105 CMR 541.000: MILK AND MILK PRODUCTS, GRADE A CONDENSED AND DRY MILK PRODUCTS, GRADE A CONDENSED AND DRY WHEY, AND MILK PASTEURIZATION PLANTS

Section

541.001: Definitions

For the purposes of 105 CMR 541.000, the following terms shall have the meanings hereinafter specified. These definitions shall be in addition to those contained within the *Federal Grade "A" Pasteurized Milk Ordinance (PMO)* and the *Federal Grade A Condensed and Dry Milk Products and Grade A Condensed and Dry Whey - Supplement I to the Grade A Pasteurized Milk Ordinance a/k/a Dry Milk Ordinance(DMO).*

Adulterated Milk or Milk Products shall mean, in addition to the definitions set forth in the PMO and DMO, any milk or milk products deemed to be adulterated in accordance with M.G.L. c. 94, § 186 through 192.

Commissioner shall mean the Commissioner of Public Health.

Cottage Cheese shall mean that product defined in 21 CFR 133.128, as may from time to time be amended.

Department shall mean the Massachusetts Department of Public Health.

Director shall mean the Director of the Division of Food and Drugs of the Massachusetts Department of Public Health.

Division shall mean the Division of Food and Drugs of the Massachusetts Department of Public Health.

Dry Curd Cottage Cheese shall mean that product defined in 21 CFR 133.128, as may from time to time be amended.

Dry Milk Ordinance (DMO) shall mean the set of federal guidelines entitled the *Federal Grade "A" Condensed and Dry Milk Products and Grade A Condensed and Dry Whey - Supplement I to the Grade A Pasteurized Milk Ordinance* published and revised from time to time by the U.S. Department of Health and Human Services.

Grade A shall mean the standard of quality which may be attached to all those products which meet the requirements of and have been processed in accordance with the requirements of the *Federal Grade "A" Pasteurized Milk Ordinance (PMO).*

Imminent Health Hazard shall mean any violation of 105 CMR 541.000 by a milk pasteurization plant or any other occurrence or condition in a milk pasteurization plant that has the potential to pose an imminent threat to public health and shall include, but not be limited to

(1) an extended loss of water supply,
(2) an extended power outage,
(3) a sewer backup into the pasteurization plant, or
(4) any condition which is defined elsewhere in 105 CMR 541.000 as an imminent health hazard. Failure to include other violations, occurrences, or conditions in this definition shall not be construed as a determination that such

other violations, occurrences, or conditions are not, or may not be considered, imminent health hazards.

Lowfat Cottage Cheese shall mean that product defined in 21 CFR 133.131, as may from time to time be amended.

Misbranded Milk or Milk Products shall mean, in addition to the definitions in the PMO and DMO, any milk or milk products deemed to be misbranded in accordance with M.G.L. c. 94, §§ 186 through 192.

Pasteurized Milk Ordinance (PMO) shall mean the set of federal guidelines entitled the *Federal Grade "A" Pasteurized Milk Ordinance* published and revised from time to time by the U.S. Department of Health and Human Services.

Pasteurization plant shall mean an establishment for the pasteurization of milk which is required to be licensed by M.G.L. c. 94, § 48A.

Regulatory Agency shall mean, whenever the term is used in the PMO and DMO, the Department of Public Health and/or the local board of health, as appropriate.

541.002: Adoption of Federal Pasteurized Grade "A" Milk Ordinance (PMO)

(A) The Department hereby adopts and incorporates by reference the Federal Grade "A" Pasteurized Milk Ordinance (hereafter "PMO")published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to milk, milk products or pasteurization plants) as well as all subsequent revisions of or amendments to said PMO, appendices or referenced documents, provided, however, that the Department does not adopt those provisions of said PMO, appendices or referenced documents specifically omitted by 105 CMR 541.002(B).

(B) The Department does not adopt any provision, or any part of any provision, of the PMO, or any of its appendices, or any other regulation, standard, memoranda or other document it refers to and/or incorporates, or any subsequent amendment to said PMO, appendices or referenced documents, which relate to and/or purport to regulate dairy farms or which refer to reconstituted or recombined milk or milk products. Furthermore, the following provisions of the PMO are specifically not adopted by the Department:

(1) Part I entitled *Federal Grade "A" Pasteurized Milk Ordinance--1989 Recommendations*.
(2) Definitions D, U, X, and Y;
(3) Sections 3,5,6,8,9,11,12,13,14,15,16, and 17;
(4) Section 7, Items 1r. through 21r., pertaining to the regulation of dairy farms.
(5) Appendixes A,B,C,D and K.

(C) The following provisions of the PMO shall apply to all pasteurization plants

that ship milk and milk products in interstate commerce and may or may not apply to pasteurization plants that ship milk and milk products only in intrastate commerce.

(1) Section 7, Item 5p, which requires that separate rooms be maintained for various functions occurring at pasteurization plants. Existing pasteurization plants that do not ship milk or milk products in interstate commerce may request a waiver from the separate room requirement from the Department, and the Department shall grant the waiver if it determines that granting of the waiver would not pose a risk to the public health. However, all new pasteurization plants and any existing pasteurization plant undergoing substantial remodeling or renovation are required to have the separate rooms required by Section 7, Item 5p.

(2) Section 7, Item 16p (E)2, and its accompanying Table 3, which require the Department to test pasteurization plant instruments and devices according to a certain frequency. For pasteurization plants that do not ship milk or milk products in interstate commerce, the Department shall conduct equipment tests and examinations at a frequency determined by the Department.

(D) References within the PMO to other provisions of the PMO which have been deleted by 105 CMR 541.002(B) and which relate to subjects covered by 105 CMR 541.010 including references to any provision of Sections 3, 5, 6, 14, 15, and 16 of the PMO, shall be deemed to be deleted and replaced by a reference to 105 CMR 541.010.

(E) References within the PMO to construction standards for toilet and sewage disposal facilities, or to Appendix C, shall be deemed to be deleted and replaced by a reference to 310 CMR 15.00, Minimum Requirements for the Subsurface Disposal of Sanitary Sewage, the State Environmental Code, Title 5, promulgated by the Department of Environmental Protection.

(F) References within the PMO to standards for water and water sources, or to Appendix D, shall be deemed to be deleted and replaced by a reference to 310 CMR 22.00: *Drinking Water Regulations*, promulgated by the Department of Environmental Protection, and such further guidelines related to Drinking Water as are developed by the Department of Environmental Protection.

(G) In addition to the boiler water additives listed in Appendix L of the PMO, milk processors may also use the boiler water additives listed in 21 CFR 173.310.

(H) In addition to the sanitizers listed in Appendix F of the PMO, milk processors may also use sanitizers listed in 21 CFR 178.1005 and 178.1010.

(I) Provisions in the PMO which refer to an unnamed political subdivision by means of an ellipsis (*e.g.*".....") shall be deemed to be amended by deleting the ellipsis and replacing it with the words "Commonwealth of Massachusetts."

(J) References within the PMO to an unspecified edition of a publication shall be deemed to refer to the current edition of that publication.

(K) References within the PMO to "milk plants" shall be deemed to be deleted and replaced by a reference to "pasteurization plants."

541.003: Adoption of Federal Grade A Condensed and Dry Milk Products and Grade A Condensed and Dry Whey - Supplement I to the Grade A Pasteurized Milk Ordinance a/k/a/ Dry Milk Ordinance (DMO)

(A) The Department hereby adopts and incorporates by reference the *Federal Grade A Condensed and Dry Milk Products and Grade A Condensed and Dry Whey - Supplement I to the Grade A Pasteurized Milk Ordinance a/k/a/ Dry Milk Ordinance* (hereafter "DMO") published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to milk, milk products or pasteurization plants) as well as all subsequent revisions of or amendments to said DMO, appendices or referenced documents, provided, however,that the Department does not adopt those provisions of said DMO, appendices or referenced documents specifically omitted by 105 CMR 541.003(B).

(B) The Department does not adopt any provision, or any part of any provision, of the DMO, or any of its appendices, or any other regulation, standard, memoranda or other document it refers to and/or incorporates, or any subsequent amendment to said DMO, appendices or referenced documents, which relate to and/or purport to regulate dairy farms or which refer to reconstituted or recombined milk or milk products. Furthermore, the following provisions of the DMO are specifically not adopted by the Department:

Sections 3, 5, 6, 8, 9, 11, 12, 13, 14, and Appendix I.

(C) References within the DMO to other provisions of the DMO which have been deleted by 105 CMR 541.003(B) and which relate to subjects covered by 105 CMR 541.010, including references to any provision of sections 3 and 10 of the DMO, shall be deemed to be deleted and replaced by a reference to 105 CMR 541.010.

(D) Provisions in the DMO which refer to an unnamed political subdivision by means of an ellipsis (*e.g.*"....") shall be deemed to be amended by deleting the ellipsis and replacing it with the words "Commonwealth of Massachusetts."

(E) References within the DMO to an unspecified edition of a publication shall be deemed to refer to the current edition of that publication.

(F) References within the DMO to "milk plants" shall be deemed to be deleted and replaced by a reference to "pasteurization plants."

541.004: Supplemental Milk Regulations

The following requirements are in addition to those established by 105 CMR

541.002 and 541.003:

(A) Open Dating. Milk and milk products covered by 105 CMR 541.000 shall meet the open dating requirements set forth in 105 CMR 520.000: *Labeling*.

(B) Water Sources. The source of water used in the production and processing of milk and milk products shall meet all the regulatory requirements of 310 CMR 22.00: *Drinking Water*, promulgated by the Department of Environmental Protection.

(C) Milk-Derived Ingredients. Whey, Caseinate, lactalbumin, and other milk-derived ingredients are required to be derived from a Grade A raw milk source.

(D) Vitamin and Mineral Fortification.

(1) Vitamins and minerals may be added to milk and milk products only in pasteurization plants licensed under the provisions of M.G.L. c. 94, § 48A. The types and amounts of vitamins and minerals that may be added to milk and milk products and Grade A dry milk products are as follows:

(a) If added, vitamins shall be present in such quantities as required by 21 CFR , as may from time to time be amended.

(b) If added, minerals, as permitted by 21 CFR 182, shall be present in amounts conforming to the requirements set forth in 21 CFR 101.9, as may from time to time be amended.

(2) Each pasteurization plant which, as of the effective date of 105 CMR 541.000, adds vitamins or minerals to milk and milk products shall develop a plan detailing the vitamin and mineral fortification process and shall submit the plan to the Department for approval within 90 days after the effective date of 105 CMR 541.000. Pasteurization plants which are not adding vitamins or minerals to milk or milk products as of the effective date of 105 CMR 541.000, but who plan to do so in the future, must submit a plan detailing the vitamin and mineral fortification process to the Department for approval prior to the addition of vitamins or minerals to their milk and/or milk products. The plan shall include, but not be limited to, the following components:

(a) Method of maintaining vitamin and mineral purchase records.
(b) Carriers to be utilized.
(c) Inventory control procedure.
(d) Inventory and daily-use log systems.
(e) Methods and procedures for addition.
(f) Pump calibration methodology.
(g) Method of determining the percent deviation of the actual amount of vitamin and mineral concentrate used to the theoretical calculated amount needed based on production volume.

(3) The pasteurization plant shall record and keep on file, for at least two years, the following records:

(a) Vitamin and mineral purchase records.
(b) Inventory control records.
(c) Daily-use log sheets.

(d) Daily production records.

(4) The pasteurization plant shall also create and keep on file for at least two years, a monthly report showing the comparison between the actual amount of vitamin or mineral concentrate used to the calculated theoretical use based on production volume of each product type. The theoretical use is calculated by determining the monthly production volume of each product type from daily production records and then calculating the amount of vitamins and minerals that should be added to this production volume based on the strength of the vitamin or mineral concentrate.

(5) The plant must immediately notify the Department, in writing, of any abnormal or unusual findings or occurrences which may include, but are not limited to, equipment malfunctions, vitamin addition errors, a deviation of greater than 5% between theoretical use and actual use of any particular vitamin or mineral in any particular month, or a deviation that falls below or exceeds the levels established by 21 CFR 101.9, as may from time to time be amended.

541.010: General Administration

(A) Scope. The following provisions shall cover the administration and enforcement of 105 CMR 541.000.

(B) State Enforcement.

(1) The Department may enforce 105 CMR 541.000 by suspending or revoking licenses in accordance with 105 CMR 541.013; or by issuing orders pursuant to 105 CMR 541.012(B); or by issuing a stop work order until critical violations are corrected.

(2) Notwithstanding any other provision of 105 CMR 541.000, if the Department determines that an imminent health hazard exists, resulting from the operation of a pasteurization plant, it may, without prior notice to the board of health, take whatever action is necessary to effect compliance with 105 CMR 541.000.

(C) Local Enforcement.

(1) Each board of health may enforce 105 CMR 541.000 by suspending or revoking licenses in accordance with 105 CMR 541.013; or by issuing orders pursuant to 541.012(B); or by issuing a stop work order until critical violations are corrected.

(2) Each board of health shall, in writing, notify the Division of any action that will be, or has been taken, to effect compliance with 105 CMR 541.000.

(D) Advisory Committee. The Director of the Division of Food and Drugs may appoint an advisory committee for pasteurization plants. Members of the committee shall include: representatives of state health and regulatory agencies, local boards of health, federal health and regulatory agencies, the dairy industry, and academia. The committee may advise the Department on matters of policy; may be consulted by the Director prior to the issuance of rules and regulations; and may perform such other duties as the Director requests.

(E) Interpretation of 105 CMR 541.000. The Director may from time to time publish interpretations of 105 CMR 541.000 and guidelines as necessary to promote uniform application of 105 CMR 541.000, and may make them available to those persons licensed under 105 CMR 541.000. The Director may advise licensees or local boards of health on particular questions regarding interpretation of 105 CMR 541.000.

541.011: License: Issuance

(A) General.

(1) No person shall operate a pasteurization plant unless that person is the holder of a valid license granted by the board of health.

(2) Only persons who comply with the requirements of 105 CMR 541.000 shall be entitled to receive and retain a license.

(3) The license shall be posted on the premises of the pasteurization plant.

(4) A license shall not be transferable from a person or a place.

(B) Application for License.

(1) Any person desiring to operate a pasteurization plant shall make written application for a license on a form provided by the board of health and approved by the Department. The application shall include:

(a) The applicant's name; the owner's name if different from the applicant; the applicant's post office address; whether such applicant is an individual, partnership, or corporation, and, if a partnership or corporation, the names of the partners or corporate officers together with their home addresses, state of incorporation, and name and address of local agent;

(b) The name and location of the existing or proposed pasteurization plant;

(c) Whether the pasteurization plant is also a condensing and/or drying plant;

(d) The signature of the applicant or applicants;

(e) A 24 hour emergency telephone number; and

(f) Any other information required by applicable law.

(2) Payment of any fee required by law shall accompany the application.

(C) License Form.

(1) The license form shall indicate:

(a) The address of the pasteurization plant;

(b) The name of the licensee;

(c) Whether the license is an original (new) or a renewal;

(d) The date of expiration; and

(e) Any other information required by the Department or the board of health.

(D) Expiration and Renewal of License.

(1) A license shall expire no later than one year from the date issued.

(2) A license may be renewed by applying at least 30 days prior to the expiration of the license. Application for a renewal license shall be made in writing on a

form provided by the board of health and approved by the Department.

(E) Conditions for Issuance.

(1) After receipt of an application for an original license or renewal license the board of health shall cause an inspection of the pasteurization plant to take place. This inspection may be conducted by the Division. When the inspection reveals that the applicable requirements of 105 CMR 541.000 have been met, a license shall be issued to the applicant by the board of health, provided that the applicant is found to be responsible and suitable for licensure in accordance with 105 CMR 541.011(E)(2).

(2) After receipt of an application for an original license or a renewal license, the board of health shall make a finding concerning the responsibility and suitability of the applicant for licensure. Factors which have a significant bearing on such finding include but are not limited to the following:

(a) The applicant's history of prior compliance with 105 CMR 541.000.

(b) The applicant's ability and willingness to take corrective action when notified by the Department or board of health of violations of 105 CMR 541.000.

(F) Copies of License. An original and two copies of the license shall be made. The original shall be given to the applicant. One copy shall be placed on file with the board of health, and one copy shall be sent to the Division.

(G) Notification of Changes.

(1) Change in ownership, name or location. A licensee shall notify the Division and the board of health within 48 hours after any change in ownership, and at least 30 days prior to any change of the name or location of the pasteurization plant, and shall promptly submit to the board of health an application for a new or amended license, along with written documentation reflecting such change.

(2) Remodeling or change in operations. A licensee shall submit plans to the Department in accordance with 105 CMR 541.024 any time a pasteurization plant is to be extensively remodeled, or an existing structure is to be converted for use as a pasteurization plant, or an operation or fixed equipment is to be changed or added, and shall promptly submit an application to the board of health if a new or amended license is required by the board of health or the Department.

541.012: Inspections

(A) General.

(1) An inspection shall be made by agents of the Department or the board of health of every pasteurization plant shipping milk and milk products in interstate commerce at least once every three months, but in any event, as often as is deemed necessary for the enforcement of 105 CMR 541.000. Pasteurization plants shipping milk or milk products only in intrastate commerce shall be inspected at a frequency determined by the Department.

(2) Agents of either the Department or the board of health, after identifying

themselves, may enter all parts of any pasteurization plant at any reasonable time for the purpose of making an inspection to ascertain whether the plant is in compliance with 105 CMR 541.000. They may examine all records of the plant which are relevant in determining whether or not the plant has complied with the requirements of 105 CMR 541.012.

(3) The licensee or person in charge at the time of the inspection shall furnish the agent of the Department or the board of health, 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.

(4) If the licensee or person in charge at the time of the inspection refuses entry to an agent of the Department or the board of health, or refuses to permit an authorized inspection, the Commissioner or his agent or the board of health may immediately suspend the license of the pasteurization plant, without prior notice or hearing, in accordance with 105 CMR 541.013(A).

(5) If the licensee or any of his employees interferes with the Department or the board of health in the performance of its duties, the Department or the board of health may take steps to suspend or revoke the license of the pasteurization plant in accordance with 105 CMR 541.013(B) or (C).

(6) It shall be unlawful for any person who, in any official capacity, obtains any information under 105 CMR 541.000 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 such information to any unauthorized person.

(B) Inspection Report.

(1) Whenever an inspection of a pasteurization plant is made, the findings shall be recorded on an inspection report. The inspection report shall serve as an order to the licensee to correct all violations of 105 CMR 541.000 noted thereon by the time of the next inspection, which inspection shall occur at a time established by the Department or board of health in accordance with 105 CMR 541.012(D)(1).

(2) The inspection report shall include, but need not be limited to, the following information:

(a) The name of the inspector;

(b) The date and time of the inspection;

(c) The name and location of the pasteurization plant inspected;

(d) A listing of the specific provisions of 105 CMR 541.000 and of the PMO or the DMO that have been violated;

(e) A determination by the inspector whether any of the violations create an imminent health hazard;

(f) A statement that the inspection report serves as a notice of intent to suspend the permit if any indicated violation of Section 7 of the PMO or the DMO, as defined in 105 CMR 541.002 and 541.003, is not in compliance at the time of the next inspection.

(g) The signature of the inspector; and

(h) Space for the signature of the person in charge of the pasteurization plant

at the time of the inspection.

(C) Conduct of Inspections.

(1) A copy of the completed inspection report form shall be furnished to the person in charge of the 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, or the board of health, upon request. An identical copy of the inspection report shall be filed with the records of the Department or the board of health and retained for at least 12 months.

(2) Inspections shall be made of pasteurization plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, processing elements, including pasteurization, equipment cleaning and sanitizing and other procedures comply with the requirements of 105 CMR 541.000.

(D) Enforcement.

(1) Should the violation of any requirement set forth in Section 7 of the PMO or the DMO be found to exist during an inspection of a pasteurization plant, a second inspection shall be conducted after a time deemed necessary by the Department or the board of health to remedy the violation, which period shall not, however, be shorter than three days, except in cases of public health emergencies, in which case the reinspection may be conducted as soon as the Department or board of health deems necessary. Any violation of the same requirement on such second inspection will result in a notice of intent to suspend the permit.

(2) When the Department or the board of health finds a critical processing element violation involving:

(a) Improper pasteurization, whereby every particle of milk or milk product and Grade A condensed and dry milk product and Grade A condensed and dry whey may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or

(b) a cross connection whereby direct contamination of pasteurized milk or milk product or Grade A condensed or dry milk product or Grade A condensed or dry whey is occurring; or

(c) conditions whereby direct contamination of pasteurized milk or milk product or Grade A condensed or dry milk product or Grade A condensed dry whey is occurring;

The Department or the local board of health shall take immediate action to prevent further processing of such milk or milk products or Grade A condensed or dry milk products or Grade A condensed or dry whey until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the violation(s) shall be considered an imminent health hazard, and the Department or the board of health shall immediately suspend the license of the plant or suspend the operation of the process, without prior notice or hearing in accordance with 105 CMR 541.013(A), and may also

institute court action.

(3) In the case of pasteurization plants producing aseptically processed milk and milk products and Grade A condensed and dry milk products and Grade A condensed and dry whey: when an inspection of the plant and its records reveals that the process used does not comply with the scheduled process specified in 21 CFR 113, as may from time to time be amended, the violation shall be considered an imminent health hazard, and the Department or the board of health shall immediately suspend the license of the plant or suspend the operation of the process, without prior notice or hearing, in accordance with 105 CMR 541.013(A), and may also institute court action.

541.013: License: Suspension, Revocation, Refusal to Issue or Renew

(A) Suspension of License or Operation(s) without a Prior Hearing.

(1) The Department or the board of health may, without prior notice or hearing, immediately suspend a license to operate a pasteurization plant or immediately suspend one or more particular operations if an imminent health hazard is found to exist.

(2) The Department or the board of health may, without prior notice or hearing, immediately suspend a license to operate a pasteurization plant or immediately suspend one or more particular operations if three of the last five bacterial counts (except those for aseptically processed milk and milk products), coliform determinations, or cooling temperature checks have been in violation of Section 7 of the PMO and the DMO.

(3) The Department or the board of health may, without prior notice or hearing, immediately suspend a license to operate a pasteurization plant if an agent of the Department or the board of health is refused entry to the plant or is prevented from conducting an authorized inspection, as specified in 105 CMR 541.012(A)(4).

(4) Whenever a suspension is ordered pursuant to 105 CMR 541.013(A)(1), (2) or (3), a written order shall be immediately provided to the person in charge of the plant and a copy shall be posted on the premises. The order shall state:

(a) The reason(s) for the immediate suspension;

(b) The violation(s) leading to the determination that an imminent health hazard exists, if applicable; and

(c) That a hearing will be held if a request for a hearing is made to the board of health or the Division, as the case may be, in writing or by telephone, by the licensee.

(5) The order immediately suspending the license or operation(s) shall be effective upon posting of the order on the premises by an authorized agent of the Department or the board of health. If the person whose name appears on the license is not present at the time of such posting, or if the licensee is a corporation or other firm, a copy of the order of suspension shall be served in accordance with 105 CMR 541.014.

(6) A hearing shall be held within 72 hours after a request for a hearing has been made by the licensee. If the 72-hour period expires on a weekend day or holiday, the hearing may be held on the next business day.

(7) Whether or not a hearing is requested, the Department or the board of health may end the suspension at any time if reasons for the suspension no longer exist.

(B) Suspension of License or Operation(s) after Opportunity for a Hearing.

(1) The Department or the board of health may, after providing opportunity for hearing, suspend a license to operate a pasteurization plant or may suspend one or more particular operations if the plant or the operation does not comply with any one or more of the requirements of 105 CMR 541.000.

(2) The Department or board of health shall issue a notice of intent to suspend, which shall be in writing and shall be served on the licensee or his authorized agent in accordance with 105 CMR 541.014.

(3) The notice of intent to suspend shall specify the specific violation(s) for which the license or operation is to be suspended; that the license or operation shall be suspended at the end of a specified reasonable time period set by the Department or the board of health unless the plant corrects all cited violations within that time; and the procedure for requesting a hearing.

(4) To obtain a hearing, the licensee shall make a written request for a hearing to the agency which issued the notice of intent to suspend within ten days after the receipt of the notice of intent to suspend. If no request for a hearing is made, the suspension shall be imposed at the end of the time period specified in the notice and shall continue until the required corrections are made. If a request for a hearing is made, the suspension may commence no sooner than the end of the hearing.

(C) Revocation of License or Termination of Operation(s) After Opportunity For A Hearing.

(1) The Department or the board of health may, after providing opportunity for a hearing, revoke a license or terminate one or more particular operations for:

(a) Serious or repeated violations of any of the requirements of 105 CMR 541.000;

(b) Interference with the Department or the board of health in the performance of its duty;

(c) A criminal conviction of the licensee relating to the operation of the pasteurization plant; or

(d) Keeping or submitting any misleading or false records or documents required by 105 CMR 541.000.

(2) The Department or board of health shall issue a notice of intent to revoke, which shall be in writing and shall be served on the licensee or his authorized agent in accordance with 105 CMR 541.014.

(3) The notice of intent to revoke shall specify the reason(s) for which the license is to be revoked or the particular operation(s) terminated, that revocation or termination shall be imposed at the end of a specified reasonable time period set by the Department or the board of health following service of such notice, and the procedure for requesting a hearing.

(4) To obtain a hearing, the licensee shall make a written request for a hearing to the agency which issued the notice of intent to revoke. Such request shall be made within ten days after receipt of the notice of intent to revoke. If no request

for a hearing is made, the revocation or termination shall be imposed at the end of the time period specified in the notice.

(D) Refusal to Issue or Renew a License After Opportunity For A Hearing.

(1) The board of health may, after providing opportunity for a hearing, refuse to issue or renew a license for any of the reasons specified in 105 CMR 541.013(C)(1) or for the reason that the licensee or applicant has been found not to be responsible and suitable for licensure pursuant to 105 CMR 541.011(E)(2).

(2) The board of health shall issue a notice of intent to refuse to issue or renew the license, which shall be in writing and shall be served on the licensee or applicant or his authorized agent in accordance with 105 CMR 541.014.

(3) The notice of intent to refuse to issue or renew shall specify the reason(s) for which the license is not to be issued or renewed, and the procedure for requesting a hearing.

(4) To obtain a hearing, the licensee shall make a written request for a hearing to the board of health. Such request shall be made within ten days after receipt of the notice of intent to refuse to issue or renew the license. If no request for hearing is made, the license shall not be issued or renewed.

541.014: Service of Orders and Notices of Intent

(A) Orders for immediate suspension, when required to be served, and notices of intent to suspend, revoke, refuse to issue or refuse to renew a license shall be served on the licensee or his authorized agent as follows:

(1) By sending him a copy of the order or notice of intent by registered or certified mail, return receipt requested; or

(2) Personally, by any person authorized to serve civil process.

(B) If, and only if, the aforementioned methods of service are unsuccessful, service may be made:

(1) By any person authorized to serve civil process by leaving a copy of the order at his last and usual place of abode; or

(2) If, and only if, his last and usual place of abode is unknown, service may be made by posting the notice in a conspicuous place on or about the pasteurization plant premises.

541.015: Hearings

(A) Any person who receives an order or notice of intent issued pursuant to 105 CMR 541.013 and 541.014 may request a hearing before the agency that issued it.

(B) Upon receipt of a request for a hearing, a time and a place for such hearing shall be established, and the petitioner shall be informed.

(1) If the license has been suspended without a prior hearing, the hearing shall be commenced within 72 hours after the request has been made. If the 72-hour period expires on a weekend day or holiday, the hearing may be held on the next business day. If the parties agree to postpone the beginning of the hearing beyond

72 hours, the hearing may be postponed.
(2) If the agency has issued a notice of intent to revoke, has issued a notice of intent to suspend, has refused to issue a license, or has refused to renew a license, the hearing shall be commenced within a reasonable period of time.

(C) At the hearing the licensee or applicant shall be given an opportunity to be heard and to show why the order should be modified or withdrawn or why the proposed action should not be taken. Any oral testimony given at a hearing shall be recorded verbatim.

(D) After the hearing, the agency shall, within a reasonable period of time, make a final decision based upon the complete hearing record, and shall, once a decision is made, forthwith inform the petitioner in writing of the decision.

(E) Every notice, order, decision and other record prepared by the agency in connection with the hearing shall be entered as a matter of public record in the office of the agency.

(F) A copy of the transcript or tape recording shall be provided upon request and a reasonable fee may be charged for the cost of providing such copy.

(G) Any person aggrieved by the final decision of the board of health or Department may seek relief in a court of competent jurisdiction.

541.016: License or Operations: Reinstatement after Suspension

(A) Any licensee whose license or operation(s) has been suspended may make written application to the agency that suspended it for the reinstatement of his or her license or operation(s).

(B) When the suspension has been due to a violation of any of the bacteriological, coliform, or cooling temperature standards set forth in Section 7 of the PMO, an inspection shall be made within one week after the receipt of an application for reinstatement. This inspection may be conducted by the Department or the local board of health. If it is determined that the condition(s) responsible for the violation(s) has been corrected, the board of health or Department shall issue a temporary license, or allow the resumption of operation(s), or sale of suspended product(s). Samples shall then be taken by the board of health or the Department at a rate of not more than two per week on separate days within a three week period. The board of health or Department shall reinstate the license forthwith, but in any event, within seven calendar days after the establishment or operation is found to be in compliance with the appropriate standards set forth in Section 7 of the PMO and the DMO.

(C) Whenever the suspension has been due to a violation of a requirement other than bacteriological, coliform, drug residue test, or cooling temperature standards set forth in Section 7 of the PMO and the DMO, the application for reinstatement shall

indicate that the violation(s) has been corrected. Within one week of the receipt of such application, an inspection shall be made, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is in compliance with 105 CMR 541.000. These inspections may be conducted by the Division or the local board of health. The Department shall reinstate the license or allow the resumption of operation(s) forthwith, but in any event, within seven calendar days after the establishment or operation is found to be in compliance.

541.017: Embargo of Milk and Milk Products, and Grade A Condensed and Dry Milk Products and Grade A Condensed and Dry Whey

(A) Pursuant to M.G.L. c. 94, § 189A, the Commissioner or his agent or the board of health may detain or embargo any milk, milk product, Grade A condensed or dry milk products, or Grade A condensed or dry whey which it finds or has probable cause to believe is adulterated or misbranded, provided that said Commissioner or his agent follows the procedures set forth in M.G.L. c. 94, §§ 186 through 189A.

(B) The Commissioner or his agent or the board of health shall tag, label, or otherwise identify any milk or milk product, Grade A condensed or dry milk product, or Grade A condensed or dry whey subject to the embargo order. The tag or label shall state that the milk or milk product:

(1) Is believed to be adulterated or misbranded;
(2) Has been embargoed for ten days; and
(3) Cannot be removed, used, sold or disposed of without permission of the Commissioner or his agent or the board of health.

(C) The Commissioner or his agent or the board of health shall permit storage of milk and milk products, Grade A condensed and dry milk products and Grade condensed and dry whey under conditions specified in the embargo order, unless storage is not possible without risk to the public health, in which case immediate destruction of the embargoed products shall be ordered and accomplished.

(D) If the milk or milk product, Grade A condensed or dry milk product, or Grade A condensed or dry whey, subject to embargo, is found to be adulterated or misbranded, the Commissioner or his agent or the board of health shall take such steps as are necessary, pursuant to M.G.L. c. 94, § 189A, to effect the condemnation and disposal or reconditioning of the milk, milk product or Grade A condensed or dry whey.

(E) If the milk, milk product, or Grade A condensed or dry whey, subject to embargo, is found not to be adulterated or misbranded, it shall be released.

541.018: Sampling, Examination and Enforcement of Standards of Milk and Milk Products, Grade A Dry and Condensed Milk Products, and Grade A Dry and Condensed Whey

(A) Sampling.

(1) During any consecutive six months, the Department shall take from every

pasteurization plant shipping milk in interstate commerce after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing at least four samples each of raw milk for pasteurization, raw milk for ultra-pasteurization and raw milk for aseptic processing, collected in at least four separate months. In the case of pasteurization plants shipping milk products only in intrastate commerce, the Department need not take samples four times every six months, but rather shall take samples of such milk at a frequency determined by the Department.

(2) During any consecutive six months, the Department shall take from every pasteurization plant at least four samples each of pasteurized milk, flavored milk, flavored low fat milk, flavored skim milk, each fat level of low fat milk and each milk product defined in 105 CMR 541.000 which is produced at the pasteurization plant, except condensed, dry and aseptically processed products. Samples of milk products produced on less than a year-round basis shall be taken as frequently as is practical in each production period. In the case of pasteurization plants shipping milk products only in intrastate commerce, the Department need not take samples four times every six months, but rather shall take samples of such milk and milk products at a frequency determined by the Department.

(3) During each month that such products are manufactured, the Department shall take from every condensing and drying plant at least one sample of each Grade A condensed milk product, Grade A dry milk product, Grade A condensed whey and Grade A dry whey. Samples of the milk products and whey resulting from processing for drying shall be taken as often as the Department may deem necessary.

(4) If the production of Grade A dry milk products or Grade A dry whey is not on a year-round basis, at least five samples shall be taken by the Department within a continuous production period.

(5) Samples of milk and milk products shall be taken while in the possession of the pasteurization plant or distributor at any time prior to delivery to the retail store or consumer.

(6) Samples of milk and milk products may be taken from retail dairy stores, food service establishments, grocery stores and other places where milk and milk products are sold or distributed periodically by the Department at its discretion. Proprietors of such establishments shall furnish the Department, upon request, with the names of all distributors from whom milk or milk products are obtained.

(B) Testing.

(1) In the case of pasteurization plants shipping milk and milk products in interstate commerce, bacterial counts, drug residue tests, and cooling temperature checks, required by Section 7 of the PMO, shall be performed by the Department, and/or an officially designated laboratory, at least four times during any consecutive six months on commingled raw milk received for pasteurization at all pasteurization plants. In the case of pasteurization plants shipping milk products only in intrastate commerce, such residue tests need not be performed four times every six months, but rather shall be conducted by the Department and/or officially designated laboratory at a frequency determined by the

Department. When a sample of commingled raw milk for pasteurization is positive for drug residues, steps required by Appendix N of the PMO shall be followed.

(2) In the case of pasteurization plants shipping milk and milk products in interstate commerce, bacterial counts, drug residue tests, coliform determinations, phosphatase, and cooling temperature checks, required by Section 7 of the PMO, shall be performed by the Department, and/or an officially designated laboratory, at least four times during any consecutive six months on at least four samples of each of pasteurized milk, flavored milk, flavored low fat milk, flavored skim milk, each fat level of low fat milk and each milk product defined in 105 CMR 541.000 which is produced at the plant, except condensed, dry and aseptically processed products, provided, however, that milk products produced at such plants on less than a year-round basis shall be examined as frequently as is practical in each production period. In the case of pasteurization plants shipping milk products in intrastate commerce, bacterial counts, drug residue tests, coliform determinations, phosphatase, and cooling temperature checks shall be conducted by the Department and/or officially designated laboratory at a frequency determined by the Department.

(3) In the case of pasteurization plants shipping milk and milk products in interstate commerce, bacterial counts, drug tests, coliform determinations, phosphatase, and cooling temperature checks, required by Section 7 of the DMO, shall be performed on Grade A condensed and dry milk products and Grade A condensed and dry whey manufactured during each month that such products are manufactured. In the case of pasteurization plants manufacturing Grade A condensed and dry milk products and Grade A condensed and dry whey for shipment in intrastate commerce only, bacterial counts, drug residue tests, coliform determinations, phosphatase, and cooling temperature checks shall be conducted at a frequency determined by the Department.

(4) If the production of Grade A dry milk products or Grade A dry whey is not on a year-round basis, at least five samples shall be examined by the Department within a continuous production period.

(5) Samples taken from retail dairy stores, food service establishments, grocery stores and other places where milk and milk products are sold or distributed may be examined periodically by the Department and the results may be used to determine compliance with Sections 2, 4, and 10 of the PMO.

(6) Samples shall be analyzed at an official laboratory or at an officially designated laboratory. If the testing is performed by the Department at its official laboratory, it shall keep one copy of the results and send one copy of the results to the pasteurization plant. If the testing is performed by an officially designated laboratory, the laboratory shall send one copy of the results to the Department and one copy to the pasteurization plant. The plant shall keep and retain all results of all tests for a period of at least two years and shall make the results of all such tests available to any authorized representative of the Department.

(7) If the pasteurization plant conducts drug residue tests on raw milk it receives from producers, the plant shall send results of all positive drug residue tests to the Department.

(8) If the pasteurization plants conduct any other tests on its milk or milk

products, it shall keep and retain all results of all tests for a period of at least two years and make the results available to any authorized representative of the Department.

(9) All sampling and laboratory examinations shall be in substantial compliance with the procedures and standards set forth in the latest edition of *Standard Methods for the Examination of Dairy Products* of the American Public Health Association, and the latest edition of *Official Methods of Analysis of the Association of Official Analytical Chemists*.

(10) Such procedures and standards, including the certification of sample collectors and the examination of samples shall be evaluated in accordance with the *Evaluation of Milk Laboratories, 1978 Recommendations of the United States Public Health Service/Food and Drug Administration*.

(11) If sampled, aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with Chapter XXI of the latest edition of the *Bacteriological Analytical Manual* of the U.S. Food and Drug Administration.

(12) If the Department has reasonable cause to believe that milk and milk products, Grade A condensed and dry milk products, or Grade A condensed or dry whey produced at a pasteurization plant may contain adulterants due to the activities of the pasteurization plant, it may require additional testing to be conducted, which testing shall be conducted by the pasteurization plant at an officially designated laboratory, as the Department requires, provided, however, that the Department shall be responsible for conducting the tests in instances where there is no reasonable cause to believe that the suspected adulterant(s) was due to the activities of the pasteurization plant.

(13) Results of all tests conducted by the plant, as required by 105 CMR 541.018(B)(1) through (13), shall be kept on file for two years at the pasteurization plant and must be made readily available upon request to any authorized representative of the Department.

(C) Enforcement.

(1) Whenever two of the last four consecutive bacterial counts (except those for aseptically processed milk and milk products), coliform determinations or cooling temperature checks, taken on separate days, exceed the limit of the standard specified in Section 7 of the PMO or the DMO for milk and/or milk products, Grade A condensed and/or dry milk products, or Grade A condensed and/or dry whey, the Department shall send a written notice thereof to the licensee. This notice shall also inform him of the provisions of 105 CMR 541.018(C)(2), and shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of three days. (See Appendix E of the PMO, Examples of three-out-of-five Compliance Enforcement Procedures.)

(2) Whenever the standard specified in Section 7 of the PMO or the DMO has been violated by three of the last five consecutive bacterial counts (except those for aseptically processed milk and milk products), coliform determinations or cooling temperature checks, taken on separate days, the Department shall

immediately suspend the license of one or more particular operations, or the sale of one or more particular products, without prior hearing, in accordance with 105 CMR 541.013(A), and may also institute court action.

(3) Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, said cause shall be eliminated through appropriate remedial action and any milk or milk product, Grade A condensed or dry milk product, or Grade A condensed or dry whey involved shall not be offered for sale.

(4) Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N of the PMO. Any milk or milk product, Grade A condensed or dry milk product, or Grade A condensed or dry whey involved shall not be offered for sale.

(5) Whenever any container of aseptically processed milk or milk product is found to be unsterile due to under processing, the Department or the board of health shall consider the pasteurization plant where it was produced to be an imminent health hazard and shall immediately suspend the license of the plant or one or more of its particular operations. No aseptically processed milk or milk product from such plant shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. Any product from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department or the board of health.

(D) Laboratory and Analyst Certification.

(1) Pursuant to M.G.L. c. 111, § 184A, the Department shall issue certificates of approval for laboratories, and individual analysts within such laboratories, to perform tests upon milk and milk products and Grade A condensed or dry milk products, and Grade A condensed or dry whey. Such certification shall be accomplished in accordance with the standards and procedures described in *Evaluation of Milk Laboratories, 1985 Recommendations of the United States Public Health Service/Food and Drug Administration*, as from time to time amended.

(2) If the Department determines that the public interest requires the revocation of any such certificate, the laboratory and/or analyst shall be given 30 days' notice and the opportunity for a hearing by the Department before the certificate is revoked.

541.019: Examination of Milk and Milk Products and Grade A Dry Milk Products for Vitamin and Mineral Fortification

(A) Sampling. Each pasteurization plant adding vitamins or minerals to milk or milk products and Grade A dry milk products shall have at least two assays made *per annum*, at approximately six month intervals. Samples shall be taken, in accordance with 21 CFR 101.9, and sealed for shipment by authorized representatives of the Department. Once the samples have been taken and sealed, it shall be the responsibility of the pasteurization plant to provide for the submission

and shipment of samples and payment for testing to an approved laboratory.

(B) Approved Methods for Laboratory Testing Samples for assay shall be analyzed at a laboratory approved by the Department using methods prescribed in the latest edition of *Official Methods of Analysis of the Association of Official Analytical Chemists*, or by such modified methods as may be approved by the Department. Results of all assays conducted on milk and milk products and Grade A dry milk products for the purpose of meeting the requirements set forth in 105 CMR 541.019(A) at approximately six month intervals shall be forwarded to the Division by said laboratory within ten days of obtaining test results. In addition, results of all assays conducted to determine if deficiencies in fortification procedures have been corrected shall also be forwarded to the Division by said laboratory within ten days of obtaining test results.

(C) Laboratory Approval. Any person who desires to have his laboratory approved by the Department for determining the vitamin D level in milk samples shall first satisfy the Department that tests to be made in such laboratory will be conducted by persons qualified by training and/or experience to make such tests accurately and will be conducted in accordance with methods prescribed by the latest edition of *Official Methods of Analysis of the Association of Official Analytical Chemists* or by such modified methods as may be approved by the Department. Laboratories operated and maintained by those persons who thus satisfy the Department shall be designated "Approved Laboratories".

(D) Enforcement.

(1) Whenever vitamin or mineral assay results indicate that fortification levels are not within the fortification levels required by 21 CFR 131, as may from time to time be amended, and/or 21 CFR 101.9, as may from time to time be amended, the pasteurization plant shall investigate its fortification procedures to determine the cause, and the cause shall be corrected. Additional samples of milk or milk products shall be taken and sealed by a representative of the Department and shall be resubmitted by the plant to the approved laboratory for analysis within 30 days of notification of the original assay results. It shall be the responsibility of the pasteurization plant to provide for the submission and shipment of samples and payment for testing to an approved laboratory. Results of these tests shall also be sent promptly to the Department.

(2) Whenever the pasteurization plant fails to comply with requirements set forth in 105 CMR 541.004(D) and/or 541.019(D), the Department may initiate proceedings to suspend or revoke the license.

541.020: Personnel

(A) Employee Health. Pasteurization plant management shall take all reasonable measures and precautions to ensure that any person who appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of milk, milk products, Grade A condensed or dry whey, product-contact surfaces, or packaging

materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(B) Employee Cleanliness. All persons working in direct contact with milk, milk products, product-contact surfaces, or packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of product. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of milk, milk products, product-contact surfaces, or packaging materials.

(2) Maintaining a high degree of personal cleanliness and conforming to good hygienic practices during all working periods.

(3) Washing hands and the exposed portions of their arms with soap or detergent and warm water (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after smoking, eating, or using the toilet, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into milk, equipment, or containers. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against contamination.

(5) Maintaining gloves, if they are used, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Confining the following to areas other than where milk and milk products may be exposed, stored, or processed or where equipment is washed: eating food, chewing gum, drinking beverages, or using tobacco.

(8) Taking any other necessary precautions to protect against contamination of product, product-contact surfaces, or product-packaging materials with microorganism or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

541.021: Procedure When Infection is Suspected

(A) Pursuant to M.G.L. c. 94, § 305B, when the board of health or Department has reasonable cause to suspect disease transmission by an employee of a pasteurization plant it shall:

(1) Secure a morbidity history of the suspected employee, and make any other investigation as warranted by the circumstances; and

(2) Take any other action required by 105 CMR 300.000: *Reportable Diseases and Isolation and Quarantine Requirements*.

(B) The board of health shall immediately notify the Director of the Division of Food and Drugs of suspected disease transmission, and shall keep the Director

informed until any investigation has been completed.

(C) The Commissioner or his designee, on his own initiative or at the request of a local board of health, may require any employee whose duties actually involve the handling of milk, milk products, Grade A condensed or dry whey, or product-contact surfaces to submit to a medical examination, which may include the taking of samples of body fluids, secretions or excretions, whenever said Commissioner or his designee has reason to believe that such examination is necessary for the protection of the public health. The examination shall be without charge to the person examined and at the expense of the Department or of the board of health requesting it.

(D) In addition, the board of health or Department may require either or both of the following measures:

(1) Restriction of a suspected employee's services to areas of the pasteurization plant where there will be no danger of the suspected employee contaminating milk or milk products, Grade A condensed or dry milk products, or Grade A condensed or dry whey, or product-contact surfaces with pathogenic organisms or transmitting disease to other persons;

(2) The immediate closing of the pasteurization plant concerned until, in the opinion of the board of health or the Department, no further danger of disease outbreak exists.

(E) The licensee, person in charge or manager of any pasteurization plant, when he or she knows, or has reason to believe, that any employee has contracted any disease transmissible through milk or milk products, Grade A condensed or dry milk products, or Grade A condensed or dry whey, or has become a carrier of such a disease, shall immediately notify the Division.

(F) Any employee who fails to cooperate with any medical or laboratory examination ordered by the Commissioner of Public Health or his or her designee or the local board of health shall immediately be excluded from the performance of duties involving the handling of milk, milk products, or Grade A condensed or dry whey, or product-contact surfaces.

(G) The following diseases are known to be transmissible through milk or milk products, Grade A condensed and dry milk products, and Grade A condensed and dry whey:

(1) Listeriosis;
(2) Yersiniosis;
(3) Campylobacteriosis;
(4) Salmonellosis;
(5) Brucellosis;
(6) Q-fever;
(7) Tuberculosis;
(8) Streptoccal Infection; and
(9) Staphylococcal Intoxication

This list is not intended to be exclusive, and the Department may, in a given case, determine that a risk of transmission exists from a disease not specified above.

541.022: Milk and Milk Products, Grade A Condensed and Dry Milk Products,and Grade A Condensed and Dry Whey Which May Be Sold

Six Months from the effective date of 105 CMR 541.000, only Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products and Grade A condensed and dry whey shall be sold in Massachusetts: except that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by the Department or the board of health; in which case, such milk and milk products shall be labeled "ungraded".

541.023: Milk and Milk Products, Grade A Condensed and Dry Milk Products, and Grade A Condensed and Dry Whey Which May Be Sold From Outside the Commonwealth

All Grade A milk and milk products, Grade A condensed milk products, and Grade A condensed and dry whey from pasteurization plant(s) outside the Commonwealth may be sold or served within the Commonwealth if such milk and milk products, Grade A condensed milk products, and Grade A condensed or dry whey, comply with the following provisions:

(a) Such pasteurization plant has met the requirements of M.G.L. c. 94, § 16K.

(b) Upon arrival at the pasteurization plant, raw milk and/or raw milk products for pasteurization shall comply with the bacteriological, chemical and temperature standards set forth in Section 7 of the PMO.

(c) After entry into the Commonwealth and while still under the control of the milk pasteurization plant, pasteurized and ultra-pasteurized milk and milk products, Grade A condensed or dry milk products, and Grade A condensed or dry whey shall comply with the bacteriological, chemical, and temperature requirements of Section 7 of the PMO and the DMO. Pasteurized milk and milk products, Grade A condensed and dry milk products, and Grade A condensed and dry whey received from sources outside the Commonwealth shall be sampled as the Department requires.

(d) The milk, milk products, Grade A condensed and dry milk products, or Grade A condensed and dry whey shall be produced and processed under regulations substantially equivalent to those of 105 CMR 541.000.

(e) The milk and milk products, Grade A condensed and dry milk products, or Grade A condensed and dry whey shall be under routine official supervision.

(f) The milk and milk product, Grade A condensed and dry milk products, and Grade A condensed and dry whey, and pasteurization plants have been awarded (by the State Milk Sanitation Rating Officers certified by the U.S. Food and Drug Administration) milk sanitation compliance and enforcement ratings of 90% or higher; and

(g) All ratings are made on the basis of procedures outlined in *Methods of Making Sanitation Ratings of Milk Supplies, 1987 Recommendations of the United States Public Health Service/Food and Drug Administration*, as from

time to time amended.

541.024: Review of Plans for Construction or Remodeling of Pasteurization Plants or Change in, or Expansion of, Operations at a Pasteurization Plant

(A) When a pasteurization plant is to be constructed or extensively remodeled, or an existing structure is to be converted for use as a pasteurization plant, or an operation is to be changed or added, properly prepared plans and specifications for such construction, remodeling or alteration, showing layout, arrangement and construction materials of work areas, and the location, size and type of fixed equipment and facilities, shall be submitted to the Division for approval before such work is begun. No work shall be started until approval is granted.

(B) Whenever plans and specifications have been submitted to the Division pursuant to 105 CMR 541.024(A), the Division shall inspect the pasteurization plant prior to the start of operation(s) to ascertain compliance with the approved plans and specifications and with the requirements of 105 CMR 541.000.

541.025: Criminal Penalties

Any person who violates any provision of 105 CMR 541.000 or who fails to comply with any order issued pursuant to the provisions of 105 CMR 541.000 shall, upon conviction, be fined not more than $100 for the first offense, and not less than $50 nor more than $300 for a subsequent offense, unless a different penalty is set by statute. Each day's failure to comply with an order shall constitute a separate offense.

541.026: Severability

If any provision of 105 CMR 541.000 shall be declared invalid for any reason whatsoever, that decision shall not affect any other portion of 105 CMR 541.000, which shall remain in full force and effect; and, to this end the provisions of 105 CMR 541.000 are hereby declared severable.

REGULATORY AUTHORITY

M.G.L. c. 94, §§ 12, 48A, 192, 305B; c. 111, §§ 5 and 184A.

NON-TEXT PAGE