

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

902 KAR 50:080. Standards of identity and labeling [Open dating] requirements.

RELATES TO: KRS 217.035, 217.037, 217C.030, 217C.060, [217C.040-]217C.990, 21 C.F.R. Parts 101, 131, 133, 135, 166

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.[The Cabinet for Human Resources is directed by] KRS [Chapter] 217C.040 requires the cabinet adopt rules and regulations regulating the [to regulate the production, transportation, processing, handling, sampling, examination, grading,] labeling, standards of identity, sale and other matters relating to milk and milk products as may be necessary to protect the public health. This administrative regulation establishes uniform standards for identifying and labeling[the open dating of] Grade A pasteurized milk and milk products sold in Kentucky [and requires that an open date be legibly applied to retail packages offered for sale to the final consumer].

Section 1. Labeling and Identification Requirements. (1) All Grade A pasteurized milk and milk products offered for sale or sold in this state shall be labeled in accordance with 21 C.F.R Part 101.

(2) Milk, cream, and yogurt shall be identified in accordance with 21 C.F.R. Part 131.

(3) Cheese and related cheese products shall be identified in accordance with 21 C.F.R. Part 133.

(4) Frozen desserts shall be identified in accordance with 21 C.F.R. Part 135.

(5) Margarine shall be identified in accordance with 21 C.F.R. Part 166.

Section 2. Use By[Open] Date Required. (1) No person shall sell or offer for sale any Grade A pasteurized milk or milk product in this state in a consumer package that does not bear the use by[open] date as required by this administrative regulation.

(2) [Section 2. Open Date Labeling. (1)] The use by[open] date shall:

(a) Be[Appear] in a form that is conspicuous, legible, and understandable;

(b) Be boldface print in contrast to the background, by typography, color, embossing, debossing, molding, or other manner on the package;

(c) Be placed on the[that] part of the container most likely to be displayed for retail sale; and

(d) Not interfere with legibility of other mandatory labeling requirements of the product.

(3)[(2)] The use by[open] date shall be expressed:

(a) By the first three (3) letters of the month followed by or preceded by the numeral or numerals constituting the appropriate calendar date;[,] or

(b) [Expressed] Numerically by the number of the month preceding the number of the day. [(For example: June 1 may be expressed "Jun 1" "1 Jun," "0601," or "06-01.")]

(3) The open dating of Grade A pasteurized milk and milk products bottled in glass containers for home delivery are exempt from this administrative regulation.]

Section 3. Certification of Use By~~[Open]~~ Date Required. (1) Each distributor or processor manufacturing, processing, or packaging Grade A pasteurized milk and milk products for sale within this state shall:

(a) Comply with the provisions of this administrative regulation; ~~[and]~~

(b) ~~[File and]~~ Certify ~~to~~~~[with]~~ the cabinet the use by~~[open]~~ date for each product; ~~and~~~~[-]~~

(c) ~~[The processor or distributor requesting an open date certification for a product shall]~~ Provide the cabinet with the research data used to support the product use by~~[open]~~ date certification request.

(2) Samples of products for use by~~[open]~~ date evaluation may be obtained at processing plants, delivery trucks, distributors, or from retail outlets. The temperature and use by~~[open]~~ date shall be officially recorded at the time of sample collection.

Section 4. Enforcement. (1) No milk or milk products shall be offered for sale as a Grade A product after the expiration of the use by date shown on the container.

(2) All milk and milk products offered for sale after the expiration of the use by date shall be deemed to be misbranded.

(3) If a product is not sold within the period specified by~~[in]~~ the use by~~[open]~~ date, the product shall~~[cabinet shall take action to remedy the condition consistent with this administrative regulation by removing the product from consumer channels and causing the product to]~~ be returned to the milk plant of origin for destruction.

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 uniform standards for identifying and labeling Grade A pasteurized milk and milk products sold in Kentucky.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to ensure all Grade A milk and milk products sold meet the highest quality standard possible.

(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 the labeling, standards of identity, and sale of 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 all Grade A milk and milk products sold to consumers in the Commonwealth are properly labeled.

(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 adds labeling requirements and standards of identifying Grade A milk and milk products, and clarifies the use by dating requirements for Grade A milk and milk products.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to ensure all Grade A milk and milk products are properly identified and labeled, and to ensure the quality of these products.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment to this administrative regulation conforms to KRS 217C.040 for labeling, standards of identity, and sale of milk and milk products by establishing the standards of identity and labeling requirements for Grade A milk and milk products.

(d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation ensures all Grade A milk and milk products are properly identified and labeled, and that no misbranded product is sold to a consumer.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts all dairy producers, dairy processing plants, all retail stores offering Grade A milk and milk products for sale, and all consumers who purchase these products. There are approximately 470 permitted dairy producers, and 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: Businesses engaged in the processing of milk and milk products will need to be aware of the standards for labeling and identifying those products. These standards are not new and will not require any change in the production and labeling processes. Stores who offer milk and milk products for sale will need to be aware of the requirements for proper labeling and will need to establish protocols for removing out of date products and returning them to the dairy plant of origin for destruction.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The requirements in this administrative regulation are not new requirements. There are no additional costs to dairy plants or retail stores to comply with these requirements.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Consistent standards of identity and labeling will increase consumer confidence in the

quality of the milk and milk products. This may reduce consumer confusion regarding the safety of the milk and milk products, and may reduce food waste.

(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 associated with this amended regulation.

(b) On a continuing basis: There will be no costs 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. There are no fees associated with this administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not applied as the requirements of this administrative regulation impact all persons 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? This administrative regulation affects 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 217.035, 217.037, 217C.040, 217C.060, 217C.990, and 21 C.F.R. Parts 101, 131, 133, 135, 166.

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:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 21 C.F.R Part 101 for food labeling, 21 C.F.R. Part 131 for milk, cream, and yogurt, 21 C.F.R. Part 133 for cheeses and related cheese products, 21 C.F.R. Part 135 for frozen desserts, and 21 C.F.R. Part 166 for margarine.

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 food labeling and identification of 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.