



Cabinet for Health and Family Services

DEPARTMENT FOR PUBLIC HEALTH,
PUBLIC HEALTH PROTECTION & SAFETY
MILK SAFETY BRANCH
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Andy Beshear
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Eric C. Friedlander
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Steven J. Stack
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REFERENCE FOR DISTRIBUTOR'S

The Kentucky Milk Safety Branch adopted the 2003 Pasteurized Milk Ordinance as reference and the below documentation is from that document. The Transfer Station/receiving station inspection sheet is used for distributors. Samples are not collected or tested by the State of Kentucky. Samples are collected and tested by the state of origin.

If a physical place of business is established in the state of Kentucky, and milk is the sole product distributed, an application is issued from the Kentucky Milk Safety Branch. If other non-dairy products are distributed, then the Kentucky Food Branch will issue the permit. Upon completion of the application and inspection(s) by a Milk Branch inspector, the permit will be issued when the facility is in compliance. Inspection frequency is every six (6) months.

Please advise this office as to the town you wish to distribute product and we will return to you an application and the name and number of the inspector in that area.

Office: 502-564-3340
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902 KAR 50:110. Grade A milk and milk products standards.

RELATES TO: KRS 217C.010-217C.990

STATUTORY AUTHORITY: KRS 194A.050, 211.090, 217C.040, 217C.040, EO 2004-726

NECESSITY, FUNCTION, AND CONFORMITY: EO 2004-726, effective July 9, 2004, reorganized the Cabinet for Health and Family Services and placed the Department for Public Health under the Cabinet for Health and Family Services. KRS 217C.040 requires the cabinet to promulgate administrative regulations concerning the production, transportation, processing, handling, sampling, examination, grading, sale and such other matters relating to Grade A milk and milk products as may be necessary to protect the public health. This administrative regulation establishes uniform permit requirements and sanitary standards for Grade A milk producers, processors, handlers and distributors, Grade A dry and condensed milk, Grade A dry and condensed whey and the fabrication of single-service containers and closures for milk and milk products.

Section 1. Grade A Milk and Milk Products. The permit requirements, sanitary and quality requirements for the production, processing, handling and distribution of Grade A milk and milk products shall be the same as the requirements established in the publication entitled, "Grade A Pasteurized Milk Ordinance," 2003 recommendations of the United States Public Health Service/Food and Drug Administration.

Section 2. Incorporation by Reference. (1) "Grade A Pasteurized Milk Ordinance," (2003 edition) is incorporated by reference.

(a) "Grade A Pasteurized Milk Ordinance", (2003 edition).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Commissioner, Department 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. (11 Ky.R. 115; eff. 8-7-84; Am. 12 Ky.R. 1918; eff. 7-2-86; 18 Ky.R. 1469; eff. 1-10-92; 29 Ky.R. 2773; 30 Ky.R. 288; eff. 8-13-2003; 31 Ky.R. 632; 946; eff. 11-17-2003; 31 Ky.R. 632; 946; eff. 11-17-2004.)

The complete PMO can be viewed on the following website.

<http://vm.cfsan.fda.gov/~ear/prime.html>



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TEM 21p. VEHICLES

All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less and are protected from contamination. Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.

PUBLIC HEALTH REASON

Milk and milk products, as well as empty containers, should be protected against contamination at all times.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All vehicles are kept clean.
2. Material that is capable of contaminating milk or milk products is not transported with milk or milk products.
3. Milk and milk products, except dry milk products, are maintained at 7°C (45°F) or less.
4. The operation of milk tank cars and shipping bins comply with the following provisions:



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- a. Milk and milk products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.
 - b. Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.
 - c. Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.
 - d. Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks, which must make more than one trip while unloading a tank car, need not be cleaned and sanitized after each time they are emptied.
 - e. Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.
5. The doors of tank cars and covers of shipping bins are sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled as prescribed in Section 4 by means of a tag attached to the tank car or shipping bin.
 6. Vehicles have fully enclosed bodies with well-fitted, solid doors.



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SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk or milk products are intended for consumption within ...of...¹ or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months.
2. Inspect each bulk milk hauler/sampler's, dairy plant sampler's and industry plant sampler's pickup and sampling procedures at least once every twenty-four (24) months.
3. Inspect each milk plant and receiving station at least once every three (3) months, except that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this



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Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K.

4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K.
5. Inspect each dairy farm at least once every six (6) months.⁶

Should the violation of any requirement set forth in Section 7, or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6 and Appendix B, be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection/audit shall be used to determine compliance with the requirements of Section 7 or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6 and Appendix B. Any violation of the same requirement of Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B, on such second inspection/audit, shall call for permit suspension in accordance with Section 3 and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by the Regulatory Agency. Provided, that when the Regulatory Agency finds that a critical processing element violation involving:



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1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;
2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance*. Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the Regulatory Agency shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products in conformance with Section 3 of this *Ordinance*.

One (1) copy of the inspection/audit report shall be handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.



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The Regulatory Agency shall also make such other inspections and investigations as are necessary for the enforcement of this *Ordinance*. Every permit holder shall, upon the request of the Regulatory Agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or milk plant operator shall furnish the Regulatory Agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records.

It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance*, which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk products or results of inspections/audits or tests thereof, to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms and transfer stations the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due. One (1) milk tank truck inspection every twelve (12) months, or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures



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inspection each twenty-four (24) months, or one (1) producer, transfer station, or milk tank truck cleaning facility inspection every six (6) months, or one (1) milk plant or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.

For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.

Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of



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satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, industry plant sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.

The penalties of suspension or revocation of permit and/or court action are provided to prevent continued violation of the provisions of this *Ordinance* but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the Regulatory Agency is authorized in Section 3, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three (3) days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this Section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or



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distributor shall have an opportunity to appeal the sanitarian's interpretation to the Regulatory Agency or request an extension of the time allowed for correction.

SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Milk and milk products, from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in..., ¹ or its jurisdiction provided they are produced and pasteurized, ultra-pasteurized, aseptically processed, concentrated (condensed) or dried under regulations which are substantially equivalent to this *Ordinance* and have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings or have been awarded a satisfactory HACCP listing, under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*.

ADMINISTRATIVE PROCEDURES

The Regulatory Agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection. Provided, that:

1. Milk and milk products upon arrival shall comply with bacteriological, physical, chemical and temperature standards of Section 7. Provided, that direct shipped producer milk that is under the supervision of more than one (1) Regulatory Agency may be exempt from the bacteriological requirement



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for commingled samples. However, the receiving Regulatory Agency shall have the right to use the individual producer samples to determine compliance with the bacteriological standards.

2. After receipt, pasteurized, ultra-pasteurized, aseptically processed, concentrated (condensed) or dried milk and milk products shall comply with Sections 2, 4 and 10.

NOTE: Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the Regulatory Agency requires.

3. The milk or milk products are produced and processed under regulations substantially equivalent to those of this *Ordinance*.
4. The supplies are under routine official supervision;
5. The supplies have been awarded, by a Milk Sanitation Rating Officer (SRO), certified by FDA, Milk Sanitation Compliance and Enforcement Ratings equal to that of the local supply or equal to ninety percent (90%) or higher; and
6. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Supplies* (MMSR).

NOTE: Names of interstate milk shippers and their ratings, as reported by State Rating Agencies, are contained in the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued semi-annually by FDA. Copies of this list may be obtained from the State Milk Rating/Regulatory Agency or



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from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

7. The supplies have been awarded, by a SRO, certified by FDA, a satisfactory listing under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*.