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

902 KAR 50:031. Standards for producer eligibility for manufactured grade milk.


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 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 authorizes the cabinet to promulgate administrative regulations for the issuance and revocation of permits for milk producers, haulers, transfer stations, processing plants, pasteurization plants, and distributors. This administrative regulation sets uniform standards for the production, handling, examination, grading, and sale of manufactured milk and milk products.

Section 1. Manufactured Milk Producer Permits and Inspections. (1) Any person seeking to offer raw milk for manufacturing shall submit an “Application for Permit to Sell Raw Milk for Pasteurization” to the department.
(2) Prior to the issuance of any permit to a manufacturing milk producer, the cabinet shall conduct an inspection of the producer's facilities.
(3) If the producer is not in substantial compliance with 902 KAR 50:032:
(a) A permit shall not be issued;
(b) The violation shall be given in writing and
(c) The violation shall be posted in a visible place at the dairy farm.
(4) A permit may be issued if the inspection reveals substantial compliance with 902 KAR 50:032.
(5) All producers shall possess a valid permit prior to beginning shipment of milk.
(6) Permits shall:
(a) Be non-transferable with respect to persons or locations; and
(b) Remain valid unless suspended or revoked by the cabinet.

Section 2. Producer Eligibility Requirements. (1) New producers.
(a) A test for bacterial quality and sediment shall be made in accordance with 7 C.F.R. 58.138 on the first shipment of milk or after a period of non-shipment for more than ten (10) days.
(b) Subsequent tests of milk shall meet the requirements for frequency of testing and producer compliance outlined in Section 3(7)(2)(a) of this administrative regulation.
(2) Transfer producers.
(a) Prior to collection and acceptance of milk from a transfer producer, the receiving station shall review the official status of the producer with the cabinet.
(b) The existing status of a transfer producer with regard to his farm sanitation and milk quality record shall be in effect with the receiving station.
(c) A producer whose permit has been suspended by the cabinet is not eligible to transfer until the permit has been reinstated, unless approved by the cabinet.
(d) The receiving station[company] shall sample each transfer producer's milk within ten (10) days after receipt of the producer's first shipment of milk.

(e) Subsequent sample results shall be in accordance with the provisions of Section 3 of this administrative regulation.

(3) Grade A Producer.

(a) Any Grade A producer whose permit has been suspended shall be allowed to sell milk as a degraded producer to a manufacturing milk company if the Grade A violative sample is within manufacturing standards set forth in this administrative regulation.

(b) A degraded producer shall not sell milk to a manufacturing milk company for a period in excess of ten (10) days without applying for and obtaining a milk for manufacturing producer permit.

(c) Grade A surplus milk shall be tested or screened by the manufacturing milk company upon arrival to ensure[assure that] the milk is in compliance with this administrative regulation.

(d) Milking by hand shall be prohibited.

Section 3. Quality Requirements for Raw Milk. (1) [Basis.] Classification of raw milk for manufacturing purposes shall be in accordance with 7 C.F.R. 58.132.

(2) Based on organoleptic examination (sight and odor), bacterial estimate, quality test for sediment content, abnormal milk, and drug residue testing.

(a) Sight and odor testing shall be in accordance with 7 C.F.R. 58.133(a).

(3) Flavor and odor of acceptable raw milk shall be fresh and sweet. Milk shall be free from feed and other off-flavors and off-odors that would adversely affect the finished product. Milk shall be observed and shall not show an abnormal condition (ropy, bloody, or mastitic).

(b) Bacterial classification shall be in accordance with 7 C.F.R. 58.135.

(4) Bacterial limit shall be 1,000,000/ml by standard plate count, plate loop method, or direct microscopic bacterial determination methods.

<table>
<thead>
<tr>
<th>Bacterial Estimate Classification</th>
<th>Direct Microscopic Clump Count, Standard Plate Count, or Plate Loop Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1 Satisfactory</td>
<td>Not Over 500,000/ml.</td>
</tr>
<tr>
<td>No. 2 Satisfactory</td>
<td>Not Over 1,000,000/ml.</td>
</tr>
<tr>
<td>Undergrade</td>
<td>Over 1,000,000/ml.</td>
</tr>
</tbody>
</table>

(c) Sediment content classification shall be in accordance with 7 C.F.R. 58.134.

(5)

<table>
<thead>
<tr>
<th>Sediment Content Classification</th>
<th>Milk in Cans (off-the-bottom method)</th>
<th>Milk in Farm Bulk Tanks sample 0.40 inch diameter diec</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1 Acceptable equivalent</td>
<td>Not to exceed 0.50 mg.</td>
<td>Not to exceed 0.50 mg.</td>
</tr>
<tr>
<td>No.</td>
<td>Equivalent</td>
<td>Not to exceed</td>
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<tr>
<td>------</td>
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</tr>
<tr>
<td>2</td>
<td>Acceptable</td>
<td>1.50 mg.</td>
</tr>
<tr>
<td>3</td>
<td>Probational</td>
<td>2.50 mg.</td>
</tr>
<tr>
<td>4</td>
<td>Reject</td>
<td>Over 2.50 mg.</td>
</tr>
</tbody>
</table>

(d) Abnormal milk. Somatic cell count shall be in accordance with 7 C.F.R. 58.133(b).

(6) Limit shall not exceed 1,000,000/ml.

(e) Drug residue classification shall be in accordance with 7 C.F.R. 58.133(c).

(7) Test results shall be negative on commingled load or individual producer test as determined in 902 KAR 50:033, Section 1(5).

(2) Examinations and tests. Examinations and tests to detect excessive water, chemical contaminants, or other adulterants shall be conducted by the cabinet as required by the Food and Drug Administration and the United States Department of Agriculture [deemed necessary].

(a) Frequency of tests.
   1. Bacterial estimate: monthly.
   2. Sediment content: monthly.
   3. Abnormal milk: four (4) times each six (6) months.
   4. Drug residues: all marketed manufacturing grade milk shall be sampled and tested for drug residues prior to processing.
   5. Excessive water, chemical contaminants, or other adulterants: as deemed necessary by the cabinet.


Section 4. Personnel Health and Cleanliness. (1) All personnel involved in production of manufactured milk shall comply with:

(a) 7 C.F.R. 58.129, Cleanliness; and
(b) 7 C.F.R. 58.130, Health.

(2) No person affected with any disease in a communicable form, or while a carrier of a communicable disease, shall work at any dairy farm in any capacity which brings him in contact with the production, handling, storage, and transportation of milk for manufacturing purposes, containers, equipment, and utensils. No milk producer shall employ in any capacity any person suspected of having any disease in a communicable form, or of being a carrier of a communicable disease. Any milk producer upon whose dairy farm any communicable disease occurs or who suspects that any employee has contacted any disease in a communicable form, or has become a carrier of a disease in a communicable form, shall notify the cabinet immediately. All
persons engaged in the milking operation shall wear clean outer garments. The milker's hands shall be kept clean.

Section 5. Procedure If Infection is Suspected. If reasonable cause exists to suspect the possibility of transmission of infection from any person involved with the handling of milk for manufacturing purposes, the cabinet shall require the following measures:

(a) Immediate exclusion of that person from milk handling;
(b) Immediate exclusion of the milk supply concerned; and
(c) Medical and bacteriological examination of the person and body discharges.

Section 5[6]. Prohibited Acts Relating to Manufactured Milk Producers. The following acts are prohibited:

1. No person shall produce, sell, or offer for sale any manufactured milk or milk products without a permit as provided in 902 KAR 50:032, 902 KAR 50:033, and this administrative regulation.
2. No person shall produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell, any manufactured milk or milk product which is adulterated, misbranded, or in violation of 902 KAR 50:032, 902 KAR 50:033, or this administrative regulation.
3. No person shall prohibit the entry of inspection, taking of a sample, or access to records or evidence to a duly authorized agent of the cabinet.
4. No person shall remove, destroy, alter, forge, or falsely represent any tag, stamp, mark, or label used by the cabinet.
5. No person shall remove or dispose of a detained or quarantined article without proper authority from the cabinet.
6. Milking by hand shall be prohibited.

Section 6[7]. Survey Procedures.
1. The department may conduct a survey at least one (1) time every two years on all groups of producers assigned to milk companies, producer associations, or producer groups.
2. A producer, company, association, or group found to have an unsatisfactory rating shall be notified and given a reasonable period of time, not to exceed six (6) months, to attain a satisfactory rating.
3. A producer who fails to receive an acceptable rating upon resurvey, the producer's rating is not an acceptable level, the producer shipping milk to the company shall be inspected by the cabinet to determine individual compliance.
4. A producer who fails a survey in violation may have his permit suspended in accordance with 902 KAR 50:032, 902 KAR 50:033, and this administrative regulation.
5. No producer shall be allowed to transfer to another company during the resurvey period unless authorized by the cabinet.

Section 7. (1) The “Application for Permit to Sell Raw Milk for Pasteurization”, 2/2020, is incorporated by reference.

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 Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

STEVEN J. STACK, MD, MBA, Commissioner
LEGISLATIVE RESEARCH COMMISSION PDF VERSION

ERIC C. FRIEDLANDER, Secretary
APPROVED BY AGENCY: July 9, 2020
FILED WITH LRC: July 15, 2020 at 9 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on September 28, 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 September 21, 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 September 30, 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 standards for the production, handling, examination, grading, and sale of manufactured milk and milk products.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to set a uniform standard for manufactured milk and milk products.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 194A.050(1) requires the secretary of the cabinet to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 217C.040 requires the secretary to adopt rules and regulations regulating standards of identity and labeling requirements for milk and milk products.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation ensures producers of manufactured milk and milk products are properly licensed by the cabinet, and that the manufactured milk and milk products meet the federal testing standards for quality specifications of raw milk.

(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 requirements for testing of manufactured milk and milk products to the applicable federal standards, ensures all personnel involved in milk manufacturing adhere to federal standards for cleanliness and health, incorporates by reference the application for a permit to produce manufactured milk, and makes additional changes for compliance with KRS Chapter 13A drafting rules.
(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to adopt updated standards and requirements for milk safety.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217C.040 requires the secretary to adopt rules and regulations relating to milk and milk products as may be necessary to protect the public health. There shall be separate regulations regulating Grade A milk products and milk for manufacturing purposes. The amendment to this administrative regulation updates the standards for manufactured milk and milk products. 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 regulations of the secretary.

(d) How the amendment will assist in the effective administration of the statutes: By adopting the federal standards for evaluation and testing of manufactured milk and milk products, and personnel standards for cleanliness and health, the cabinet is able to ensure manufactured milk and milk products meet the highest standard available, and is better able to enter into reciprocal agreements with federal and state agencies.

(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, fifty-three (53) 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 question (3) will have to take to comply with this administrative regulation or amendment: Producers of manufactured milk and milk products will need to be aware of the permitting and inspection process, as well as the federal standards for evaluation and testing of milk and milk products. A receiving station will need to be aware of the producer's status with the cabinet before accepting raw milk.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Compliance with this administrative regulation will have no cost impact for producers of manufactured milk and milk products.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Producers of manufactured milk and milk products will be able to ensure their products meet the highest standards available.

(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 state general fund.

(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 and funding is not necessary 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 established by this administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not applied. The standards for manufactured milk and milk products are applied equally.
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? The Milk Safety Branch in the Department for Public Health administers this program.

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, 217C.040, and 7 C.F.R. Part 58 Subpart B.

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? There is no additional cost in administering this program for the first year.
   (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 Subpart B, General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

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 applicable section of 7. C.F.R. Part 58 Subpart B related to testing and evaluation of manufactured milk and milk products, and for personnel cleanliness and health, the cabinet is assuring a uniform standard for all aspects related to the manufactured milk industry.

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.