishes enforcement procedures to prevent the sale of Grade A and manufactured milk and milk products adulterated with antibiotics and other inhibitory substances, chemicals, and excessive water.

Section 1. Antibiotics and other Inhibitory Substances Enforcement Procedure.

(1) Sampling procedure.

(a) Antibiotic tests shall be performed a minimum of four (4) times during any consecutive six (6) months on each producer's milk~~[milk producer]~~ or on raw commingled loads and all Grade A processed milk (except cultured products). When commingled milk is tested, milk from each individual producer~~[all producers]~~ shall be represented in the sample.

(b) Commingled loads that show~~[Any loads showing]~~ any level of antibiotics shall require each individual producer's milk on the load to be tested.

(c) 1. An individual producer's milk sample found to be positive shall be reported to the Milk Safety Branch and confirmed by laboratory report; and

2. No additional milk shall be collected from the individual producer until the producer is compliant with enforcement procedures listed in subsection (4) of this section.

(2) All loads of raw milk shall be screened for antibiotics and other inhibitory substances prior to receipt by the plant.

(3) Utilization of milk on a load showing levels of antibiotics shall be as follows:

(a) A load of raw milk with an antibiotic level~~[1. Loads showing levels of antibiotics]~~ below the M-a-85 (Revision #16) standards~~[acceptable standard of sixteen (16) mm zone size by the Bacillus stearothermophilus disk assay method, or any procedure approved in the 15th edition of "Standard Methods for the Examination of Dairy Products"]~~, may be accepted by the plant ~~;~~ however, each individual producer's milk on the load shall be tested, and any producer sample found to be positive shall be reported to the Milk Control Branch and confirmed later in writing (laboratory report). ~~No additional milk shall be collected from that producer until enforcement procedures listed in this administrative regulation are complied with].~~

(b) A load of raw milk with a positive antibiotic level above the M-a-85 (Revision #16) standards~~[2. Loads testing positive (sixteen (16) mm zone size or greater)]~~ shall not be utilized by the plant~~[company]~~ and shall be reported to the Milk Safety~~[Control]~~ Branch.

~~(c) If a load of raw milk is [Also, all producers' milk represented on the load shall be tested, and any producer sample found to be positive shall be reported to the Milk Control Branch and confirmed later in writing (laboratory report). No additional milk shall be collected from that producer until enforcement procedures listed in this administrative regulation are complied with.~~

~~3. Should a load be] commingled into a plant storage tank with other loads and later found to be positive, the storage tank shall be tested and found to be negative prior to processing.~~

~~(d)[4.] Intentional blending of loads found to be positive for antibiotics shall be prohibited.~~

~~(e)[5.] Raw milk inadvertently processed and later found to be positive for antibiotics or other inhibitory substances shall be reported to the Milk Safety[Control] Branch prior to shipment for sale. Each case will be handled individually and may require testing to determine if antibiotics are present which would prohibit sale.~~

~~(4)[(d) It is recommended that all loads of raw milk be screened for antibiotics and other inhibitory substances prior to receipt by the plant.~~

~~(2)] Enforcement procedures.~~

~~(a) [All loads found to be positive for antibiotics or other inhibitory substances prior to receipt by the plant shall not be received. All producer samples included in the load shall be tested, and the results of the load and producer samples reported to the Milk Control Branch by telephone as soon as possible and confirmed later in writing (laboratory report).~~

~~(b) No milk shall be collected from producers with a positive antibiotic test until the following conditions are met:~~

~~1.] Producers with first antibiotic or other inhibitory substances violation during the past twelve (12)[twenty-four (24)] months shall require a negative sample to be obtained from the producer's milk[producer] supply by a certified sample collector prior to the milk being collected by the hauler. Test[The negative] results shall be reported to the Milk Safety[Control] Branch as soon as possible.~~

~~(b)[2.] Producers with the second antibiotic or other inhibitory substances violation during the past twelve (12)[twenty-four (24)] months shall:~~

~~1.[a.] Be notified by the Milk Safety[Control] Branch of the suspension by telephone and confirmed by letter. The letter confirming the suspension shall include an Application for Reinstatement of [the] Permit, DFS-7A, incorporated by reference in 902 KAR 50:033.~~

~~2.[b.] Prior to an official sample being collected for reinstatement purposes, the producer shall request permit reinstatement in writing and indicate [he believes] the problem has[to-have] been corrected.~~

~~3.[c. Require] A representative of the Milk Safety[Control] Branch shall[te] visit the dairy producer [dairy] after the request for reinstatement is received and prior to the first official sample being taken.~~

~~4. During this farm visit the producer shall demonstrate a method of marking cows treated with antibiotics to[which will] assure milk from treated cows is not offered for sale.~~

~~5. Upon acceptance of the exclusion procedure for treated cows, an official sample shall be collected and found to be negative for antibiotics prior to shipment.~~

~~6. The first shipment of milk following the negative sample shall not exceed four (4) milkings for Grade A purposes or six (6) milkings for manufacturing purposes.~~

~~(c)[limits listed in this administrative regulation.~~

~~d. After receipt of the written request for reinstatement and a farm visit by the Milk Control Branch, a sample of the producer's milk shall be collected by a certified sample collector and found to be free of antibiotics prior to the first shipment.~~

~~e. Milk collected on the first shipment shall not exceed four (4) milkings for Grade A purposes or six (6) milkings for manufacturing purposes.~~

~~3.] Producers with more than two (2) antibiotic or other inhibitory substances violations during the past twelve (12)~~twenty-four (24)~~ months shall:~~

~~1.[a.] Have their permits suspended [in accordance with the provisions of paragraphs 2a and b of this subsection]; and~~

~~2.[b.] May request an administrative hearing by submitting a Request for a Hearing, incorporated by reference in 902 KAR 50:033, to the Milk Safety Branch within ten (10) days, [be required to attend a hearing with the Milk Control Branch and/or other representatives of the Department for Health Services] to show cause why their permit should not be revoked.~~

~~3. The hearing shall be conducted in accordance with KRS 217C.100.~~

~~(5)[(3)] Company or producer association policy. Companies or producer associations having policies requiring producer penalties for offering milk for sale containing antibiotics or other inhibitory substances may have precedence over the enforcement policy outlined in this administrative regulation provided that:~~

~~(a) The policy is filed in writing with the Milk Safety~~Control~~ Branch;[-]~~

~~(b) The policy is approved by the Milk Safety~~Control~~ Branch as being as or more stringent than the enforcement procedures listed in this administrative regulation; and[-]~~

~~(c) Evidence is forwarded in writing that company policy was carried out on each positive producer's milk~~producer~~ sample found.[-]~~

~~(d) The procedures outlined in this administrative regulation apply to both Grade A milk and milk for manufacturing whose permits are suspended because of a positive antibiotic test shall not be allowed to ship milk to a manufacturing or Grade A plant until the procedures outlined in this administrative regulation have been complied with.~~

Section 2. ~~[Sale of]~~ Adulterated Milk (Excessive Water). (1)~~(a) Producers whose milk [producers whose] supplies are found to contain over ten (10) percent excessive water shall be issued a notice requiring the supply to be withheld from sale immediately.~~

~~(b) Milk from this supply shall not be sold until a sample is collected by a certified sample collector, analyzed in a certified laboratory, and is negative for excessive water.~~

~~(2)(a) Producers whose milk ~~[producers whose]~~ supplies are found to contain more than~~[over]~~ two (2) percent but less than~~[to]~~ ten (10) percent excessive water shall be issued a notice of adulteration and the milk supply resampled after the lapse of three (3) days.~~

~~(b) Should the resample continue to show more than~~[over]~~ two (2) percent excessive water, the producer shall be issued a notice requiring the supply to be withheld from sale immediately.~~

~~(c) Milk shall not be sold from this supply until a sample is collected by a certified sample collector, analyzed in a certified laboratory, and is negative for excessive water.~~

~~(3)(a) Producers whose milk ~~[producers whose]~~ supplies are found to contain between five-tenths (.5) percent to two (2) percent excessive water shall be notified and the milk supply resampled after a lapse of three (3) days.~~

~~(b)[; and] Should the resample continue to have between~~[following sample show]~~ five-tenths (.5) percent to two (2) percent excessive water, a supervised sample shall be collected by an inspector or other authorized person. The supervised sample shall be used as a future reference point for the accurate freezing point for the supply.~~

~~(4) Producers who repeatedly have milk samples test positive for excessive water shall be issued a notice of permit suspension.~~

~~(5) A producer whose permit has been suspended may, at any time, submit an "Application for Reinstatement of Permit", DFS-7A, incorporated by reference in 902 KAR 50:033, to the Milk Safety Branch.~~

~~(6) Suspension of a permit shall remain in effect until a negative excessive water sample is obtained~~[repeated violation of any of these procedures listed in this administrative regulation]~~~~

~~may require permit suspension, a written request for reinstatement, and the resample to be collected by the inspector. Also, the sample shall be negative for excessive water prior to reinstatement of the permit].~~

Section 3. Procedures for Testing Milk Samples for Chemical Contaminants. (1) Raw milk samples ~~shall~~will be collected and analyzed for chemical contaminants a minimum of annually from all bulk tank truck loads ~~[of raw milk]~~ representing Kentucky dairy producers and imported supplies from other states.

(2) Semiannual samples ~~shall~~will be collected from loads having a previous history of chemical contaminants.

(3) Finished milk and milk products manufactured and sold within Kentucky ~~shall~~will also be collected and analyzed~~[screened]~~.

(4)(a)(2) Whenever a Kentucky inspected bulk tank load of raw milk tests positive for~~[is found to contain]~~ any level of a chemical contaminant, the individual milk producers represented on the load will be immediately notified by telephone and~~[,]~~ confirmed by letter.

(b) Milk from each individual producer shall be~~[, and individually]~~ sampled on a screening basis after notification.

(c) If out-of-state bulk tank loads are found to be contaminated, the shipping state regulatory agency will be immediately notified by telephone and confirmed in writing.

(5)(a)(3) Whenever laboratory results of an individual producer's milk~~[producer]~~ sample shows a violation of an established tolerance level for a particular chemical contaminant, the supply ~~shall~~will be withheld from the market channels.

(b) The producer shall be notified~~[Notice shall be]~~ by telephone and confirmed in writing.

(c) An additional follow-up confirming sample shall be collected within ten (10) working days after notification of exclusion.

(d)(4) Continued sampling of an excluded milk producer's supply ~~shall~~will be maintained until an acceptable level of the contaminant is attained.

(e) The frequency of additional sampling may be at seven (7), fifteen (15), thirty (30), or sixty (60) day intervals~~[, depending on laboratory workload capabilities and levels found in the confirming sample and as experienced from previous test indicators]~~. Higher levels will be sampled on a more frequent basis~~[at lesser frequencies]~~.

(f)(5) Whenever levels based on an official sample fall below acceptable tolerance levels, the producer will be notified by telephone and confirmed in writing that the supply is again acceptable for sale.

(6)(a) A producer may assist with ~~[Producer assistance in]~~ testing individual cows, feeds, and water supplies at their own expense~~[may be obtained on an unofficial basis from the Kentucky Diagnostic Laboratories and commercial laboratories]~~.

(b) Results from producer obtained testing shall be submitted to the Milk Safety Branch.

(7) The following procedure will be followed whenever any level of polychlorinated biphenyls (PCBs) ~~[PCB's]~~ are found in a producer's milk supply:

(a) The milk producer shall be notified of the level of PCBs in the milk supply by telephone, confirmed by letter, and the milk supply excluded.

(b)~~[Whenever levels of PCB's are found in a producer's milk supply,]~~ A farm inspection shall be made to determine the type of silo~~[silo(s)]~~ being used.

(c)~~(b)~~ All producers ~~(showing levels of PCB's in their milk supply) having]~~ Concrete silos coated with cumar~~[“eumar”]~~ or other sealers containing PCBs shall~~[PCB's will]~~ be condemned for use with the dairy herd.

(d)~~(c)~~ The following options may be used by] A producer with a condemned silo may:

1. Abandon the silo (do not store feed); or~~[,]~~

2. Recoat the silo. If a silo is recoated, the producer shall notify the Milk Safety~~[Control]~~ Branch for approval prior to the silo being filled.

~~(e) The producer's milk supply shall~~~~(d) Once a producer is notified that a silo(s) has been condemned, continued use of the silo may require immediate suspension of the milk supply whenever any level of PCB's are found by the regulatory agency.~~

~~(8) The producer's supply will~~ be placed on a continuous surveillance program until a negative sample is obtained.

Section 4. Incorporation by Reference. (1) "M-a-85 (Revision #16)", December 2018, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at Milk Safety Branch, Division of Public Health Protection and Safety, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. ~~[The following material is integrated by reference:~~

~~(1) "Standard Methods for Examination of Dairy Products"~~

~~(2) A copy of the publication is available for inspection and copying, 8 a.m. until 4:30 p.m., at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.]~~

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: August 7, 2020

FILED WITH LRC: August 11, 2020 at 1 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on October 26, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by October 19, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until October 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621, phone 502-564-6746, fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes enforcement procedures to prevent the sale of milk and milk products adulterated with antibiotics and other inhibitory substances, chemicals, and excessive water.

(b) The necessity of this administrative regulation: KRS 217C.040 authorizes the cabinet to adopt rules and regulations for sampling and examination of milk and milk products, and regulating all other such matters relating to milk and milk products as may be necessary to protect the public health. This administrative regulation is necessary to ensure antibiotics or other inhibitory substances, chemicals, and excessive water do not adulterate milk and milk products.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217C.040 authorizes the secretary to adopt rules and regulations regulating such matters relating to milk and milk products as may be necessary to protect the public health.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure all personnel involved in producing, transporting, processing, handling, sampling, examining, grading, and labeling milk and milk products are able to ensure the products are not adulterated with antibiotics and other inhibitory substances, chemicals, or excessive water.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation updates the standards and testing methods for testing antibiotics in milk by incorporating M-a-85 (Revision #16) regarding Beta Lactam and Other Test Methods For Use Under Appendix N And Section 6 of the Grade "A" Pasteurized Milk Ordinance (PMO) issued by the Food and Drug Administration through the National Conference on Interstate Milk Shipments (NCIMS) and makes other changes necessary for compliance with KRS Chapter 13A.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to ensure the most up to date testing methods are utilized to protect the supply of milk and milk products.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217C.040 authorizes the cabinet to adopt rules and regulations for sampling and examination of milk and milk products and regulating all other such matters relating to milk and milk products as may be necessary to protect the public health. KRS 217C.060 authorizes the cabinet to enter into reciprocal agreements with milk control officials of federal or state agencies having standards substantially equivalent to the requirements of this chapter and the regulations of the secretary, which are enforced with equal effectiveness.

(d) How the amendment will assist in the effective administration of the statutes: By incorporating the most up to date standards and test methods to detect antibiotics and other inhibitory substances, chemicals, and excessive water, the Milk Safety Branch can ensure the safety of milk and milk products and is better able to enter into reciprocal agreements with other states.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The amendment to this administrative regulation will impact 470 registered dairy farms, forty-nine (49) registered dairy plants, 202 haulers of raw milk, ninety-two (92) collectors, and twenty (20) distributors.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All those engaged in the production of milk and milk products, including haulers of raw milk, will need to be aware of the updated standards and test methods.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The average cost for a beta lactam test kit is \$326 for 100 count. There would be costs associated with the laboratory analysis as well.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): By testing milk and milk products for antibiotics and other inhibitory substances, chemicals, and excessive water, producers can assure they are offering a quality product that is safe for human consumption.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There will be no cost to the cabinet to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the cabinet to implement this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Milk Safety Branch operates with approximately \$1 million from the General Fund. There are no costs associated with this amendment.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in fees or funding is not necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This administrative regulation does not establish or increase fees.

(9) TIERING: Is tiering applied? Tiering is not applied. The requirements of this administrative regulation are applied equally to the regulated community.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Milk Safety Branch in the Department for Public Health.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194.050(1), 211.180(1)(c), and 217C.040.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? The Milk Safety Branch operates with approximately \$1 million from the General Fund. This is an ongoing program and there will be no increase in cost to administer this program.

(d) How much will it cost to administer this program for subsequent years? This is an ongoing program and there will be no increase in cost to administer this program.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: