

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

902 KAR 50:010. Definitions for milk and milk products.

RELATES TO: KRS 217.015, 217.025, 217.035, 217C.030, 247.4453, 247.453, 7 C.F.R. 58.101[217C.010-217C.990], 21 C.F.R. 131.3(b), 133.3(d), 135.3, 178.1010[Part 113, Subpart B]

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 217C.040 authorizes the cabinet 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 defines terms applicable to 902 KAR Chapter 50[all milk and milk product administrative regulations in 902 KAR 50:050].

Section 1. Definitions. [for Milk and Milk Products Administrative Regulations. As used in all administrative regulations of the Cabinet for Human Resources relating to milk and milk products the following definitions shall apply unless specifically indicated otherwise:]

(1) "Adulterated [milk and milk products]" means any milk or milk product adulterated as provided by KRS 217.025.

(2) ["Aseptic processing" means a milk product that has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 Code of Federal Regulations, Subpart B, Food for Human Consumption, Part 113, and maintain the commercial sterility of the product under normal nonrefrigerated conditions.

(3) "Butter" means the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than eighty (80) percent by weight of milk fat, all tolerances having been allowed for; provided the labeling of butter shall not be deemed misbranded if it does not bear a statement relating to artificial coloring.

(4) "Cabinet" is defined by KRS 217C.030(2).

(3) [means the Cabinet for Human Resources.

(5) "Certified sample collector" or "Certified sampler" means an employee of the department, fieldman or milk hauler who has been approved to collect milk samples for regulatory purposes.

(4) [(6) "C-I-P" or] "Cleaned-in-place" means the procedure by which sanitary pipeline or pieces of dairy equipment are mechanically cleaned-in-place by circulation.

(5) [(7) "Culinary steam" means steam used in contact with milk or milk products which is produced according to "Recommended Practices for Producing Culinary Steam for Processing Milk and Milk Products", National Association of Dairy Equipment Manufacturers, 1012 14th Street, N.W., Washington, D.C. 20036.

(8) "Dairy farm" means a place where one (1) or more milking cows or goats are kept for milking purposes, and from which a part or all of the milk produced is [thereon being] delivered, sold, or offered for sale to a dairy, plant, receiving station or transfer station.

~~(6) [(9) "Milk or dairy plant, receiving station or company" means any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, packaged or prepared for distribution.~~

~~(10)] "Department" means the Department for Public Health.~~

~~(7) "Distributor" means a permitted person, place, or location that sells or contributes permitted products to the consumer.~~

~~(8) [Services.~~

~~(11) "Fieldman" means a person employed by a milk company who is qualified and trained in sanitary methods of production and handling of milk and who performs dairy farm quality control work. (A "fieldman" shall not considered an agent of the department.)~~

~~(12)] "Goat milk" is defined by 7 C.F.R. 58.101(k)(2).~~

~~(9) [means the lacteal secretion, practically free from colostrum, obtained by the complete milking of healthy goats.~~

~~(13)] "Grade A milk and milk products" means those[milk and milk] products produced, processed, transported and distributed in accordance with 902 KAR 50:110.~~

~~(10) [the department's Grade A milk administrative regulations. It includes but is not limited to the following:~~

- ~~(a) Acidified sour cream;~~
- ~~(b) Acidified sour half and half;~~
- ~~(c) Buttermilk;~~
- ~~(d) Chocolate milk;~~
- ~~(e) Chocolate lowfat milk;~~
- ~~(f) Chocolate skim milk;~~
- ~~(g) Concentrated milk;~~
- ~~(h) Cottage cheese, lowfat cottage cheese, cottage cheese dry curd;~~
- ~~(i) Cultured buttermilk;~~
- ~~(j) Cultured milk;~~
- ~~(k) Cream;~~
- ~~(l) Eggnog;~~
- ~~(m) Half and half;~~
- ~~(n) Heavy cream;~~
- ~~(o) Light cream;~~
- ~~(p) Light whipping cream;~~
- ~~(q) Lowfat milk;~~
- ~~(r) Milk;~~
- ~~(s) Skim milk;~~
- ~~(t) Sour cream;~~
- ~~(u) Sour half and half;~~
- ~~(v) Yogurt, lowfat yogurt and nonfat yogurt;~~
- ~~(w) Acidified milk;~~
- ~~(x) Concentrated milk;~~
- ~~(y) Sweetened condensed milk;~~
- ~~(z) Sweetened condensed skim milk;~~
- ~~(aa) Lowfat dry milk;~~
- ~~(bb) Nonfat dry milk;~~
- ~~(cc) Nonfat dry milk fortified with vitamins A and D;~~
- ~~(dd) Evaporated milk;~~
- ~~(ee) Evaporated skimmed milk;~~
- ~~(ff) Acidified lowfat milk;~~

- ~~(gg) Cultured lowfat milk;~~
- ~~(hh) Acidified skim milk;~~
- ~~(ii) Cultured skim milk;~~
- ~~(jj) Dry whole milk; and~~
- ~~(kk) Dry cream.~~

~~(14) "Grade A dry milk products" means milk products which have been produced for use in Grade A pasteurized milk products and which have been manufactured under the provisions of the "Grade A Condensed and Dry Milk Products - and Condensed and Dry Whey, Supplement to the Grade A Pasteurized Milk Ordinance recommended by the United States Public Health Service, Food and Drug Administration."~~

~~(15)] "Handler" is defined by KRS 247.453(7).~~

~~(11)[, "distributor" or "retailer" means any association, organization, person or other group that offers for sale, sells or otherwise handles milk or milk products.~~

~~(16) "Imitation milk products" mean a milk, cheese, frozen dessert or other milk product for which the nutritional equivalency is inferior to the product it simulates.~~

~~(17)] "Inspector" means an employee of the department who is qualified, trained, and authorized to:~~

~~(a) Perform dairy farm or plant inspections, or both;~~

~~(b)[, to] Grade raw milk;~~

~~(c)[, to] Evaluate quality control programs of milk plants; and~~

~~(d) Carry out the enforcement procedures of the department's administrative regulations relating to milk and milk products.~~

~~(12) "Manufactured[(18) "Low-calorie" means any milk, milk product, cheese or frozen dessert which contains no more than forty (40) calories per serving.~~

~~(19) "Manufacturing] milk and milk products" means those[milk and milk] products produced, processed, transported and distributed in accordance with the department's manufacturing milk administrative regulations.~~

~~(13) "Milk" is defined by 21 C.F.R. 131.110(a).~~

~~(14)[It includes but is not limited to the following:~~

~~(a) Butter;~~

~~(b) Cheeses, processed cheeses, cheese foods, cheese spreads and related foods;~~

~~(c) Evaporated milk;~~

~~(d) Frozen desserts;~~

~~(e) Sweetened condensed milk and any other manufactured milk or milk product as may be designated by the department.~~

~~(20) "Mechanical cleaning" or "mechanically cleaned" means cleaning, solely by circulation or flowing chemical detergent solutions and water rinses onto and over the surface to be cleaned by mechanical means.~~

~~(24)] "Milk grader" means a person who is qualified for the grading of raw milk in accordance with quality standards and procedures.~~

~~(15)[(For the purpose of grading and sampling milk, a "milk grader" may be considered a duly authorized agent of the department.)~~

~~(22)] "Milk hauler" or "hauler" means any person who transports milk or raw milk products to or from a milk plant, receiving station or transfer station.~~

~~(16) "Milk plant" or "plant" means any place, premises, or establishment where milk or milk products are processed, stored, pasteurized, aseptically processed and packaged, or prepared for distribution.~~

~~(17) [For the purpose of collecting official samples of raw milk, a "milk hauler" may become a certified sample collector and a duly authorized agent of the department.~~

~~(23) "Milk producer" means any person who operates a dairy farm and provides, offers for sale or sells raw milk to a milk plant, receiving station, transfer station or handler.~~

~~(24) "Milk product substitute" means milk, cheese, frozen dessert or other milk products which possess similar physical and organoleptic properties to the product simulated and the fat and solids not fat content meets the standard of identity of the counterpart product but whose ingredients have been replaced all or in part with safe and suitable nonmilk ingredients.~~

~~(25)] "Misbranded [milk and milk products]" means any milk or milk product misbranded as provided by KRS 217.035.~~

~~(18)[(26)] "Official laboratory" means the biological, chemical, or physical laboratory which is under the direct supervision of the department.~~

~~(19)[(27) "Official methods" means the current edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists".~~

~~(28)] "Officially designated laboratory" means a designated milk industry or commercial laboratory authorized by the department for the examination of~~[to do official work on]~~ producer samples, commingled milk tank truck samples, ~~[or on]~~ milk containers, ~~[for tests required by the department's administrative regulations or a commercial laboratory officially designated by the department for the examination of producer samples, milk containers]~~ or finished products.~~

(20) "Pasteurized" is defined by:

(a) 7 C.F.R. 58.101(n) for products having dairy ingredients with a fat content of ten (10) percent or more, or contain added sweeteners, and condensed milk;

(b) 21 C.F.R. 131.3(b) for milk and cream;

(c) 21 C.F.R. 133.3(d) for cheese and related cheese products; and

(d) 21 C.F.R. 135.3 for frozen desserts.

~~(21)[(29) "Open date" means the date which shall be affixed on a consumer package or container of Grade A pasteurized milk or milk products subsequent to the date of manufacturing, processing or packaging and which represents the period of time that the product will remain unspoiled and acceptable for consumption when transported, handled and stored under approved conditions.~~

~~(30) "Pasteurization or pasteurized" means that every particle of such product shall have been heated in properly operated equipment, approved by the department, to one (1) of the temperatures specified in the table of this subsection, and held continuously at or above that temperature for the specified time (or other time or temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction).~~

~~(a) Milk and milk products (including cheese whey).~~

Temperature	Time
145°F*	30 minutes
161°F*	15 seconds
191°F	1 second
194°F	0.5 second
201°F	0.1 second
204°F	0.05 second
212°F	0.01 second

*If the dairy ingredient has a fat content of ten (10) percent or more, or if it contains added sweeteners, the specified temperature shall be increased by five (5) degrees Fahrenheit.

~~(b) Cream for buttermaking.~~

Temperature	Time
165°F*	30 minutes
180°F*	15 seconds
*If plastic or frozen cream is used for buttermaking, the specified temperature shall be increased by five (5) degrees Fahrenheit.	

~~(c) Frozen desserts and eggnog.~~

Temperature	Time
155°F	30 minutes
175°F	25 seconds
180°F	15 seconds

~~(31) "Permit" means permission given by the department to produce, buy, transport, process, store, distribute or sell any milk or milk products or to collect official samples thereof.~~

~~(32) "Person" is defined by KRS 217.015(32).~~

~~(22) "Producer" is defined by KRS 247.4453(3).~~

~~(23) "Receiving station" is defined by 7 C.F.R. 58.101(y).~~

~~(24) [means any individual, plant, operator, partnership, corporation, company, firm, trustee, or association.~~

~~(33) "Reconstituted or recombined milk and milk products" means milk or milk products which results from the recombining of milk constituents with potable water.~~

~~(34) "Reduced calorie" shall apply to any milk, milk product, cheese or frozen dessert for which a standard of identity exists and whose calorie content has been reduced at least one-third (1/3) lower than a similar food.~~

~~(35) "Sanitizing solution" is defined by 21 C.F.R. 178.1010.~~

~~(25) [or bactericidal treatment" means the application of an effective sanitizing agent to a clean surface for the destruction of pathogens and other organisms as far as is practicable. The sanitizing agents used shall comply with the Federal Food, Drug and Cosmetic Act and the administrative regulations of the department.~~

~~(36) "Standard methods" means the current edition of the "Standard Methods for the Examination of Dairy Products".~~

~~(37) "Sterilization or sterilized" means the complete in-container method of heating the container and contents at a minimum of 212 degrees Fahrenheit for sufficient time and vacuum to give complete destruction to all living organisms.~~

~~(38) "3-A sanitary standards and accepted practices" means the standards and practices for dairy equipment formulated by the 3-A sanitary standards committees representing the International Association of Milk, Food and Environmental Sanitarians, the U.S. Public Health Service and the Dairy Industry Committee.]~~

~~(39) "Transfer station" is defined by 7 C.F.R. 58.101(z).~~

~~(26) "Use by" means the date on a consumer package or container of Grade A pasteurized milk or milk products subsequent to the date of manufacturing, processing or packaging that represents the period of time the product will remain unspoiled and acceptable for consumption when transported, handled and stored under approved conditions. The terms "Sale by" or "Best if used by" shall have the same meaning as "use by". [means any place, premises or establishment where milk or milk products are transferred directly from one (1) transport tank to another.~~

~~(40) "Ultrapasteurized" means that such product shall have been thermally processed at or above 280 degrees Fahrenheit for at least two (2) seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.~~

~~(41) "Unsafe food additives" means any food additive prohibited by KRS 217.045.~~

~~Section 2. The following material is integrated by reference:~~

~~(1) 21 C.F.R., Subpart B, Food for Human Consumption Part 113;~~

~~(2) "Recommended Practices for Producing Culinary Steam for Processing Milk and Milk Products";~~

~~(3) "Grade A Condensed Dry Milk Products and Condensed and Dry Whey, Supplement to the Grade A Pasteurized Milk Ordinance";~~

~~(4) "Official Methods of Analysis of the Association of Official Analytical Chemists";~~

~~(5) "Standard Methods for the Examination of Dairy Products";~~

~~(6) "3-A Sanitary Standards".~~

~~(7) A copy of the material is available for inspecting and copying, 8 a.m. until 4:30 p.m. at the Office of the Commissioner, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.]~~

STEVEN J. STACK, MD, MBA, Commissioner

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 provides the defined terms for 902 KAR Chapter 50.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to define the terms used in the regulations for 902 KAR Chapter 50.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 194A.050 authorizes the secretary to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.180(c) authorizes the secretary to promulgate administrative regulations for the safe handling of food

and food products. KRS 217C.040 authorizes the secretary to adopt rules and regulations regulating all processes for the production and sale of milk and milk products, including both Grade A milk products and milk for manufacturing purposes.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation ensures a consistent understanding of the terms used in the regulations for 902 KAR Chapter 50.

(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 defined terms used in the regulations for 902 KAR Chapter 50, and makes changes necessary to comply with KRS 13A drafting rules.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to ensure the most current definitions are applied to the applicable regulations in 902 KAR Chapter 50.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment removes defined terms that are not used 902 KAR Chapter 50, and updates other defined terms to be consistent with milk industry standards.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will ensure all regulated entities and other interested parties have a consistent understanding of the terms as used throughout 902 KAR Chapter 50.

(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 questions (3) will have to take to comply with this administrative regulation or amendment: The regulated entities will need to review the updated terms to ensure understanding of how the terms are used in 902 KAR Chapter 50.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): There are no anticipated costs to the regulated entities for compliance with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All regulated entities will have a consistent understanding of defined terms as a result of compliance with this administrative regulation.

(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? (Explain why or why not.) Tiering is not applied to this administrative regulation as all regulated entities should have a consistent understanding of the terms used for the production and sell of Grade A milk products and milk for manufacturing.

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 personnel involved in the inspection, permitting, and grading milk production 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, 7 C.F.R. 58.101, 21 C.F.R. 131.3(b), 133.3(d), 135.3, and 178.1010.

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? 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. 7 C.F.R. 58.101, Grading and inspection, general specifications for approved plants and standards for grades of dairy products; 21 C.F.R. 131.3(b), Milk and cream; 21 C.F.R. 133.3(d), Cheeses and related cheese products; and 21 C.F.R.135.3 Frozen desserts, and 21 C.F.R. 178.1010 Sanitizing solutions.

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 federally defined terms related to milk and milk products, the cabinet is assuring a uniform standard. By reference the federally defined process for sanitizing solutions that are safe for food

processing equipment and utensils, the cabinet is assuring milk and milk products are handled in a safe and sanitary manner.

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.