

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

902 KAR 50:050. Manufacturing plant requirements.

RELATES TO: KRS 211.090, 217C.010~~[, 217C.040]~~, 217C.070, 217C.990, 260.813, 7 C.F.R. 58 Subpart B

STATUTORY AUTHORITY: KRS 194A.050(1), 211.180(1)(c)~~[211.090]~~, 217C.040, 217C.060

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Cabinet for Health and Family Services 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. KRS 217C.040 requires the secretary to regulate, in the interest of the public health, all aspects relating to the production and sale of milk. KRS 217C.060 authorizes the cabinet to enter into reciprocal agreements with milk control officials of federal and state agencies having standards substantially equivalent to the regulations of the secretary. This administrative regulation establishes:~~(1)~~ uniform sanitary and operational standards for manufactured~~[manufacturing]~~ milk plants, receiving stations, transfer stations, and handlers~~;~~ and ~~(2)~~ the process for issuance and revocation of permits ~~[relating thereto]~~.

Section 1. Permits and Inspections. (1) All persons desiring to operate a manufactured milk plant, receiving station, transfer station, or be a handler of manufactured milk, shall submit to the cabinet a "Plant Application for Permit".

~~(2)(a) A person who does not possess a valid permit, issued as provided in this administrative regulation, shall not:~~

- ~~1. Operate a manufacturing milk plant;~~
- ~~2. Operate a receiving station;~~
- ~~3. Operate a transfer station; or~~
- ~~4. Be a handler of manufacturing milk.~~

~~(b) A qualified representative of the cabinet shall inspect each plant, receiving station, and transfer station:~~

- ~~(a)~~~~1.~~ Prior to issuance of a permit; and
- ~~(b)~~~~2.~~ At least annually thereafter.

~~(3)(2) Only a person in [satisfactory] compliance with the requirements of this administrative regulation shall be entitled to a permit.~~

~~(4) A permit shall not be transferable with respect to persons or locations.~~

~~(5)(3) Manufactured milk and milk products from points beyond the limits of routine inspection of the Commonwealth of Kentucky, or its police jurisdiction, may be sold in the Commonwealth of Kentucky, or its police jurisdiction, if the milk or milk products are:~~

~~(a) Produced and processed under administrative regulations substantially equivalent to this administrative regulation; and~~

~~(b) The out-of-jurisdiction governmental unit concerned accepts Kentucky's manufactured~~[manufacturing]~~ milk and milk products on a reciprocal basis.~~

~~(6)(4) Properly prepared plans for transfer stations, receiving stations, and milk plants regulated under this administrative regulation ~~that~~~~[which]~~ are ~~hereafter~~ constructed, reconstructed or extensively altered, shall be submitted to the cabinet for approval before work is begun.~~

Section 2. Standards for Manufactured Milk Plants, Receiving Stations, Transfer Stations, and Handlers. (1) All premises, buildings, facilities, equipment and utensils shall comply with 7 C.F.R. 58.125 through 128.

(2) All personnel shall comply with:

(a) 7 C.F.R. 58.129 for cleanliness; and

(b) 7 C.F.R. 58.130 for health.

(3) The transport of raw milk shall be in compliance with 7 C.F.R. 58.131 except that milk shall not be transported in milk cans.

(4) Receiving stations shall comply with 7 C.F.R. 58.131(b)(1).

(5) Transfer stations shall comply with 7 C.F.R. 58.131(b)(2).

Section 3. Prohibited Acts Relating to ~~Manufactured~~[Manufacturing] Milk Plants, Receiving Stations, Transfer Stations, and Handlers[~~, within the Commonwealth of Kentucky~~]. A person shall not:

(1) [~~Process, handle, sell or offer for sale milk or a milk product for manufacturing purposes without a permit issued in accordance with this administrative regulation;~~

(2)] Process, handle, provide, sell, offer or expose for sale, or have in possession with intent to sell a milk or milk product for manufacturing purposes which is adulterated, misbranded or otherwise in violation of this administrative regulation;

(2)[(3)] Prohibit, to a duly-authorized agent of the cabinet:

(a) Entry or inspection;

(b) The taking of a sample; or

(c) Access to records or evidence;

(3)[(4)] Remove, destroy, alter, forge or falsely represent[~~, without proper authority,~~] a tag, stamp, mark, or label used by the cabinet; or

(4)[(5)] Remove or dispose of a detained or quarantined article without proper authorization from the cabinet.

Section 4. ~~Manufactured~~ [3- Manufacturing] Milk Plant, Receiving Station, Transfer Station and Handler Permit Suspension and Reinstatement. (1) In addition to the penalties established in KRS 217C.990, the cabinet may suspend or revoke a permit issued under this administrative regulation.

(2) The cabinet shall, upon notice to the permit holder, immediately suspend the permit if:

(a) There is reason to believe that an imminent public health hazard exists;

(b) The permit holder or an employee has interfered with the cabinet in the performance of the cabinet's duties; or

(c) The permit holder or an employee has falsified any records or documents.

(3) In all other instances of violation of this administrative regulation, the cabinet shall:

(a) Serve on the permit holder a written notice stating the violation; and

(b) Afford the permit holder a reasonable opportunity to correct the violation.

(4) A permit holder whose permit has been suspended may, at any time, submit an "Application for Reinstatement of Permit", incorporated by reference in 902 KAR 50:033.

(5) Suspension of a permit shall remain in effect until the violation has been corrected to the satisfaction of the cabinet.

(6) For serious or repeated violations of this administrative regulation the permit may be permanently revoked.

(7) Prior to revocation, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit is subject to revocation and advising the permit shall be permanently re-

voked at the end of ten (10) days following the service of the notice, unless the "Request for a Hearing", incorporated by reference in 902 KAR 50:033, is filed with the Milk Safety Branch[A permit issued under this administrative regulation may be suspended if:

- ~~(a) The cabinet has reason to believe that a public health hazard exists;~~
- ~~(b) The permit holder has violated the requirements of this administrative regulation; or~~
- ~~(c) The permit holder has interfered with the cabinet in the performance of its duties.~~

~~(2) The cabinet shall serve upon a permit holder a written notice of intent to suspend the permit, except in a case in which:~~

~~(a) The milk or milk product involved creates, or reasonably appears to create, an imminent hazard to the public health; or~~

~~(b) There has been a willful refusal to permit authorized inspection.~~

~~(3) The cabinet's written notice of intent to suspend shall:~~

~~(a) Specify with particularity the violation alleged; and~~

~~(b) Afford the permit holder reasonable opportunity to correct the violation alleged.~~

~~(4) A permit shall remain in suspension until the violation has been corrected to the satisfaction of the cabinet, in accordance with the requirements of this administrative regulation.~~

~~(5) The cabinet may require a second inspection if, during an annual inspection, a violation of a requirement established in this administrative regulation is found to exist. The second inspection shall occur at least three (3) days after the violation is discovered and verbal or other notice given. If, upon reinspection, the violation continues to exist, the cabinet shall issue official written notice, specifying a time in which the violation shall be corrected. Failure of the permit holder to comply with the requirements of the official notice shall be cause for permit suspension, in accordance with this administrative regulation.~~

~~(6) Appeal rights.~~

~~(a) A person who has been served with a notice of intent to suspend may, within forty-eight (48) hours of receipt of notice, apply in writing for an informal appeal. The cabinet shall, prior to suspension, proceed to informal hearing to ascertain the facts of the alleged violation.~~

~~(b) A person whose permit has been suspended may apply in writing for an informal appeal. The cabinet shall, within a reasonable time, proceed to informal hearing to ascertain the facts of the alleged violation.~~

~~(c) The cabinet, upon evidence presented at the hearing, shall affirm, modify, or rescind the suspension or intent to suspend. A permit suspended under the provisions of this subsection may be reinstated by submission of evidence that the violation has been corrected, in accordance with the requirements of this administrative regulation.~~

~~(d) A party aggrieved by a decision of the cabinet may appeal the decision in accordance with KRS Chapter 13B].~~

Section 5[4]. Trade Secrets. A person who, in an official capacity, obtains under the provisions of this administrative regulation, information which is entitled to protection as a trade secret, including information as to quantity, quality, source of disposition of milk or milk products, or results of an inspection or test, shall not use the information to his own advantage or reveal it to an unauthorized person.

Section 6. Incorporation by Reference.~~[5.]~~ (1) ~~[The]~~ "Plant Application for Permit", 1/2020, [following material] is incorporated by reference[:

~~(a) Requirements for Manufactured Milk Product Plants in Kentucky; and~~

~~(b) Code of Federal Regulations, Title 7, Part 58, Subpart B, effective August 28, 2002].~~

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Milk Safety Branch, Division of Public Health Protection and Safety, Department for Pub-

~~lic Health[Office of the Commissioner for Health Services], 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.[~~

~~(3) Copies are also available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402.]~~

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 the uniform sanitary and operational standards for manufactured milk plants, receiving stations, transfer stations, and handlers, and outlines the process for issuance and revocation of permits relating to these activities.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the quality standards specific to the activities related to milk for manufacturing purposes.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217C.040 authorizes the secretary to adopt separate regulations regulating grade A milk products and milk for manufacturing purposes, and for the transportation, processing, handling of milk and milk products, the inspection of milk plants, and the issuing and revocation of permits to milk producers, haulers, transfer stations, and processing plants.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation ensures that all persons engaged in activities related to manufactured milk and milk products are following uniform sanitary and operational standards.

(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 incorporates by reference the Plant Application for Permit, adds citations to the applicable code of federal regulation for manufactured milk and milk products, updates the permit revocation procedures, and makes other changes necessary to comply with KRS 13A drafting rules.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to ensure uniform sanitary and operational standards for all persons engaged in activities related to manufactured milk and milk products.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217C.040 authorizes the secretary to adopt rules and regulations regulating the transportation, processing, handling of milk and milk products, the inspection of milk plants, and the issuing and revocation of permits to milk producers, haulers, transfer stations, and processing plants.

(d) How the amendment will assist in the effective administration of the statutes: 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 KRS Chapter 217C. By adopting the code of federal regulations related to manufactured milk and milk products the cabinet is better able to enter into reciprocal agreements with federal and state milk control agencies.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts fifty-three (53) permitted dairy processing plants.

(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 personnel engaged in the manufacture of milk and milk products, those operating a receiving or transfer station, and handlers of milk and milk products will need to be aware of the uniform sanitary and operational standards contained in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): There should be no costs associated with implementing the requirements in this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The amendment to this administrative regulation simplifies the permitting process for dairy processing plants. By incorporating the federal standards, dairy plants will be better able to offer products under reciprocal agreements with other states.

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

(a) Initially: This is an ongoing program. There are no initial costs.

(b) On a continuing basis: There are no ongoing costs.

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

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. There are no fees associated with this administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not applied. The standards in this administrative regulation are applied equally to all manufactured dairy plants.

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 will impact the Milk Safety Branch in the Division of Public Health Protection and Safety.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050(1), 211.180(c), 217C.040, 217C.060, and 7 C.F.R. Part 58.

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? 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? The entire Milk Safety program operates with approximately \$1 million from the General Fund.

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:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 7 C.F.R Part 58.

2. State compliance standards. KRS 217C.010 provides for uniform state standards and requirements for milk and milk products. Pursuant to KRS 217C.050 the cabinet is designated as the single state agency for the purpose of carrying out a statewide milk control program and pursuant to KRS 217C.060 the cabinet is authorized to enter into reciprocal agreements with milk control officials of federal or state agencies having standards substantially equivalent to the requirements of the regulations of the secretary.

3. Minimum or uniform standards contained in the federal mandate. By referencing the federal standards for manufactured milk and milk products, the cabinet is assuring a uniform standard.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. A stricter standard, or additional or different responsibilities or requirements is not imposed by this administrative regulation.