

330 CMR 28.00: MILK AND MILK PRODUCTS

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28.01: General Provisions

(1) Purpose 330 CMR 28.00 has been prepared for the purpose of insuring the quality and safety of milk and milk products consumed in Massachusetts. 330 CMR 28.00 establish administrative and enforcement procedures for the inspection of milk plants and out-of-state pasteurization plants; and the permitting of receiving stations, transfer stations and out-of-state pasteurization plants. For the purpose of 330 CMR 28.00 out-of-state pasteurization plants which process ultra-pasteurized and/or aseptic milk or milk products are not subject to 330 CMR 28.00 at this time. 330 CMR 28.00 is consistent with regulations issued by the Food and Drug Administration, Public Health Service, United States Department of Health and Human Services; however, the bacteriological and temperature standards may be more stringent in some cases.

(2) Scope. 330 CMR 28.00 applies to every milk plant and out-of-state pasteurization plant which offers for sale or transports milk or milk products in final package form into Massachusetts. Out-of-state pasteurization plants which process ultra-pasteurized and/or aseptic milk or milk products are not subject to 330 CMR 28.00 at this time.

28.02: Definitions

For the purpose of 330 CMR 28.00, the Department adopts the definitions for the items in the most recent edition of the Grade "A" Pasteurized Milk Ordinance as promulgated by the United States Department of Health and Human Services. The following additional definitions shall apply in the interpretation and enforcement of 330 CMR 28.00.

Bureau - shall mean the Bureau of Animal Health and Dairying of the Massachusetts Department of Food and Agriculture.

Commissioner - means the Commissioner of the Department of Food and Agriculture.

Department - means the Massachusetts Department of Food and Agriculture.

Raw Milk For Pasteurization - means Grade "A" milk and raw products thereof which comply with the sanitary standards for their production, transportation, receiving, handling, storage, processing, distribution and sale as determined by the Commissioner of Food and Agriculture in 330 CMR 27.00 through 29.00.

Regulatory Agency - is any out-of-state regulatory agency with functions, powers, and authority similar to that accorded the Massachusetts Department of Food and Agriculture or its subdivisions.

28.03: Adoption of the Pasteurized Milk Ordinance (PMO)

- (1) The Department hereby adopts and incorporates by reference the Grade "A" Pasteurized Milk Ordinance (PMO) as promulgated by the United States Department of Health and Human Services along with its appendixes and any updates, amendments and changes, and including any documents referenced or incorporated by the PMO, as they relate to milk processors, except for those provisions specifically omitted by 330 CMR 28.03.
- (2) The Department does not adopt any part of the PMO, along with any updates, amendments and changes, and any documents referenced or incorporated by the PMO, for the sole purpose of regulating dairy farms. In addition, the following provisions are specifically not adopted by the Department:
  - (a) Definitions D, U, X and Y;
  - (b) Sections, 3, 5, 6, 8, 9, 11, 12, 15, 16, 17 and 18.
- (3) References within the PMO to administration and enforcement, including those references to sections 3 and 13 of the PMO, shall refer to 330 CMR 28.20 *et seq.* Administrative procedures within the PMO not specifically deleted shall remain in effect.
- (4) References within the PMO to construction standards for toilet and sewage disposal facilities or to Appendix C, shall refer to and meet the requirements of the appropriate state regulatory requirements of the state of origin.
- (5) References within the PMO to standards for water source or to Appendix D, shall refer to and meet the requirements of the state of origin.
- (6) In addition to the boiler water additives listed in Appendix L, milk processors may also use boiler water additives listed in the Code of Federal Regulations, Title 21, part 173.1010, as from time to time amended.
- (7) In addition to the sanitizers listed in Appendix F, milk processors may also use sanitizers listed in the Code of Federal Regulations, Title 21, parts 178.1005 and 178.1010, as from time to time amended.
- (8) References to an ellipsis within the PMO that refer to a political subdivision shall refer to the "Commonwealth of Massachusetts".
- (9) References within the PMO to an unspecified edition of a publication shall refer to the current edition.

28.20: General Administration

- (1) Scope. The following provisions shall cover the administration and enforcement of 330 CMR 28.00.
- (2) State Enforcement.
  - (a) The Department may enforce 330 CMR 28.00 by suspension or revocation of permits in accordance with 330 CMR 28.23.
  - (b) If the Commissioner or his designee determines, as a result of any study, inspection or survey made by the Department, that compliance with 330 CMR 28.00 has not been effected, he shall take appropriate action to effect compliance.
  - (c) Notwithstanding any other provision of 330 CMR 28.00, if the Commissioner or his agent determines that an imminent health hazard exists, resulting from the operation of an out-of-state pasteurization plant, milk plant, transfer station or receiving station, he may take whatever action is necessary to effect compliance with 330 CMR 28.00.

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(3) Interpretation of 330 CMR 28.00. The Department may from time to time publish interpretations of 330 CMR 28.00 and guidelines as necessary to promote uniform application of 330 CMR 28.00, and may make them available to those persons holding permits under these provisions. The Department may advise the permittee on particular questions regarding interpretations of 330 CMR 28.00.

28.21: Permit: Issuance and Renewal

(1) General.

- (a) No person desiring to ship milk into or within the Commonwealth of Massachusetts shall operate a milk plant, receiving station, transfer station, or pasteurization plant wherever located outside the Commonwealth or a milk plant, receiving station, or transfer station within the Commonwealth unless he is the holder of a valid permit or permits issued by the Commissioner.
- (b) Only those who comply with the requirements of 330 CMR 28.00 shall be entitled to receive and retain a permit.
- (c) The permit(s) shall be posted on the premises of the milk plant, receiving station, transfer station, or out of state pasteurization plant.
- (d) A permit shall not be transferable from a person or a place.

(2) Application for a Permit.

- (a) Any person desiring to operate a milk plant, receiving station, transfer station, or out of state pasteurization plant wherever located shall make a written application for a permit on a form provided by the Commissioner. The application shall include:
  - 1. The applicant's name; the applicant's post office address;
  - 2. The name and location of the milk plant, receiving station, or transfer station located in the Commonwealth of Massachusetts or the name of the milk plant, receiving station, transfer station, or pasteurization plant wherever located outside the Commonwealth of Massachusetts;
  - 3. The signature of the applicant(s);
  - 4. Any other information necessary for the implementation of 330 CMR 28.000;
- (b) Payment of any fees required by law shall accompany the application.

(3) Permit Form. The permit form shall indicate:

- (a) The address of the milk plant, receiving station, transfer station, or out of state pasteurization plant;
- (b) The name of the permittee;
- (c) The dates of issuance and expiration;
- (d) The signature of the Commissioner.

(4) Expiration and Renewal of Permit.

- (a) A permit shall expire on the 30th day of June following its issue.
- (b) A transfer station, receiving station or out-of-state pasteurization plant permit may be renewed by applying at least 30 days prior to the expiration of the permit. Application for a renewal permit shall be made in writing on a form provided by the Commissioner.

(5) Conditions for Issuance.

- (a) After receipt of an application for a permit the Commissioner shall make a finding concerning the responsibility and suitability of the applicant bearing on such a finding, including but are not limited to the following:
  - 1. The applicant's history of prior compliance with 330 CMR 28.00.
  - 2. The applicant's ability and willingness to take corrective action when notified by the Commissioner of violations of 330 CMR 28.00.
  - 3. The applicant's operation has been awarded, by the State Milk Sanitation Rating Officer certified by the U.S. Food and Drug Administration, a milk sanitation compliance and enforcement rating of 90% or higher. All ratings must be made on the basis of procedures outlined in the most recent edition of the *Methods of Making Sanitation Ratings of Milk Supplies, Recommendations of the United States Public Health Services/Food and Drug Administration*.

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4. The Department conducts an inspection of milk plants located in Massachusetts pursuant to 330 CMR 28.22 and determines that the applicant's plant is in compliance with the standards and practices of the PMO. An inspection may be conducted of out of state pasteurization plants if deemed necessary by the Commissioner.
- (6) Copies of Permit. A copy of the permit shall be made. The original shall be given to the applicant. The copy shall be placed on file with the Bureau.
- (7) Notification of Changes. Change in ownership, name or location. A permittee shall notify the Commissioner within 48 hours after any change in ownership, and at least 30 days prior to any change of the name or location of the milk plant, receiving station, transfer station, or out of state pasteurization plant, and shall promptly submit to the Commissioner an application for a new or amended license, along with written documentation reflecting such change.

28.22: Inspections

- (1) General.
  - (a) The Department may inspect every milk plant or out-of-state pasteurization plant as necessary for the enforcement of 330 CMR 28.00.
  - (b) The Commissioner or agents of the Department, after identifying themselves, may enter all parts of any milk plant, receiving station, transfer station, or out of state pasteurization plant at any reasonable time for the purpose of making an inspection to ascertain whether the plant is in compliance with 330 CMR 28.00. They may examine the records of the plant or station to obtain information pertaining to milk, milk products, ingredients thereof and supplies purchased, received or used.
  - (c) The permittee or person in charge at the time of the inspection shall furnish an agent of the Department, upon request, a true statement of the actual quantities of each grade of milk and milk products purchased and sold by the plant, a list of all sources of such milk and milk products, and records of inspections, tests and pasteurization times and temperatures.
  - (d) If the permittee or person in charge at the time of the inspection refuses entry to an agent of the Department, or refuses entry to the Commissioner to permit an authorized inspection, the Commissioner or his agent may immediately suspend the permit of the receiving station, transfer station, or out-of-state pasteurization plant, without prior notice or hearing, in accordance with 330 CMR 28.23(1).
  - (e) If the permittee or any of his employees interferes with the Commissioner or an agent of the Department in the performance of its duties, the Commissioner or agent of the Department may take steps to suspend or revoke the permit of the receiving station, transfer station or out-of-state pasteurization plant in accordance with 330 CMR 28.23(3) or (4).
  - (f) It shall be unlawful for any person who, in any official capacity, obtains any information under 330 CMR 28.00 which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of milk and milk products or results of inspections or tests thereof) to use such information to his or her advantage or to reveal it to any unauthorized person.
- (2) Inspection Report.
  - (a) Whenever an inspection of a milk plant or out-of-state pasteurization plant is made, the findings shall be recorded on an inspection report. The inspection report shall serve as an order to the permittee to correct all violations of 330 CMR 28.00 noted thereon by the time of the next inspection.
  - (b) The inspection report shall include, but need not be limited to, the following information:
    1. The name of the inspector;
    2. The date and time of the inspection;
    3. The name and location of the milk plant or out-of-state pasteurization plant inspected;
    4. A listing of the specific provisions of 330 CMR 28.00 that have been violated;

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5. A determination by the inspector whether any of the violations create an imminent health hazard;
  6. The signature of the inspector;
  7. The signature of the person in charge of the milk plant or out-of-state pasteurization plant at the time of the inspection.
- (3) Conduct of Inspections
- (a) inspections performed pursuant to 330 CMR 28.21(5) and 330 CMR 28.22(1)(a) shall be full inspections.
  - (b) A copy of the completed inspection report form shall be furnished to the person in charge of the receiving station, transfer station or out-of-state pasteurization plant at the conclusion of the inspection or posted in a conspicuous place on an inside wall of the plant. This inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department and retained for at least 12 months.
- (4) Enforcement
- (a) Should the violation of any requirement set forth in 330 CMR 28.03 be found to exist during an inspection of a transfer station, receiving station or out-of-state pasteurization plant, a second inspection shall be required after a time deemed necessary by the Department, Commissioner, or agent thereof to remedy the violation, but not before three days. Any violation of the same requirement on such second inspection may result in the immediate suspension of the permit or of one or more particular operations, without a prior hearing, in accordance with 330 CMR 28.23(1), and may also result in court action.
  - (b) Provided, that when the regulatory agency finds that a critical processing element violation involving:
    1. Improper 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 operating equipment; or
    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 Commissioner shall take immediate action to prevent further processing of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the Commissioner or the Department shall take prompt action to suspend the permit as provided for in 330 CMR 28.23.

28.23: Permit: Suspension, Revocation, Refusal to Issue or Renew

- (1) Suspension Without a Prior Hearing.
- (a) The Commissioner or her/his agent may, without prior notice or hearing, immediately suspend a permit to operate a transfer station, receiving station or out-of-state pasteurization plant if an imminent health hazard is found to exist.
  - (b) The Commissioner or her/his agent may, without granting a prior hearing, immediately suspend a permit if:
    1. A second violation of the same requirement of 330 CMR 28.00 is found to exist on a second inspection, in accordance with 330 CMR 28.00 or
    2. A violation as specified in 330 CMR 28.03 is found to exist.
  - (c) The Commissioner or her/his agent may without prior notice or hearing immediately suspend a permit if an agent of the Department is refused entry to or is prevented from conducting an authorized inspection of a transfer station, receiving station or an out-of-state pasteurization plant.
  - (d) Whenever a suspension is ordered pursuant to 330 CMR 28.23, the order shall state:
    1. The reason(s) for the immediate suspension;
    2. The violation(s) leading to the determination that an imminent health hazard exists, if applicable; and

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3. That a hearing will be held if a request for a hearing is made to the Department or Commissioner, as the case may be, in writing or by telephone, by the permittee.
- (e) The order immediately suspending the permit or operation(s) shall be effective upon posting of the order on the premises by an authorized agent of the Department. If the permittee whose name appears on the permit is not present at the time of such posting, or if the permittee is a corporation or other firm, a copy of the order of suspension shall be served in accordance with 330 CMR 28.24.
- (f) The Bureau shall hold a hearing after a request for a hearing has been made to the Bureau, in writing or by telephone to a person authorized to schedule a hearing by the permittee.
- (g) Whether or not a hearing is requested, the Commissioner, the Department or an agent thereof may end the suspension at any time if reasons for the suspension no longer exist.
- (2) Ten Day Letter Process.
- (a) The Commissioner may take steps to exclude milk from the markets of the Commonwealth of Massachusetts and may suspend a permit if the milk has come from a transfer station, receiving station or out-of-state pasteurization plant when the permittee is not in compliance with the conditions for the issuance of the permit, pursuant to 330 CMR 28.21(5).
- (b) If a serious sanitary code violation is found to exist during an inspection, the Bureau may issue a notice to provide for an additional inspection at least ten days after the date of the receipt of such notice. Such notice may be given during either an initial or subsequent inspection.
- (c) The notice shall specify the violation(s) for which the transfer station, receiving station or out-of-state pasteurization plant is under question, and that the permit may be suspended.
- (d) To obtain a hearing after the subsequent reinspection, the permittee shall make a request for a hearing to the bureau, in writing or by telephone to a person authorized to schedule a hearing, within five days of the reinspection following notice. If no request for a hearing is made within the five day period, the revocation or suspension shall be imposed at the end of the time period specified in the order; six days after the reinspection.
- (3) Suspension after a Hearing.
- (a) The Commissioner may, after providing opportunity for hearing, suspend a permit if the permittee does not comply with any one or more of the requirements of 330 CMR 28.21(5).
- (b) The order shall be in writing and sent to the permittee or her/his authorized agent in accordance with 330 CMR 28.24.
- (c) The order shall specify the specific violations for which the permit is to be suspended and that the permit shall be suspended by the Department following notice of such order.
- (4) Revocation of Permit.
- (a) The Commissioner may after providing opportunity for a hearing, order the revocation of permit for any one of the following:
1. Serious or repeated violations of any of the requirements of 330 CMR 28.21(5);
  2. Interference with the Department in the performance of its duty;
  3. A criminal conviction of the permittee relating to the operation of the transfer station, receiving station or out-of-state pasteurization plant; or
  4. Keeping or submitting any misleading or false records or documents required by 330 CMR 28.00.
- (b) The order shall be in writing and shall be served on the permittee or her/his authorized agent in accordance with 330 CMR 28.24.

28.24: Service of Orders for Suspension or Revocation

- (1) If pursuant to 330 CMR 28.23, the Department orders the suspension or revocation of a permit, the permittee shall be so notified by a written order.
- (2) The order shall include but need not be limited to the following:
  - (a) The name and location of the transfer station, receiving station or out-of-station pasteurization plant;
  - (b) The reason(s) for the suspension or revocation, and a description of such operation;
  - (c) The date the suspension or revocation is or will become effective.
- (3) Orders for suspension or revocation shall be served on the permittee or her/his authorized agent as follows:
  - (a) By sending a copy of the order by registered or certified mail, return receipt requested; or
  - (b) Personally, by any person authorized by the Department to serve; or
  - (c) If the aforementioned methods of service are unsuccessful, service may be made by any person authorized to serve civil process as follows:
    1. By leaving a copy of the order at her/his last and usual place of abode or;
    2. By posting a copy of the notice in a conspicuous place on or about the premises if her/his last and usual place of abode is unknown.

28.25: Hearings

- (1) The person(s) to whom any order issued pursuant to 330 CMR 28.23 has been directed may request a hearing before the Bureau.
- (2) A request for a hearing may be made by the permittee to the Bureau in writing or by telephone to a person authorized to schedule a hearing.
- (3) Upon receipt of a request for a hearing, the Bureau shall set a time and a place for such hearing and shall inform the petitioner thereof.
- (4) At the hearing, the petitioner shall be given an opportunity to be heard and to show why the order should be modified or withdrawn. Any oral testimony given at a hearing may be recorded verbatim.
- (5) After the hearing, the Bureau shall make a final decision based upon the complete hearing record, and shall inform the petitioner in writing of the decision. If the Bureau sustains or modifies an order, it shall be carried out within the time period allotted in the original order or in the modification.
- (6) Every notice, order, decision and other record prepared by the Bureau in connection with the hearing shall be entered as a matter of public record in the office of the agency.
- (7) Any person aggrieved by the final decision of the Department may seek relief in a court of competent jurisdiction.

28.26: Permit: Reinstatement after Suspension

Any permittee whose permit has been suspended may make written application to the Department for the reinstatement of his permit. A permit may be reinstated if the permittee has corrected all violations and is in compliance with the conditions for issuance of a permit, pursuant to 330 CMR 28.21(5).

28.27: Criminal Penalties

Any person who sells, exchanges or delivers or has in his possession with intent to sell, exchange, or deliver, milk shipped within or into Massachusetts from a milk plant or out-of-state pasteurization plant which has not been issued a permit is subject to a fine of not less than \$500 but not more than \$1,000 for the first offense; not less than \$1,000 but not more than \$5,000 for the second offense, and \$5,000 and imprisonment for not less than six months for subsequent offenses.

28.28: Severability

If any provision of 330 CMR 28.00 shall be declared invalid for any reason whatsoever, that decision shall not affect any other portion of 330 CMR 28.00, which shall remain in full force and effect; and to this end the provisions of 330 CMR 28.00 are hereby declared severable.

REGULATORY AUTHORITY

M.G.L. c. 94, §§ 13, 16K, 16L.