

105 CMR 500.000: GOOD MANUFACTURING PRACTICES FOR FOOD

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500.001: Purpose

The purpose of 105 CMR 500.000 is to establish minimum standards for those persons engaged in the business of preparing, processing, or distributing food for sale in Massachusetts. 105 CMR 500.000 shall be liberally construed and applied to promote the underlying purpose of protecting the public health.

500.002: Scope

- (A) 105 CMR 500.000 applies to every person who prepares, manufactures, packs, repacks, cans, bottles, keeps, exposes, stores, handles, sells, transports, or distributes food in Massachusetts, whether or not for profit. It applies to wholesale food processing operations within food establishments licensed by local boards of health, but does not apply to activities regulated by 105 CMR 590.000: *State Sanitary Code, Chapter X - Minimum Sanitation Standards for Food Establishments*.
- (B) The requirements of 105 CMR 500.000 include but are not limited to every person who:
 - (1) Operates a residential kitchen to prepare or process food for wholesale sale;
 - (2) Operates as a retail seafood dealer, a wholesale seafood dealer, or a wholesale seafood truck;
 - (3) Cooks, smokes, or otherwise processes seafood, or combines seafood with non-seafood ingredient(s), for sale at wholesale;
 - (4) Engages in the business of slaughtering livestock or poultry or processing meat or poultry for sale at wholesale; engages in the business of custom slaughtering of livestock or poultry; or engages in the business of custom processing of meat or poultry;
 - (5) Operates a milk pasteurization plant;
 - (6) Manufactures butter or cheese for sale at wholesale;
 - (7) Manufactures within Massachusetts frozen desserts or frozen dessert mix, or manufactures frozen desserts or frozen dessert mix outside Massachusetts and sells such products in Massachusetts;
 - (8) Manufactures or bottles within Massachusetts carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption; or engages in such business outside Massachusetts and sells such products in Massachusetts;
 - (9) Manufactures juice or apple cider for sale at wholesale;
 - (10) Operates a cold storage or refrigerating warehouse, or a food warehouse;
 - (11) Transports or causes to be transported any bakery product into Massachusetts for the purpose of sale; or
 - (12) Manufactures, processes, or distributes any food not specifically named in 105 CMR 500.002(B)(1) through (11), including dietary supplements, for sale at wholesale.

500.003: Definitions

For the purposes of 105 CMR 500.000, the following terms shall have the following meanings.

Administrative Penalty means a civil monetary fine that the Department may assess pursuant to statutory authority.

Adulterated Food means the definition in M.G.L. c. 94, § 186.

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Air Temperature means that steady temperature determined by allowing the probe of an accurate thermometer or other appropriate means of temperature measurement to equilibrate to the temperature of a representative area of the air environment in question.

Allergen: *see Major Food Allergen*.

Approved Laboratory means a laboratory approved by the Department as a milk laboratory as provided in 105 CMR 500.062(C).

Approved Water-testing Laboratory means a laboratory certified by the Massachusetts Department of Environmental Protection (DEP) or certified by the U.S. Environmental Protection Agency (EPA) or approved by another state or jurisdiction to perform drinking water analyses in accordance with standard water quality testing methods.

Bait means any food, used for the attraction and harvest of seafood, which may or may not be of sufficient sanitary quality for human consumption.

Board of Health means the appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within Massachusetts having the usual powers and duties of the board of health or health department of a city or town.

Bottled Water means Bottled Drinking Water as defined in 21 CFR § 129.3(b).

Bulk Water means water intended for potable uses, which is transported via tanker truck or an equivalent means from one area to another for the purpose of treatment, processing, packaging, and/or human consumption.

Carbonated Non-alcoholic Beverage means a carbonated beverage of any flavor containing no alcohol and includes but is not limited to soda water, sparkling water made with added carbon dioxide, seltzer water, carbonated water, and tonic water.

CFR means the Code of Federal Regulations.

Commissioner means, except where otherwise specified, the Commissioner of the Department of Public Health.

Critical Violation or Critical Deficiency means any violation of 105 CMR 500.000 by a facility or any other occurrence or condition in a facility that has the potential to pose a threat to public health and shall include but not be limited to the following:

- (1) Use or presence of food or a food ingredient from an unapproved or unknown source;
- (2) Use or presence of food or a food ingredient that is or may be adulterated, misbranded, contaminated, or otherwise unfit for human consumption;
- (3) Any activity that misrepresents the origin, source, date, and/or disposition of any food product intended for human consumption;
- (4) Potentially hazardous food that is held at a temperature which is
 - (a) Greater than 45° F (7.2° C) in the case of milk or milk products or raw molluscan shellfish;
 - (b) Greater than 41° F (5° C) in the case of cold food other than milk or milk products; or
 - (c) Less than 140° F (60° C) in the case of hot food;
- (5) Inability to maintain appropriate product temperature;
- (6) A person infected with a communicable disease that can be transmitted by food is working as a food handler;
- (7) A worker in the facility is not practicing strict standards of cleanliness and personal hygiene (as an example only, bare-hand contact with ready-to-eat food), which may result in the potential transmission of illness through food;
- (8) Equipment, utensils, or food contact surfaces are not cleaned and sanitized effectively and may contaminate food during preparation, processing, storage, transportation, or service;

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- (9) Sewage or liquid waste is not disposed of in an approved and sanitary manner, or the sewage or liquid waste contaminates or may contaminate any food, areas used to store or prepare food, or any areas frequented by customers or employees;
- (10) Toilets and facilities for washing hands are not provided, or are not properly installed, designed, equipped, accessible, or convenient;
- (11) The supply of water is not from an approved source or is not under pressure and the facility does not have approval from the Department to use single service articles and/or bottled water from an approved source on a temporary basis;
- (12) A defect exists in the system supplying potable water that may result in the contamination of the water;
- (13) There is evidence of the presence of insects, rodents, vermin, or other animals (except service animals) on the premises;
- (14) Toxic items are improperly labeled, stored, or used;
- (15) There is a power outage that poses an imminent danger to the public health;
- (16) Drug residues have been found in a second sample of raw milk or a raw milk product and the manufacturer has failed to destroy the violative products as required by 105 CMR 500.082(A)(1)(c); or
- (17) The facility does not have a Hazard Analysis Critical Control Point (HACCP) plan when such a plan is required by section 105 CMR 500.016(A)(2), 500.020(F) or (G), or 500.021(A).

The failure to include other violations, occurrences, or conditions in 105 CMR 500.003: Critical Violation or Critical Deficiency shall not be construed as a determination that such other violations, occurrences, or conditions are not, or may not be, considered a critical violation.

Custom Processing means the preparing or processing of meat or poultry, the product of which is not to be sold or given away and is only for the personal use of the owner of the animal, members of his or her household, and his or her nonpaying guests or employees.

Custom Slaughter means the slaughter of livestock or poultry which is not to be sold or given away and is only for the personal use of the owner of the animal, members of his or her household, and his or her nonpaying guests or employees.

Denature means to use a material to render an article unfit for human consumption.

DEP means the Massachusetts Department of Environmental Protection.

Department means the Massachusetts Department of Public Health.

Dietary Supplement means a product defined in 21 U.S.C. § 321(ff).

Division of Marine Fisheries means the Division of Marine Fisheries of the Massachusetts Department of Fish and Game.

Edible means intended for use as human food.

Embargo means action taken pursuant to M.G.L. c. 94, § 189A and 105 CMR 500.209.

Employee means the licensee or permit holder, individual having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or any other person working in the facility, excluding persons whose tasks do not involve the operation of the facility, such as an outside plumbing contractor.

EPA means the U.S. Environmental Protection Agency.

Equipment means items used in the storage, preparation, display, or transportation of food such as stoves, ovens, hoods, slicers, grinders, mixers, scales, cutting blocks, tables, food shelving, reach-in refrigerators and freezers, sinks, ice makers, dishwashers, steam tables, utensils, and similar items used in the operation of a food processing operation.

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Facility means the premises or parts thereof, and delivery or other vehicles used for or in connection with the slaughtering, preparing, processing, manufacturing, packaging, repackaging, canning, bottling, keeping, exposing, storing, handling, distributing, transporting, or holding of food. It does not include a food establishment as defined in 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments*.

FDA means the U.S. Food and Drug Administration.

Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin, and the roe of such animals) other than birds or mammals, and all molluscan and non-molluscan shellfish, when such animal is intended for human consumption.

Fishery Product means any human food product in which fish is a characterizing ingredient.

Food means all articles whether simple, mixed, or compound, used for food or drink, confectionery or condiment, by man or animal. Food includes dietary supplements as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(ff).

Freezing means the removal of latent heat from the product, so that it enters a solid state.

Frozen means the temperature of the product (except frozen desserts) has reached 0°F (-18°C) or lower at the thermal center, after thermal stabilization.

Frozen Dessert includes but is not limited to ice cream, French ice cream, low fat ice cream, nonfat ice cream, frozen custard, gelato, ice milk, sherbet, sorbet, frozen yogurt, water ice, quiescently frozen confection, quiescently frozen dairy confection, frozen dietary dairy dessert, any soy-based frozen dessert, any rice-based frozen dessert, and any other similarly constituted product marketed as a frozen dessert. Frozen Dessert includes products made from the milk of cows, sheep, goats, and other dairy animals.

Frozen Dessert Mix means any unfrozen mixture to be used in the manufacture of frozen desserts or milk shakes.

Frozen Food means articles in package form used for food or drink for man or other animals, which have been preserved by freezing.

FSIS means the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Grade A means 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 Department's administrative guidelines based on the Grade "A" Pasteurized Milk Ordinance (PMO).

Harvest means to catch, dig, take or attempt to catch, dig or take any fish, shellfish or bait.

Hermetically Sealed Container means a container designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

Imminent Danger to the Public Health means any violation of 105 CMR 500.000, or any other occurrence or condition, that has the potential to pose a serious threat to public health and shall include, but not be limited to:

- (1) A loss of water supply that may result in adulteration of food;
- (2) The use of an unapproved source of water within the facility;
- (3) A failed sewer system or a sewage backup into the facility;
- (4) A power outage that may result in adulteration of food;
- (5) Information that indicates that food may have been intentionally adulterated;
- (6) The facility has been subject to one or more of the following: flood, fire, chemical exposure, natural disaster, and/or other catastrophic event;

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- (7) An employee is found to be infected with a communicable disease as described in 105 CMR 500.008;
- (8) A food-borne illness outbreak that appears to be associated with the facility;
- (9) Severe unsanitary conditions that threaten to contaminate the facility, a part of the facility, or a particular product;
- (10) Failure to comply with an order to correct a critical deficiency immediately;
- (11) Failure to submit an approved correction plan for a critical deficiency in a timely manner;
- (12) Failure to comply with an approved correction plan for a critical deficiency in a timely manner; or
- (13) Failure to carry out a product recall as specified in 105 CMR 500.005(K).

The failure to include other violations, occurrences, or conditions in Imminent Danger to the Public Health shall not be construed as a determination that such other violations, occurrences, or conditions are not, or may not be, considered an imminent danger to the public health.

Inedible means adulterated or not intended for use as human food.

Inspector means an agent of the Commissioner of the Massachusetts Department of Public Health, as defined in M.G.L. c. 111, § 9.

Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

Landing means that point in time when seafood has been brought on-shore after harvesting.

Law means any applicable federal, state, or local statutes, ordinances, and regulations.

License means any license or permit issued by the Department or by a board of health pursuant to 105 CMR 500.000 and applicable statutes. License does not include a permit issued jointly by the Department and the Division of Marine Fisheries.

Licensee means any person who holds a license or permit issued by the Department or by a board of health pursuant to 105 CMR 500.000 and applicable statutes. Licensee does not include the holder of a permit issued jointly by the Department and the Division of Marine Fisheries.

Livestock means any animal raised commercially or privately, excluding poultry, which can or may be used in and for the preparation of meat or meat food products. In 105 CMR 500.000, livestock includes so-called non-amenable animals raised for sale as food, including but not limited to buffalo, rabbits, frogs, and turtles.

Long Shelf-life Food means a food product having an estimated shelf life of 90 days or more, including foods preserved by dehydration or packaged in a hermetically sealed container, but excluding frozen foods.

Major Food Allergen means a major food allergen as defined by 21 U.S.C. § 321(qq).

Master Digger means an individual holding a permit for the digging or taking of shellfish from an area determined under M.G.L. c. 130, § 74 to be contaminated.

Meat, except as used in 105 CMR 500.020 through 500.021, means the edible portion of livestock or wild-caught animals after slaughter.

Meat Food Product means any article used as human food which is made wholly or in part from any meat or other portion of the carcass of any livestock, except those exempted from definition as a meat food product pursuant to 9 CFR Part 317.

Milk means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats, sheep, or other dairy animals.

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Milk-based means a product or ingredient derived from milk or a component of milk.

Minimal Treatment means treatment of water for disinfection limited to the use of filters (paper, activated carbon, and/or particulate), ozonation, and/or the use of ultraviolet light. Any other treatment activity, including but not limited to ion exchange and reverse osmosis, is considered more than minimal treatment.

Misbranded Food means the definition in M.G.L. c. 94, § 187.

Molluscan Shellfish means all species of:

- (1) Oysters, clams and mussels, whether:
 - (a) Shucked or in the shell;
 - (b) Raw, including post harvest processed;
 - (c) Frozen or unfrozen; or
 - (d) Whole or in part; and
- (2) Scallops in any form, except when the final product form is the adductor muscle only.

Noncompliance, Failure to Comply, and Violation each mean any act or failure to act that constitutes or results in one or more of the following:

- (1) Engaging in any operation subject to regulation by 105 CMR 500.000 or applicable statute, without a license, permit, or approval, whenever engaging in such an operation requires a license, permit, or approval.
- (2) Engaging in any activity prohibited by, or not in compliance with, 105 CMR 500.000 or other applicable statute or regulation, or prohibited by or not in compliance with any order, license, permit, approval, certification, guideline, policy, or protocol issued by the Department pursuant to 105 CMR 500.000 or applicable statute.
- (3) Failing to do, or failing to do in a timely manner, anything required by 105 CMR 500.000 or other applicable statute or regulation, or required by any order, license, permit, approval, certification, guideline, policy, or protocol issued by the Department pursuant to 105 CMR 500.000 or applicable statute.

Non-molluscan Shellfish means any type of shellfish not included in the National Shellfish Sanitation Program. Examples include but are not limited to crustaceans, conch, whelk, snails, periwinkles and shrimp.

Open Date means a recommended last date of retail sale of a food product which provides for a reasonable subsequent period of home shelf life. An open date on a food package is preceded by terminology such as "sell by," "best by," "use by," or similar words.

Operations Water means water that is delivered under pressure to a facility for container washing, hand washing, plant and equipment cleanup, and for other sanitary purposes.

Pasteurization Plant means a facility for the pasteurization of milk.

Perishable Food means a food product having an estimated shelf life of 60 days or less.

Permit means a permit issued jointly by the Department and the Division of Marine Fisheries to a wholesale or retail seafood dealer or to a wholesale truck, pursuant to 105 CMR 500.020 and M.G.L. c. 130, § 80.

Permit Holder means a person who holds a permit issued jointly by the Department and the Division of Marine Fisheries as a wholesale or retail seafood dealer or as a wholesale truck, pursuant to 105 CMR 500.020 and M.G.L. c. 130, § 80.

Permit Number means the number assigned to a permit holder by the Division of Marine Fisheries.

Person means any individual, partnership, corporation, association, or other legal entity.

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Person in Charge means the individual present in the facility who has actual or apparent authority to supervise the activities of the facility and the employees at the time of the inspection.

Potentially Hazardous Food (PHF) means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

- (1) Included are any foods of animal origin, either raw or heat-treated, and any foods of plant origin, which have been heat-treated, and raw seed sprouts.
- (2) Excluded are the following:
 - (a) Air dried hard-boiled eggs with shells intact;
 - (b) Foods with a water activity (aw) value of 0.85 or less;
 - (c) Foods with a hydrogen ion concentration (pH) level of 4.6 or below;
 - (d) Foods in unopened hermetically sealed containers, which have been commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; and
 - (e) Foods for which laboratory evidence acceptable to the Department demonstrates that rapid and progressive growth of infectious and toxigenic microorganisms or the slower growth of *C. botulinum* cannot occur.

Poultry means any bird, whether live or dead, intended for use as food.

Poultry Food Product means any product capable of use as human food which is made wholly or in part from any poultry carcass or part thereof, except those exempted from definition as a poultry product pursuant to 9 CFR § 381.15.

Prepackaged means packaged prior to being displayed or offered for sale at retail or retail self-service.

Production Day means a period of 24 consecutive hours.

Program means the Food Protection Program of the Massachusetts Department of Public Health.

Public Water System means a system for the provision to the public of water for human consumption, as defined by 42 U.S.C. § 300f, the Safe Drinking Water Act, in compliance with standards of the Massachusetts DEP or comparable standards of the state or foreign country where the public water system is located.

Reduced Oxygen Packaging means the removal or partial removal of oxygen from a package, with or without replacing it with a gas mixture, to control food spoilage. Reduced Oxygen Packaging (ROP) includes controlled atmospheric packaging (CAP), modified atmospheric packaging (MAP), straight vacuum packaging (VP), sous vide and cook-chill.

Refrigeration means mechanical lowering of the temperature of food to, at a maximum, 41°F (5°C), or to a temperature required by other applicable law, regulation, or ordinance.

Regulatory Agency means the Department of Public Health (Food Protection Program) and/or the board of health, as applicable.

Remodel means to make a material change to the facility.

Residential Kitchen means a kitchen in a private home that processes food for sale at wholesale.

Retail means sale to the ultimate consumer.

Retail Seafood Dealer means a person who sells raw, fresh, or frozen seafood directly to the consumer.

Ritual Slaughter means slaughter in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument.

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Seafood means all fish and/or fishery products.

Sell means to sell, offer or expose for sale, barter, trade, deliver, give away, possess with intent to sell, or dispose of in any other commercial manner.

Semi-perishable Food means a food product having an estimated shelf life greater than 60 days but less than 90 days.

Shelf Life means a period of time after the date of packaging during which a food product has no significant risk of spoilage, loss of nutritional value, or loss of palatability, given compliance with recommended conditions of storage and handling as disclosed on the label of such product.

Shellfish means molluscan shellfish, whether alive or shucked.

Shellfish Transaction Card means a card issued by the Division of Marine Fisheries to a permitted shellfish harvester to be used in connection with each sale of shellfish by the harvester to a wholesale dealer.

Shellstock means live shellfish in the shell.

Shucked Shellfish means shellfish that have one or both shells removed.

Slaughter means the act of killing livestock or poultry for human food.

Soft-serve Machine means any equipment used in the conversion of milk-based frozen dessert mix into frozen desserts for sale at retail.

Source Approval means approval by the Department, with or without conditions, of a water source, of substantial modification of a water source, of treatment of source water, and/or of substantial modification of treatment of source water, for use in a facility producing bottled water or carbonated non-alcoholic beverages, or for use in water vending, or for sale as bulk water for bottling. *See 105 CMR 500.091.*

Substantial Modification of a water source or treatment of source water means any deviation from approved plans or specifications affecting capacity, hydraulic conditions, operating units, the functioning of water treatment processes or systems, the source, or the quality of water delivered to a facility that manufactures, collects, and bottles water or carbonated non-alcoholic beverages.

Transaction Slip means a serialized multi-copy form approved by the Department used by wholesale dealers to record original shellfish purchase transactions by mechanical imprinting (or by another means approved by the Department and the Division of Marine Fisheries) from the Shellfish Transaction Card.

USDA means the United States Department of Agriculture.

Water Source means any ground or surface water body and the site from which water is withdrawn.

Wholesale means sale to other than the ultimate consumer.

Wholesale Seafood Dealer means a person who in a facility does any or all of the following: handling, storing, preparing, heading, eviscerating, shucking, freezing, manufacturing, preserving, packing, labeling, or shipping raw fish and/or shellfish, whether frozen or unfrozen, for sale at wholesale.

Wild Game means an animal that is used for food, that is not domesticated and that is harvested in the wild, including but not limited to wild deer, elk, moose, rabbits, squirrels, and raccoons, and wild birds such as ducks, pheasants, quail, and turkeys.

500.004: Federal Regulations Applicable to All Licensees and Permit Holders

All licensees and permit holders shall comply with all federal regulations that are applicable to the type of food processing that they conduct. Such regulations include but are not necessarily limited to the following.

(A) Food Processing.

- (1) 21 CFR Part 106: *Infant Formula Quality Control Procedures*;
- (2) 21 CFR Part 110.00: *Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food*;
- (3) 21 CFR Part 111: *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*;
- (4) 21 CFR Part 113.00: *Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers*, and 21 CFR § 108.35: *Thermal Processing of Low-acid Foods Packaged in Hermetically Sealed Containers*;
- (5) 21 CFR Part 114.00: *Acidified Foods*, and 21 CFR § 108.25: *Acidified Foods*;
- (6) 21 CFR 173.315: *Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables*;
- (7) Enforcement of 105 CMR 500.005(A)(1) through (6). When the Department receives a complaint alleging a violation of any provision of 105 CMR 500.004(A)(1) through (6) with respect to a business that participates in interstate commerce, the Department may refer the complainant to the U.S. Food and Drug Administration or take other appropriate action.

(B) Food Labeling.

- (1) 9 CFR Part 317: *Labeling, Marking Devices, and Containers*;
- (2) 9 CFR Part 381: *Poultry Products Inspection Regulations*:
 - (a) Subpart N: *Labeling and Containers*;
 - (b) Subpart Y: *Nutrition Labeling*.
- (3) 21 CFR Part 1: *General Enforcement Regulations*:
 - (a) Subpart A: *General Provisions*;
 - (b) Subpart B: *General Labeling Requirements*.
- (4) 21 CFR Part 100: *General*:
 - (a) Subpart F: *Misbranding for Reasons Other than Labeling*;
 - (b) Subpart G: *Specific Administrative Rulings and Decisions*.
- (5) 21 CFR Part 101: *Food Labeling*;
- (6) 21 CFR Part 102: *Common or Usual Name for Nonstandardized Foods*;
- (7) 21 CFR Part 104: *Nutritional Quality Guidelines for Foods*;
- (8) 21 CFR Part 105: *Foods for Special Dietary Use*;
- (9) 21 CFR Part 107: *Infant Formula*;
- (10) Enforcement of 105 CMR 500.004(B)(1) through (9). When the Department receives a complaint alleging a violation of any provision of 105 CMR 500.004(B)(1) through (9) with respect to a business that participates in interstate commerce, the Department may refer the complainant to the U.S. Department of Agriculture or the U.S. Food and Drug Administration, or take other appropriate action.

(C) Standards of Identity.

- (1) 21 CFR Part 130: *Food Standards: General*;
- (2) 21 CFR Part 131: *Milk and Cream*;
- (3) 21 CFR Part 133: *Cheeses and Related Cheese Products*;
- (4) 21 CFR Part 135: *Frozen Desserts*;
- (5) 21 CFR Part 136: *Bakery Products*;
- (6) 21 CFR Part 137: *Cereal Flours and Related Products*;
- (7) 21 CFR Part 139: *Macaroni and Noodle Products*;
- (8) 21 CFR Part 145: *Canned Fruits*;
- (9) 21 CFR Part 146: *Canned Fruit Juices*;
- (10) 21 CFR Part 150: *Fruit Butters, Jellies, Preserves, and Related Products*;
- (11) 21 CFR Part 152: *Fruit Pies*;
- (12) 21 CFR Part 155: *Canned Vegetables*;
- (13) 21 CFR Part 156: *Vegetable Juice*;
- (14) 21 CFR Part 158: *Frozen Vegetables*;
- (15) 21 CFR Part 160: *Eggs and Egg Products*;

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- (16) 21 CFR Part 161: *Fish and Shellfish*;
- (17) 21 CFR Part 163: *Cacao Products*;
- (18) 21 CFR Part 164: *Tree Nut and Peanut Products*;
- (19) 21 CFR Part 166: *Margarine*;
- (20) 21 CFR Part 168: *Sweeteners and Table Sirups*;
- (21) 21 CFR Part 169: *Food Dressings and Flavorings*;
- (22) Enforcement of 105 CMR 500.004(C)(1) through (21). When the Department receives a complaint alleging a violation of any provision of 105 CMR 500.004(C)(1) through (21) with respect to a business that participates in interstate commerce, the Department may refer the complainant to the U.S. Food and Drug Administration or take other appropriate action.

(D) General Enforcement Regulations. 21 CFR Part 1, Subpart B: *General Labeling Requirements*, as they relate to food. When the Department receives a complaint alleging a violation of 105 CMR 500.004(D) with respect to a business that participates in interstate commerce, the Department may refer the complainant to FDA or take other appropriate action.

500.005: Additional Requirements for Good Manufacturing Practices Applicable to All Licensees and Permit Holders¹

All licensees and permit holders shall comply with the following requirements.

(A) Person in Charge. There shall be a person in charge present in the facility during all hours of operation. The person in charge shall be responsible for the facility's compliance with all relevant requirements of 105 CMR 500.000.

(B) Source of Food; Ingredients.

- (1) All food shall be obtained from approved sources that comply with law.
- (2) Food and ingredients for use in any food product shall not bear or contain any pesticide chemical or other residues in excess of levels permitted pursuant to state or federal law.

(C) Non-food Uses: Prohibition. No food or food ingredient, including water intended for bottling, shall be stored, transported, processed, or bottled through equipment or lines used for any non-food product.

(D) Source of Water and Ice. All water and ice used in the manufacture of food products, whether used in facility or equipment operations or as an ingredient in any product, shall be from an approved source of water as follows:

- (1) Water from a Massachusetts public water supply source shall meet the quality standards of 310 CMR 22.00: *Drinking Water*, promulgated by the Massachusetts Department of Environmental Protection (DEP), and of any additional maximum contaminant levels promulgated by the U.S. Environmental Protection Agency (EPA) and in effect.
- (2) Water from a private source of water in Massachusetts, if used:
 - (a) As an ingredient in any product, shall meet the standard in 105 CMR 500.005(D)(1), and
 - (b) Solely in facility or equipment operations, shall meet standards established by the Department.
- (3) Water from a source outside Massachusetts shall meet the quality standards of 40 CFR Parts 141 and 143: *National Primary and Secondary Drinking Water Regulations*, promulgated by the EPA, and any additional maximum contaminant levels promulgated by EPA and in effect.
- (4) Sea water may be used to deliver, chill, or hold live or unprocessed seafood, except as otherwise determined by the Department.

(E) Major Food Allergens. Whenever a facility uses the same equipment for processing multiple products and makes a transition from processing a product containing a major food allergen to a product containing no major food allergen or a different major food allergen, it shall:

¹ The requirements in 105 CMR 500.005 apply to all facilities that are not subject to USDA inspection, and are recommended for all facilities that are subject to USDA inspection.

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- (1) Ensure that all of the product-contact surfaces of the equipment are fully washed and rinsed in a manner sufficient to clear the equipment of any residual allergen before the second product is processed, or
- (2) Process products containing a particular major food allergen on dedicated processing equipment.

(F) Ready-to-eat Foods. Food handlers shall not contact exposed, ready-to-eat food with their bare hands but shall use suitable utensils such as deli tissue, spatulas, tongs, single-use non-latex gloves, or dispensing equipment.

(G) Cooling of Potentially Hazardous Foods.

- (1) Food manufacturing shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms and for the contamination of food. The licensee or permit holder shall use processes that are adequate to prevent adulteration of food and growth of harmful microorganisms.
- (2) Specific processes outlined in the Sanitation Standard Operating Procedure, as required by 105 CMR 500.005(H)(4), shall be validated by means of laboratory testing or monitoring of specific control factors such as pH, water activity, temperature, time/temperature, acidification, flow rate, and similar factors.

(H) Sanitation Standard Operating Procedure (SSOP). Each licensee and permit holder shall develop and implement a Sanitation Standard Operating Procedure (SSOP). The SSOP shall be modified as necessary and shall adequately address the following areas:

- (1) Safety of the operations water in the facility;
- (2) Construction, condition, maintenance of, and cleaning procedures for the facility, holding tanks, piping and all related equipment, utensils, washing equipment, and food transportation vehicles under the control of the licensee or permit holder;
- (3) Prevention of cross-contamination;
- (4) Manufacturing processes, including thermal processing and product cooling;
- (5) When a major food allergen is an ingredient of any product, procedures for the use of all equipment that comes in contact with the allergen, including procedures for cleaning and flushing/rinsing the equipment in a manner sufficient to clear the equipment of any residual allergen;
- (6) Production records for each production run, including information on cleaning and sanitizing the equipment;
- (7) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- (8) Protection of packaging and product contact surfaces from contamination;
- (9) Proper labeling, storage, and handling of all toxic substances in the facility;
- (10) Sanitization procedures;
- (11) Employee health and hygiene;
- (12) Employee training;
- (13) Exclusion of pests;
- (14) Food transportation defense as provided in 105 CMR 500.007(D); and
- (15) Procedures for daily monitoring and recording compliance with the SSOP.

(I) Records. At all times, the facility shall maintain, and make available to inspectors, records sufficient to conduct trace-back and trace-forward of food products in the distribution system.

(J) Emergency Action Plan.

- (1) Each facility shall develop, maintain on file, and follow a written emergency action plan. Appropriate personnel shall be trained in the implementation of the plan. The plan shall contain, but need not be limited to:
 - (a) Contact information for, and procedures for notification of, local emergency services, the board of health, the Department, and FDA or USDA as appropriate;
 - (b) Procedures to be followed in the case of foreseeable emergency events, including but not limited to loss of water or power, flood, fire, and intentional or accidental contamination of food;
 - (c) Procedures to implement a product recall; and

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- (d) Names and contact information for the primary suppliers of ingredients to the facility (to enable trace-back) and for the facility's primary customers (to enable trace-forward).
- (2) A licensee or permit holder shall notify the Department immediately when an imminent danger to the public health is present in the facility or its products.
- (3) Any licensee or permit holder may present for advance review and approval by the regulatory agency a plan to continue operations during an emergency and/or to respond to an emergency due to natural or man-made causes.

(K) Product Recall.

- (1) A facility operator who knows or has reason to believe that circumstances exist that may adversely affect the safety of products, including but not limited to major spills, serious accidents, introduction of toxins or contaminants, natural disasters, or major breakdowns in production, shall notify the Program immediately.
- (2) Each facility operator shall develop and maintain on file a current written contingency plan for use in initiating and accomplishing a product trace and recall, and shall follow the plan as appropriate. The plan shall include procedures for the notification of the Program, consumer notification, and recall of the product.
 - (a) Recalls of meat or poultry products shall conform to the procedures and policies established by USDA.
 - (b) Recalls of products other than meat or poultry products shall conform to the procedures and policies of 21 CFR Part 7: *Enforcement Policy*.
- (3) The facility shall use sufficient coding of products to make possible positive lot identification and to facilitate effective recall of all violative lots. The code shall be designed to remain affixed to the container during retail distribution and consumer use.
- (4) The facility shall maintain such product distribution records as are necessary to enable location of products if a recall is initiated. These records shall be maintained for two years after December 31st of the year in which the product was processed.
- (5) The facility shall implement the recall procedures as necessary with respect to any product which the facility or the Department knows or has reason to believe may adversely affect its safety for the consumer.
- (6) If the Department determines that the circumstances present an imminent danger to the public health and that a form of consumer notice and/or product recall can effectively avoid or significantly minimize the threat to public health, the Department may advise the facility:
 - (a) To initiate a level of product recall approved by the Department, and/or
 - (b) If appropriate, to issue a form of notification to consumers.
 - 1. The facility shall be responsible for disseminating the notice in a manner designed to inform consumers who may be affected.
 - 2. The facility shall, where appropriate, provide the notice to the news media serving the affected public, and/or shall directly notify affected consumers when doing so effectively avoids or minimizes the risk to health.

(L) Maintenance of Records. All records required to be kept by 105 CMR 500.000 shall be maintained on file for at least two years, or for the time required by another specific record-keeping requirement in 105 CMR 500.000, and shall be made available to agents of the regulatory agency for inspection and copying upon request.

500.006: Labeling of Food

- (A) All packaged food products shall comply with the federal labeling regulations specified in 105 CMR 500.004(B) and (C), and shall be labeled in accordance with all additional relevant state and/or federal labeling requirements.
- (B) Open Date Labeling.
 - (1) Open Dating of Perishable and Semi-perishable Food Products.
 - (a) No person shall sell, offer for sale, or have in his or her possession with intent to sell any prepackaged perishable or semi-perishable food products unless it is identified with an open date determined by the manufacturer, processor, packer, repacker, retailer, or other person who packaged such food products, and which is displayed in the form specified in 105 CMR 500.006(B)(5).

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(b) No person receiving a perishable or semi-perishable product in bulk intended for use as a repacked product or as a component of a larger food item shall offer such item for prepackaged retail self-service sale without placing an open date on such product, and the date shall be no later than the date specified on the bulk container from which it was obtained.

(2) Open Dating of Frozen and Long Shelf Life Food Products. A manufacturer, processor, packer, repacker, retailer, or other person who prepackages frozen or long shelf life food products may mark the individual retail packages of such products with an open date, and shall be subject to the requirements as to form outlined in 105 CMR 500.006(B)(5).

(3) Once an open date has been placed on a product, the date may not be altered.

(4) Sale of Past Date Food Products. No person shall offer for sale in Massachusetts any food product after the open date unless:

- (a) It is safe for human consumption and its sensory and physical qualities have not significantly diminished;
- (b) It is segregated from food products that are not "past date"; and
- (c) It is clearly and conspicuously marked either on the package or through the use of shelf markers or placards, as being offered for sale after the recommended last date of sale or use.

(5) Placement of the Date.

- (a) The term "sell by," "best by," "use by," or similar words shall be either immediately adjacent to, above, or below the designated date.
- (b) The date shall consist of the common abbreviation for the calendar month and numerals for the day and year, *e.g.*, Feb. 10, 2020; or numerals for the month, day and year, *e.g.*, 2/10/20, except that perishable food products need not have the year identification included in the date, and frozen and long shelf life foods need not have the day identification included in the date.
- (c) The date shall be accompanied by disclosure of recommended product storage conditions, if such conditions significantly affect the validity of the date.
- (d) The date and any recommended storage conditions shall be printed, stamped, embossed, perforated, or otherwise shown on the retail package. Such label on such package, or a tag attached to such package, shall be affixed in a manner that is easily readable and separate from other information, graphics, or lettering so as to be clearly visible to a prospective purchaser.
- (e) An individual prepackaged food product which is not labeled in accordance with 105 CMR 500.006(B)(5) shall be deemed misbranded pursuant to M.G.L. c. 94, § 187.

(6) Product Rotation, Storage and Handling Information. Any person who prepackages a food product for sale in Massachusetts shall disclose to the retailer of such product:

- (a) Whether or not such product is open dated;
- (b) Any required or recommended storage and handling conditions; and
- (c) Information to facilitate the sequential rotation of product inventory.

Information shall be conveyed in a readily understandable form.

(7) Factors for Shelf Life Determination.

- (a) A person who is responsible for placing an open date on a food product shall estimate the shelf life of the product, using a scientifically valid method, taking into consideration the quality, characteristics, formulation, processing impact, packaging or container and other protective wrapping or coating, and typical transportation, storage, and display conditions of the food product.
- (b) Considerations shall also include those of the retail store and consumer. For purposes of estimating shelf life, home storage conditions shall be considered similar to the usual retail store, except that refrigerated food may be calculated using a home temperature storage standard of 45°F (7.2°C).
- (c) Such factors shall be measured or otherwise determined utilizing testing and sampling procedures customarily utilized by the food industry for such purposes.

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(8) Required Records.

- (a) A person responsible for estimating the shelf life of a food product shall keep a record of the method used for the determination of such shelf life and the corresponding open date. A record revision is necessary whenever a factor affecting such date determination is altered. Such record shall be retained for not less than six months after the most recent open date and shall be made available to the Department upon written request.
- (b) If, after conducting an investigation, the Department determines that such records do not support the date selected, it may direct the responsible person to change the date in accordance with its findings.

(9) Exemptions.

- (a) 105 CMR 500.006(B)(1) through (8) does not apply to:
 1. Fresh meat, fresh poultry, fresh fish, fresh fruits, or fresh vegetables offered for sale unpackaged or in a container permitting sensory examination;
 2. Salt;
 3. Crystallized refined sugar;
 4. Individually packaged food products which are prepackaged as components of a larger food item, if the larger food item is identified with a date no later than the corresponding date for any such components;
 5. Food products prepackaged for retail sale with a net weight of less than 1½ ounces; or
 6. Food products manufactured, processed, or stored for sale outside Massachusetts.
- (b) Any person may apply to the Department for an exemption from the provisions of 105 CMR 500.006(B), which exemption may be granted if the product for which the exemption is sought is open dated in accordance with the regulations of another agency, and compliance with the regulations of the other agency will result in the disclosure of substantially the same information as is required by 105 CMR 500.006(B).

500.007: Transportation of Food

(A) The licensee or permit holder shall ensure that the following requirements are observed, whether the vehicle is operated by the licensee or permit holder, or by a contracted transporter.

(B) Design, Construction, and Maintenance.

- (1) Vehicles and trailers shall:
 - (a) Be designed and built to facilitate locking and sealing and to prevent infestation by pests.
 - (b) Permit effective inspection, cleaning, disinfection, and temperature control.
 - (c) Be maintained in a clean and sanitary condition to protect the food from contamination.
 - (d) Be constructed to prevent waste products such as iced poultry wastes from leaking onto the ground.
- (2) Open (uncovered) commercial vehicles shall not be used for the transportation of food intended for sale.
- (3) Self-contained Units. Self-refrigerated containers and other self-contained units utilized in making shipments of refrigerated or frozen food shall be constructed so as to give the food adequate protection.
- (4) Bulk Tanker Trailers.
 - (a) The entire interior surface of the tank shall be clean-bore, with the exception of those that require baffles to promote product flow.
 - (b) If compartments are used, they shall be equipped with double bulkheads with evacuated airspace between bulkheads.
 - (c) With the exception of center-discharge (belly drop) tanks, all tanks shall have a positive drain (minimum four inch slope from front to back of tankers).
 - (d) All internal accessories shall be capable of being disassembled to clean product contact surfaces.
 - (e) Gaskets shall be removable and non-porous.
 - (f) Vehicle-mounted product transfer equipment, if used, shall meet the requirements established for the tanker.

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- (g) Bulk tanker trucks shall be cleaned, sanitized, and inspected internally for integrity on a routine basis in compliance with the sanitary standards in 21 CFR Parts 110: *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food* and 129: *Processing and Bottling of Bottled Water*, if applicable. A record of all cleaning and sanitizing showing the date, time, place, and signature or initials of the person doing the work shall be maintained with the vehicle.
- (h) Upon filling, all access points to the contents of the tanker shall be sealed with a tamper-evident seal printed with a unique identifier. The seals may only be removed by the receiving facility. Seal numbers shall be recorded on the bill of lading or other appropriate document.

(5) **Product Loading.**

- (a) All vehicles shall be examined for deficiencies that would prevent their use as food carriers.
- (b) Residues from previous cargoes as well as from cleaning and sanitizing compounds shall be removed.
- (c) Trailers and trucks shall be pre-cooled before loading to remove residual heat from the insulation and inner lining of the trailer. The doors shall be kept closed during any period when loading and unloading operations cease or are interrupted.
- (d) Refrigerated food shall be kept refrigerated at the appropriate temperature, as specified in 105 CMR 500.007(C)(2)(a).
- (e) No food shall be loaded in such manner so as to interfere with the free flow of air into or out of the refrigeration unit, nor with the free flow of air around the load.

(C) **Food Safety.**

- (1) At all times, all food shall be protected from cross-contamination between foods and from potential contamination by insects, chemicals, rodents, waste products, toxic material, unclean equipment, tank cleaning products, unnecessary handling, and other materials that pose a risk to public health.
- (2) Adequate temperatures for food shall be maintained. All food that must be refrigerated or frozen shall be transported only in vehicles provided with sufficient refrigeration and/or freezing capabilities for product temperature maintenance. Vehicles transporting refrigerated or frozen food shall be:
 - (a) So constructed and properly insulated that, when equipped with appropriate refrigeration units, they will maintain an air temperature of 41°F (5°C) (or a temperature required by other applicable law) for refrigerated loads, and 0°F. (-18°C) or less for frozen goods, throughout the load in all movements;
 - (b) Equipped with an appropriate temperature-measuring device to indicate accurately air temperature inside the vehicle. The dial or reading element of the device shall be mounted in a readily accessible position outside the vehicle;
 - (c) Equipped with tight fitting doors and suitable closures for drain holes to prevent air leakage; and
 - (d) Racked, stripped, baffled, or otherwise so constructed as to provide clearance for air circulation around the load, unless the vehicle is of cold-wall or envelope type construction.
- (3) Food items that are spoiled or that are in damaged containers that may affect the integrity of the product being transported shall be removed from the transporting vehicle and stored properly pending satisfactory disposition.
- (4) Any materials that have a potential to adulterate food shall not be shipped in a vehicle containing food.
- (5) To prevent any cross contamination and/or contact between potentially hazardous foods, or between known allergens and foods that are not allergens, different types of raw ingredients and food shall not be transported in subsequent loads without proper sanitization of the cargo area (example: produce being transported after chicken, or rice flour being transported after peanuts).
- (6) All food, including seafood; hanging primal cuts, quarters, or sides of meat; poultry; *etc.*, shall be protected from contamination by the use of packaging or covered containers while being transported.
- (7) All transportation vehicles shall be secured to prevent tampering when not in use.

(D) **Food Transportation Defense.** The licensee or permit holder shall ensure that the following food transportation defense requirements are observed, whether the vehicle is operated by the licensee or permit holder, or by a contracted transporter.

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- (1) Each licensee and permit holder that owns, or contracts for, food transportation vehicle(s) shall develop, maintain on file, and follow a written food transportation defense plan. The plan shall include but need not be limited to:
 - (a) Methods and procedures to prevent tampering of food while in transit, such as the use of tamper-evident seals corresponding to specific shipments; and
 - (b) A means to identify and track food products during transportation to the destination.
- (2) Security measures shall be identified and implemented at each point of delivery to ensure the protection of raw ingredients and food products from the time they are loaded for shipment through delivery to the final destination.
- (3) Vehicles transporting any food or ingredient, including water, to a facility from sources of supply other than those owned by the shipping facility shall be marked with the name and address of the hauler. For each shipment, a shipping statement shall be prepared for each recipient containing at least the following information:
 - (a) Name and address of the owner of the food, ingredient, water, or water source, and site of the water source if applicable;
 - (b) Date of loading;
 - (c) Amount of food, ingredient, or water delivered; and
 - (d) Date and time delivered at the facility.A copy of the shipping statement shall be retained on file for at least two years at both the shipping and receiving facilities.
- (4) Any licensee or permit holder utilizing a contracted transporter (*e.g.* air, ground, maritime, or rail) shall verify that the transporter and any storage/warehouse facilities utilized by the transporter have a security program in effect.
- (5) The licensee or permit holder shall develop and implement methods to check and document the condition of raw ingredients, food products, and packaging upon receipt.

500.008: Prevention of Disease Transmission²

All licensees and permit holders shall comply with the following requirements.

- (A) In accordance with 21 CFR 110.10: *Personnel*, it is the responsibility of the licensee to protect the integrity of food products by:
 - (1) Developing and implementing a written plan for personnel health and hygiene (as part of the SSOP developed pursuant to 105 CMR 500.005(H)) that ensures that all personnel report to their supervisors illnesses or health conditions through which there is a reasonable possibility of products, product-contact surfaces, or packaging materials becoming contaminated; and
 - (2) Taking appropriate protective steps in accordance with Department policies or directives.
- (B) The licensee or permit holder, person in charge, or manager of any facility shall immediately notify the regulatory agency when he or she knows, or has reason to believe:
 - (1) That any worker has been exposed to or contracted any disease transmissible through food or food products, or has become a carrier of such a disease, and/or
 - (2) That an illness has occurred that may have been caused by a food product from the facility.
- (C) Pursuant to M.G.L. c. 94, § 305B, when the Program or the board of health knows or has reason to believe that a worker has contracted a disease transmissible through food or has become a carrier of such a disease, it may:
 - (1) Obtain a confidential medical history of the suspected person and make other investigations as deemed appropriate; and
 - (2) Take any other action required by 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*.

² The requirements in 105 CMR 500.008 apply to all facilities that are not subject to USDA inspection, and are recommended for all facilities that are subject to USDA inspection.

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(D) The board of health shall immediately notify the Program of suspected transmission of disease through food to any person, and shall keep the Program informed until any investigation is completed.

(E) The Commissioner or his or her designee, on his or her own initiative or at the request of a board of health, may require any person whose duties actually involve the handling of ingredients, products, 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 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.

(F) Any person who fails to cooperate with any medical or laboratory examination ordered by the Commissioner or designee shall immediately be excluded from the performance of duties involving the handling of ingredients, products, or product contact surfaces.

(G) In addition, the Department or the board of health, where applicable, may issue an order instituting one or more of the following control measures:

- (1) Restricting particular persons' services to specific areas and tasks in the facility that present no risk of transmitting the disease;
- (2) Excluding particular persons from the facility;
- (3) Removing particular food products from sale; or
- (4) Closing the facility by summarily suspending the license or permit in accordance with 105 CMR 500.207(B).

(H) The following diseases or disease organisms are known to be transmissible through food or food products:

- (1) *Amebiasis*;
- (2) *Bacillus cereus*;
- (3) *Campylobacteriosis*;
- (4) *Cholera*;
- (5) *Cryptosporidiosis*;
- (6) *Cyclosporiasis*;
- (7) *E. coli* O157 H:7 and other *Shiga* toxin-producing *E. coli* and *Shiga* toxin-producing organisms;
- (8) *Giardiasis*;
- (9) Hepatitis A virus;
- (10) *Listeria monocytogenes*;
- (11) Noroviruses;
- (12) *Salmonella Typhi*;
- (13) *Salmonella* spp. (Non-typhi)
- (14) *Shigellosis*;
- (15) *Vibriosis* (non-Cholera);
- (16) *Yersiniosis*; and
- (17) Any other disease transmissible through food so designated by the Department.

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 or organism not specified in 105 CMR 500.008(H)(1) through (17).

500.015: Supplemental Regulations for Residential Kitchens: Wholesale Sale

(A) Scope.

- (1) Persons who operate a residential kitchen to prepare food for sale at wholesale shall comply with 105 CMR 500.015 in addition to 105 CMR 500.004 through 500.008.
- (2) Persons who prepare food in a residential kitchen for sale at retail are subject to 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments*, and should consult their board of health about any additional requirements and restrictions.

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(B) No person shall operate a residential kitchen to prepare food for sale at wholesale without a valid license granted by the Department, or in violation of any of the requirements for residential kitchens specified in 105 CMR 500.000. NOTE that municipal zoning regulations may prohibit residential kitchens in some cities and towns.

(C) Exceptions. Federal regulation sections 21 CFR 110.37(e)(4) and 110.80(b)(3) are not applicable to residential kitchens. Furthermore, 21 CFR Parts 113: *Thermally Processed Low-acid Foods* and 114: *Acidified Foods* are not applicable to residential kitchens, because residential kitchens are not permitted to process food in these ways.

(D) Food Preparation and Protection.

- (1) Only non-potentially hazardous foods and foods that do not require refrigeration shall be prepared in or distributed from a residential kitchen for sale at wholesale. Ingredients that are potentially hazardous foods, such as milk, cream, and eggs, may be used in food preparation provided that the final product is not a potentially hazardous food.
- (2) Food preparation surfaces and areas shall be kept clean.
- (3) Residential kitchens are prohibited from undertaking high-risk operations, including but not limited to:
 - (a) Smoking food as a method of food preservation;
 - (b) Curing food;
 - (c) Using food additives or adding components such as vinegar as a method of food preservation or to render a food non-potentially hazardous;
 - (d) Packaging a food using reduced oxygen packaging;
 - (e) Operating a molluscan shellfish life-support system;
 - (f) Slaughtering or processing animals; and
 - (g) Canning low-acid foods.
- (4) Residential kitchen workers may not contact exposed, ready-to-eat food with their bare hands but shall use suitable utensils such as deli tissue, spatulas, tongs, single-use non-latex gloves, or dispensing equipment.
- (5) Fruits and vegetables shall be washed before use.

(E) Who May Work. Only people residing in the household may prepare food for wholesale in a residential kitchen.

(F) General Requirements for Residential Kitchens Preparing Food for Wholesale Sale.

- (1) Storage. Separate dry and refrigerated storage facilities shall be utilized for raw ingredients and finished food products.
- (2) Hand Washing. A soap dispenser and disposable towels for use in hand washing shall be provided at the kitchen sink. This sink shall not be used for hand washing after toilet use but may be used for food preparation and ware washing provided that it is cleaned and sanitized prior to use and between different uses.
- (3) Toilet Room. A toilet room shall be available for use by food workers. Toilet rooms opening to the kitchen shall have adequate ventilation. Ventilation shall be provided by mechanical means or by a screened window(s). A soap dispenser and disposable towels shall be provided for hand washing in toilet rooms used by food workers.
- (4) Manual Cleaning and Sanitizing. For manual cleaning and sanitizing of cooking equipment, utensils, and tableware, three-compartment sinks shall be provided and used; or a two-compartment sink may be used when an approved detergent sanitizer is used in accordance with manufacturer's instructions. The strength of the sanitizer must be measured in accordance with manufacturer's instructions.
- (5) Mechanical Cleaning and Sanitizing. A domestic or home-style dishwasher may be used provided that the following performance criteria are met:
 - (a) The dishwasher must effectively remove physical soil from all surfaces of dishes, equipment, and utensils.
 - (b) The operator shall provide and use daily a maximum registering thermometer or a heat thermal label to determine that the dishwasher's internal temperature is a minimum of 150°F after the final rinse and drying cycle. Records of this testing shall be kept on file for 90 days.

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- (c) The dishwasher must be installed and operated according to the manufacturer's instructions for the highest level of sanitization possible when sanitizing residential kitchen facilities' utensils and tableware, and a copy of the instructions must be available on the premises at all times.
- (d) There shall be sufficient area or facilities such as portable dish tubs and drain boards for the proper handling of soiled utensils prior to washing and of cleaned utensils after sanitization, so as not to interfere with safe food handling, hand washing, and the proper use of ware washing facilities. Equipment, utensils, and tableware shall be heat-dried or air-dried.
- (6) Premises.
 - (a) There shall be adequate storage and preparation areas on the premises to support food preparation activities in the kitchen. All such areas shall be kept clean.
 - (b) Pets may be present on the premises, but shall be kept out of food preparation areas during food preparation and out of food storage areas at all times.
 - (c) Laundry facilities may be present in the kitchen, but shall not be used during food preparation.
 - (d) Cooking facilities in the kitchen shall not be used for domestic purposes during preparation of food for wholesale.
 - (e) Garbage Receptacles. A sufficient supply of impervious covered receptacles shall be provided for storage of garbage and refuse.
 - (f) Water Supply. A sufficient supply of hot and cold water under pressure shall be provided to food preparation areas and toilets, and shall be from an approved source of water as provided in 105 CMR 500.005(D).
 - (g) Sewage. Sewage shall be disposed of through an approved system that is:
 1. A public sewage treatment facility; or
 2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to law.

500.016: Supplemental Regulations for the Production of Juice and Apple Cider

- (A) General Requirements.
 - (1) No person shall manufacture juice or apple cider in Massachusetts for sale at wholesale without a license issued by the Department or in violation of any of the requirements specified in 105 CMR 500.000.
 - (2) Persons who manufacture juice in Massachusetts for sale at wholesale shall comply with 21 CFR Part 120: *Hazard Analysis and Critical Control Point (HACCP) Systems.*
- (B) Additional Requirements for the Production of Apple Cider.
 - (1) Apples.
 - (a) The use of wormy, decayed, damaged, or rotten fruit is prohibited, and such fruit shall be discarded. A log identifying the source of all apples used in each production lot shall be maintained.
 - (b) The licensee shall ensure that appropriate personal hygiene is practiced in the harvesting of apples.
 - (c) All apples for processing shall be kept in cold storage or in an enclosed area, free of insects, rodents, and vermin. Wild and domestic animals are prohibited from the processing and storage areas of the building. Fruit flies and other insects shall be effectively controlled.
 - (d) All apples shall be inspected, culled, and thoroughly washed and brushed before crushing. Facilities shall employ commercial scrubbers or equivalent means to accomplish a thorough washing and brushing. This can be accomplished as part of the grading operation but only if there is no storage or holding time between grading and pressing.

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- (e) The use of sodium hypochlorite or other approved chemicals may be used during the washing and brushing step(s) to reduce the microbial population. The chemicals shall not be used in excess of the minimum amount required to accomplish their intended effect. Following the use of wash water with added chemicals, apples and any other produce used in making cider shall be rinsed with potable water to remove chemical residues. Chlorine solutions used to wash produce shall not exceed 200 parts per million (ppm).
- (f) Chemicals used to wash apples shall meet the requirements specified in 21 CFR 173.315: *Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables*. Such chemicals shall be used in accordance with manufacturers' instructions.

(2) Processing Operations.

- (a) Filter cloths shall be specifically designed for this purpose, made of durable materials, and replaced frequently. During processing, the cloths shall be handled in a sanitary manner. All press cloths shall be washed, sanitized, and dried daily. The use of automatic laundry equipment (washers and dryers) is recommended. Other laundry shall not be mixed with the washing or drying of the press cloths.
- (b) Press racks shall be made of food-grade plastic or hardwood, which has been properly coated with paraffin or other food-approved coating prior to the start of the cider season. Press racks shall be kept off the floor at all times. At the end of each day, all used press racks shall be washed, sanitized, and allowed to dry. While drying, the racks shall be placed off the floor in a well-ventilated, screened location.
- (c) All tubing carrying cider shall be approved for food use, and all plastic tubing shall be transparent. Tubing shall be protected from abrasion or breakage and shall be easily replaceable. If the tubing passes through spaces that are not readily accessible, the tubing shall be of one piece and easily cleanable. Tubing shall be as continuous as possible, with couplings kept to a minimum. After each production run the disassembling, cleaning, and sanitizing of tubing, clamps, couplings, and connections shall be performed. Tubing shall be positioned so that no pockets of liquid remain when the tubing is rinsed.
- (d) Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 40 CFR 180.940: *Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food-contact Surface Sanitizing Solutions)*. Such chemicals shall be used in accordance with manufacturers' instructions. The concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.
- (e) After each day's operation, all equipment shall be thoroughly rinsed with clean water under adequate pressure and in sufficient volume to dislodge particles of fruit and film from all surfaces. A suitable high-velocity circulation pump for clean-in-place (CIP) systems and a suitable high-pressure washer for external cleaning of equipment shall be used for this purpose. All equipment shall then be dismantled or disassembled for cleaning and sanitizing. Equipment shall not be rinsed after sanitizing. All equipment shall be air-dried on racks.
- (f) Cider shall only be sold in new containers with new caps.

(3) Labeling of Cider. The following information shall be provided on the container label.

- (a) Statement of product identity or usual name, *e.g.*, apple cider;
- (b) Ingredients, including any additives or preservatives;
- (c) Open date;
- (d) Name, address, city, state, and zip code of manufacturer, packer, or distributor;
- (e) The statement "Keep Refrigerated";
- (f) Net quantity;
- (g) "Pasteurized" or "treated with UV light" (or other approved method) to control pathogens" or other wording approved by the FDA; and
- (h) Brand name (optional).

(4) Off-season Storage. During the off-season, press racks and cloths shall be stored and protected from contamination. Racks and cloths shall be thoroughly cleaned, sanitized, dried, and wrapped before storage.

Supplemental Regulations for Fish and Fishery Products500.020: General Requirements

(A) Permit Requirements. No person shall operate as a wholesale seafood dealer, retail seafood dealer, or wholesale seafood truck ³ without a valid permit issued jointly by the Department and the Division of Marine Fisheries. No person shall operate as such a dealer in violation of applicable laws or in violation of any of the requirements specified in 105 CMR 500.000.

(B) Explanation of Permit Categories, Additional Requirements, and Restrictions.

(1) Wholesale Dealer.

- (a) Allows the permit holder to acquire, handle, store, distribute, process, fillet, ship, and sell raw seafood products, whether frozen or unfrozen, in bulk or for resale from a single, fixed location;
- (b) Allows the purchasing of seafood products from a harvester or commercial fisherman;
- (c) Allows retail sales from a single, fixed location;
- (d) Requires an inspection and approval from the Department before initial permitting; and
- (e) The wholesale dealer is prohibited from engaging in any activity not specifically inspected for and approved by the Department, and endorsed on the permit.

(2) Retail Dealer.

- (a) Allows the sale of raw fish, whether frozen or unfrozen, shellfish and crustaceans, at one fixed retail location;
- (b) Allows the purchase of shellfish from an appropriately permitted wholesale dealer or wholesale truck, or from a certified interstate shellfish shipper;
- (c) Allows the purchase of seafood except shellfish directly from a commercial fisherman;
- (d) Prohibits high hazard processing, such as shucking and meat picking, and prohibits wet storing, re-labeling, and repacking of seafood;
- (e) Prohibits removing shellfish meats from the shell. Shellfish meat prepared and served "on the half-shell" is permitted as authorized by written policy of the Department;
- (f) Requires compliance with 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments*;
- (g) Requires that proper shellfish tags must be attached to each container and requires the retention of tags for 90 days; and
- (h) Requires an inspection by the local board of health and approval from the Department for initial permitting.

(3) Wholesale Truck.

- (a) Allows the permit holder to acquire, handle, distribute, ship, and sell from the permitted truck raw seafood, whether frozen or unfrozen, in bulk or for resale only;
- (b) Allows the purchase of finfish, crustaceans, and other non-molluscan shellfish seafood products directly from a commercial fisherman;
- (c) Prohibits the holder from processing, re-labeling, or repacking seafood, and prohibits storing of seafood on the vehicle;
- (d) Prohibits the holder from purchasing shellfish directly from anyone other than a wholesale dealer; and
- (e) All wholesale trucks operating in Massachusetts require a separate inspection and approval from the Department.

(C) Permit Procedures.

(1) Application. Any person seeking to operate as a wholesale seafood dealer, a retail seafood dealer, or a wholesale seafood truck within Massachusetts shall submit an application for a permit to the Division of Marine Fisheries.

- (a) The application shall be on a form provided by the Division of Marine Fisheries.
- (b) No permit shall be issued prior to an inspection by and written approval from the Department, except that in the case of a retail dealer permit, an inspection and approval by the local board of health shall suffice.

³ A retail seafood truck requires a permit from the Division of Marine Fisheries and a permit from the local board of health under 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments*.

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- (c) A copy of an approved inspection report must be submitted by the applicant to the Division of Marine Fisheries prior to the issuance of a permit.
- (2) A permit shall be valid only for the activities and products inspected and approved by the Department and endorsed on the permit by the Division of Marine Fisheries, and only for the specific location indicated on the permit.
- (3) A permit holder shall notify the Department in advance of any intention to change endorsed products or activities. Upon notification, the Department shall inspect the facility to verify compliance with applicable regulations, except that in the case of a retail dealer permit, an inspection by the local board of health shall suffice. No new product may be sold or new activity commenced until the facility is inspected and approved by the Department, and endorsed by the Division of Marine Fisheries for such product or activity.
- (4) A permit may be renewed by applying at least 30 days prior to the expiration of the permit. Application for renewal shall be made in writing on a form provided by the Division of Marine Fisheries.
- (5) Suspension or Revocation of Permit. The Department may suspend or revoke a permit for the reasons specified in 105 CMR 500.207 and pursuant to the procedures specified in 105 CMR 500.208.

(D) License Requirements. Pursuant to M.G.L. c. 94, § 305C, no person shall cook, smoke, or otherwise process seafood, or combine seafood with non-seafood ingredient(s), for sale at wholesale, without a valid license issued by the Department.

(E) Additional Storage and Transportation Requirements for Frozen and Refrigerated Seafood.

- (1) Any facility used to store seafood shall comply with the requirements of 21 CFR Part 110: *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*.
- (2) Any vehicle engaged in the wholesale transportation of seafood products shall have the name of the company and permit number clearly displayed on the two sides of its exterior. At a minimum, the lettering shall be four inches in height and of a color in contrast to the truck exterior.
- (3) Vehicles used for the wholesale transportation of seafood shall not be used for any other food products without adequate separation and protection to avoid cross-contamination.
- (4) Seafood products transported by a harvester or retail dealer shall be adequately protected from temperature abuse and environmental contamination. A retail dealer, transporting seafood products from a wholesale facility to the retail location, shall use mechanical refrigeration or ice from an approved source to maintain the product at an ambient temperature of 45° F (7.2° C), or below (or at a temperature required by other applicable law).
- (5) When a wholesale dealer is also a master digger, separate vehicles are required for transporting shellfish from contaminated areas to the depuration facility and transporting depurated products for sale, unless the dealer adequately addresses the potential hazards in its HACCP plan (see 105 CMR 500.020(G)) and SSOP.
- (6) If a person holding a wholesale dealer permit or a wholesale truck permit leases a vehicle for 30 days or longer to transport seafood products, the person shall provide the Department and the Division of Marine Fisheries with the vehicle identification number and the registration number of the vehicle(s) leased. Any time a vehicle is added, removed or exchanged, the dealer shall notify the Department in writing and provide the new numbers, within ten business days of the change(s).

(F) All wholesale dealers and licensees shall comply with the following sections of federal regulation 21 CFR Part 123.00: *Fish and Fishery Products*, to the extent they are applicable to the type of business conducted by the wholesale dealer or licensee.

- (1) Subpart A - *General Provisions*, 21 CFR §§ 123.3 through 123.12;
- (2) Subpart B - *Smoked & Smoke-flavored Fishery Products*, 21 CFR §§ 123.15 through 123.16; and
- (3) Subpart C - *Raw Molluscan Shellfish*, 21 CFR §§ 123.20 through 123.28.

(G) Additional Hazard Analysis Critical Control Point (HACCP) Requirements. In addition to the record keeping requirements in 105 CMR 500.020(F) and 500.021(A), each wholesale dealer and licensee shall keep and maintain the following information:

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- (1) For those products for which it is determined that no hazard exists, a written justification in the form of a hazard analysis supporting that finding;
- (2) A written Sanitation Standard Operating Procedure (SSOP);
- (3) A written Corrective Action Plan for deviations from the HACCP plan or SSOP; and
- (4) A written contingency plan for use in initiating and accomplishing a product recall in accordance with 105 CMR 500.005(K).

(H) Failure to Comply with HACCP Regulations. Failure of a wholesale dealer to comply with the HACCP requirements of 21 CFR 123.6(a) through (f) or 105 CMR 500.021(A), where applicable, may render the fish or fishery product(s) adulterated and/or may constitute a violation of 105 CMR 500.000.

(I) Finfish Operations in a Facility.

- (1) Tanks used to chill large species of fish (tuna, swordfish, *etc.*) shall be constructed of materials that meet the requirements for a food-contact surface. The use of canvas or plastic tarps and wood construction is not permitted.
- (2) Filleted fish shall be cooled to a temperature of 45°F (7.2°C) or less within two hours after packing, and shall be stored and shipped under conditions that will maintain such temperature.
- (3) Filleting areas shall be equipped with a hand-wash sink supplied with adequate hot and cold running water and a three-compartment sink for ware washing.
- (4) Mechanical pumps used to move water shall be constructed of food grade materials.
- (5) All receptacles for waste or gurry shall be watertight and covered and shall be thoroughly cleaned after each emptying.
- (6) Only clean refined food-grade salt or filtered brine of a temperature not exceeding 50°F (10.0°C) shall be used in the brining of fish.
- (7) Only salt, sugar, wood smoke, vinegar, pure spices, spice flavoring, sodium benzoate, or other additives Generally Recognized as Safe (GRAS) by FDA may be used as fish preservatives.
- (8) All processing activities, including but not limited to storing, thawing, filleting, packing, ice making, and fish washing shall be performed within the physical confines of the facility.

(J) Cooked Lobster Meat Processing/Meat Picking Operations.

- (1) Picking Area. In facilities where the meat is removed from the animal, *e.g.* lobsters, crabs, whelks, urchins, *etc.*, the room used for the picking shall be separated from other rooms or space in the building by a suitable full partition or walls. Doors to such rooms shall be equipped with self closing devices.
- (2) The picking area shall be equipped with a hand-wash sink supplied with adequate hot and cold running water and a three-compartment sink for ware washing.
- (3) Dead Lobsters. The use of dead lobsters, or parts thereof, for processing or sale for human consumption is strictly prohibited.
- (4) Meat not immediately removed from the shell after cooking shall not be sold for human consumption unless it has been kept in a sanitary container and promptly refrigerated at 40°F (4.4°C) or less.
- (5) Meats shall be cooled to a temperature of 40° F (4.4° C) or less within two hours after picking.

(K) Processing of Uncooked Frozen Shell-on Lobster Tails.

- (1) A wholesale seafood dealer must be approved in writing by the Department and endorsed by the Division of Marine Fisheries prior to preparing and freezing uncooked lobster tails with shells on.
- (2) The use of dead lobsters is strictly prohibited; the wholesale seafood dealer shall use only live lobsters killed specifically for this activity.
- (3) Following separation of tails for freezing, the remaining portions of each lobster shall be processed by cooking within 30 minutes, or they must be discarded.

(L) Reduced Oxygen Packaging (ROP).

- (1) Only refrigerated seafood that has one of the following safety barriers may be packaged in a reduced oxygen atmosphere:

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- (a) Water activity (a_w) below .91;
- (b) Acidity (pH) of less than 4.6;
- (c) High levels of non-pathogenic competing organisms that prohibit the growth of pathogenic bacteria;
- (d) Held at $\leq 38^{\circ}\text{F}$; or
- (e) Frozen at 0°F except during processing, when for a maximum of two hours the product may exceed 0°F but shall not exceed 10°F .

(2) If refrigerated seafood has two or more of the barriers specified in 105 CMR 500.020(L)(1) (a) through (c) and (e), it may be held at $\leq 40^{\circ}\text{F}$.

(M) Bait Operations.

- (1) The processing and storage of seafood for use as bait shall be conducted in areas separate from the processing and storage of seafood intended for human consumption. There shall be sufficient physical separation in place to protect food intended for human consumption from contamination by seafood intended for bait.
- (2) Containers of bait product shall be plainly marked "BAIT" in red lettering no less than two inches in height. The word "BAIT" shall appear on a minimum of two sides and the top of each container.
- (3) Seafood intended for bait shall not enter a facility, including loading dock areas, without the container having clear markings indicating the product's intended use.

500.021: Additional Requirements for Handlers of Shellfish

All wholesale dealers and wholesale trucks that handle shellfish shall comply with 105 CMR 500.021.

(A) Requirements for wholesale dealers and wholesale trucks that handle shellfish shall be established as administrative guidelines by the Department, based on the National Shellfish Sanitation Program (NSSP) Model Ordinance (NSSP Model Ordinance), published by the United States Department of Health and Human Services and the Interstate Shellfish Sanitation Conference. All wholesale dealers and wholesale trucks that handle shellfish shall comply with the administrative guidelines.

(B) Shellfish Transactions.

- (1) A harvester may sell shellfish only to a Massachusetts wholesale dealer holding a permit endorsed for shellfish issued by the Division of Marine Fisheries and the Department. A harvester is prohibited from selling shellfish directly to a retail dealer, wholesale truck, restaurant, or consumer.
- (2) The direct sale of shellfish to a consumer from a vehicle is prohibited, except as authorized by written policy of the Department.
- (3) Each transaction between a harvester and a wholesale dealer shall be recorded on a serialized transaction slip approved by the Department. Information recorded on the transaction slip shall include the wholesale dealer's name and permit number, the type and amount of shellfish purchased, date of purchase, and the area from which the shellfish were harvested. Also, the transaction slip documenting the purchase of shellfish shall be imprinted by the wholesale dealer to show the number from the harvester's Shellfish Transaction Card issued by the Division of Marine Fisheries.
- (4) The wholesale dealer, master digger, and harvester shall retain their copies of the transaction slip for at least 90 days.
- (5) A wholesale dealer shall purchase shellfish only from another wholesale dealer or from a harvester or master digger who presents a Shellfish Transaction Card and who is either known to the wholesale dealer or who presents photo identification.
- (6) Sales of shellfish by a harvester to a wholesale dealer shall only be conducted by:
 - (a) The harvester transporting his or her product directly from the landing site to the wholesale dealer's physical facility for sale; or
 - (b) The harvester selling the product to an employee of a wholesale dealer at the landing site, provided that the employee transports the product to the wholesale dealer's facility. Shellfish purchased at the landing site must be transported to the wholesale dealer's facility for washing, grading, and tagging prior to its entering the marketplace.

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- (7) It is prohibited to land shellfish without an approved tag attached to the container as described in the Department's administrative guidelines based on the NSSP Model Ordinance. Containers with improper tags or no tags are misbranded and subject to embargo.
- (8) Wholesale dealers shall retain tags for a minimum of 90 days. Tags shall be maintained in an orderly manner, *e.g.* chronologically, by harvester/dealer, or in some other appropriate manner, which facilitates the tracking of dealer purchases.
- (9) Any commingling of different lots of shellfish shall be conducted in conformance with written Department policy.
- (10) Dealers who receive shellstock from harvesters whose commercial shellfishing permits are subject to conditions imposed by the Division of Marine Fisheries or the Department, including but not limited to the requirement of a Vibrio management plan, or requirements related to participation in the Massachusetts Program for Onboard Screening and Dockside Testing for PSP Toxins in Molluscan Shellfish in Federally Closed Waters, shall comply with requirements of all plans or memoranda of understanding related to such conditions. Failure to comply may result in enforcement action, including coordination with the Division of Marine Fisheries on appropriate enforcement.

(C) Clam Juice.

- (1) Clam juice intended for human consumption shall not be sold or offered for sale without first being pasteurized in a manner and with equipment approved by the Department.
- (2) A timer and thermometer shall be used to insure that the product has been heated sufficiently to destroy pathogens. Records of timer and thermometer calibration shall be maintained for one year.

(D) Wet Storage.

- (1) Wet storage activities shall be conducted in accordance with the Department's administrative guidelines based on the NSSP Model Ordinance.
- (2) Wholesale dealers shall receive written approval from the Department prior to conducting a wet storage activity.

(E) Shucked Shellfish.

- (1) Packing operations shall be conducted in a room separated from other rooms in the facility by suitable full partitions or walls.
- (2) Doors to the packing room shall be self-closing and tight-fitting.
- (3) A shucked shellfish delivery window shall be installed in the partition or wall to the packing room and shall be equipped with a corrosion-resistant shelf that tilts away from the packing room.
- (4) The packing room shall be equipped with a hand-wash sink, adequate hot and cold running water, and a three-compartment sink for ware washing.
- (5) The packing room shall be large enough to permit the thorough cleaning of all equipment.

(F) Sanitary Standard for Shellfish Sold in Massachusetts.

- (1) Sanitary Standard. Any shellfish, fresh or frozen, shall be deemed to meet the sanitary standard for shellfish sold in Massachusetts if:
 - (a) It was harvested from an area approved by the appropriate shellfish control agency, or it was harvested from a restricted area and was subjected to a process of controlled purification ("depuration") approved by the Department; and
 - (b) It meets the Department's administrative guidelines based on the NSSP Model Ordinance standards for fecal and pathogenic contamination.
- (2) Procedure when Shellfish Do Not Comply with Sanitary Standard.
 - (a) When a sample of shellfish is not in compliance with the sanitary standard specified in 105 CMR 500.021(F)(1), the Department may re-sample or cause to be re-sampled shellfish from the same source in order to verify the test result and attempt to ascertain the cause of the problem.
 - (b) If upon re-sampling and retesting, the shellfish again do not comply with the sanitary standard, the Department may undertake one or more of the following:

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1. Issue a warning notice to the person or persons responsible for harvesting, handling, processing, or transporting the shellfish and/or notify the responsible permitting authority;
2. Seize or embargo all shellfish from the same lot as those that have been found not to comply with the sanitary standard; and/or
3. Notify the person or persons responsible for harvesting, handling, processing, or transporting the shellfish that all future lots of shellfish from such person or persons shall be subject to embargo.

(c) The embargo against all shipments specified in 105 CMR 500.021(F)(2)(b)3. shall remain in effect until:

1. Test results obtained from sampling by the Department from two consecutive lots of shellfish, harvested on different days, indicate compliance with the sanitary standard; or
2. Test results obtained from sampling by the responsible out of state shellfish control agency from two consecutive lots of shellfish, harvested on different days, under time and temperature conditions which duplicate transportation and delivery to Massachusetts, indicate compliance with the sanitary standard.
3. In either case specified in 105 CMR 500.021(F)(2)(c)1. or 2., if the shellfish are to be shipped to Massachusetts from out of state, the out of state shellfish control agency shall certify in writing to the Department that the sources of contamination or handling problems causing the failure of the shellfish to comply with the sanitary standard have been identified and corrected.

(3) Prohibition on Sale of Shellfish in Massachusetts.

(a) When the Commissioner of Public Health, upon the recommendation of the Program, finds with respect to shellfish from a particular state or country, which serves as a source of shellfish sold in Massachusetts, that:

1. There is evidence of substantial and continuing noncompliance with the shellfish sanitary standard, or
2. Multiple notices of embargoes have been issued pursuant to 105 CMR 500.021(F)(2)(b), or
3. Epidemiological evidence indicates that illnesses traceable to shellfish from multiple sources within a particular state or country have occurred, or
4. There is other evidence that shellfish from that state or country may pose a danger to public health and that other regulatory initiatives have failed to control the problem, the Commissioner may notify the appropriate shellfish control agency that all shellfish originating from or handled in that state or country shall be prohibited from being sold in Massachusetts.

(b) Prohibitions on the sale of shellfish under 105 CMR 500.021(F)(3)(a) shall continue until the appropriate shellfish control agency in the state or country satisfactorily certifies to the Commissioner that the shellfish distributed in Massachusetts will meet the sanitary standard in 105 CMR 500.021(F)(1). Until such certification has been reviewed and accepted by the Commissioner upon the recommendation of the Program, no shellfish originating from any person in a state or country notified pursuant to 105 CMR 500.021(F)(3)(a) shall be sold in Massachusetts.

(G) Certification for Interstate Shipment.

- (1) In certifying wholesale dealers for listing on the Interstate Certified Shellfish Shippers List (ICSSL), the Department shall follow the procedures in administrative guidelines of the Department based on the NSSP Model Ordinance.
- (2) Only those wholesale dealers who voluntarily request certification, and who meet the standards specified in the Department's administrative guidelines based on the NSSP Model Ordinance for listing on the ICSSL, and who are certified for listing by the Department, shall be allowed to ship shellfish or shellfish products interstate or to another certified dealer within the Commonwealth.
- (3) The Department shall annually certify wholesale dealers for listing on the ICSSL. All certifications shall expire at the end of each calendar year.
- (4) The Department shall certify for listing on the ICSSL for the following calendar year only those wholesale dealers who meet the requirements specified in the Department's administrative guidelines based on the NSSP Model Ordinance.

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(5) Inspection reports and Notices of Violation/Orders to Correct shall constitute *prima facie* evidence of the conditions listed therein.

(6) Wholesale dealers who are removed, either voluntarily or involuntarily, from the ICSSL shall promptly notify their customers and the Department in writing that they are no longer involved in the interstate shipment of shellfish.

(7) Immediate Suspension of an ICSSL Certification without a Prior Hearing. The Department may, without a prior hearing, suspend the ICSSL certification of a certified dealer for any violation or series of violations of the standards established in the Department's administrative guidelines based on the NSSP Model Ordinance, including but not limited to:

- (a) A deficiency or activity that presents an imminent danger to the public health;
- (b) Failure to immediately correct a critical deficiency;
- (c) Failure to submit an approved correction plan in a timely manner;
- (d) Failure to comply with an approved correction plan for a key or critical deficiency in a timely manner;
- (e) Citation for improper tagging; or
- (f) Citation for operation without a proper endorsement.

The Department may end the suspension of the certification at any time if reasons for the suspension no longer exist. In such a case, the Department shall notify the federal program to include the dealer's name in the next available publication.

(8) Refusal to Issue an ICSSL Certification. The Department may refuse to issue an ICSSL certification if the applicant fails to meet the standards for initial certification established in the Department's administrative guidelines based on the NSSP Model Ordinance. These standards include but are not limited to the facts that the applicant must have:

- (a) No critical deficiencies;
- (b) Not more than two key deficiencies; and
- (c) Not more than three other deficiencies.

The initial certification shall include a compliance schedule to correct the deficiencies, if necessary.

(9) Refusal to Renew an ICSSL Certification. The Department may refuse to renew an ICSSL certification if the applicant fails to comply with the standards for certification renewal established in the Department's administrative guidelines based on the NSSP Model Ordinance. These standards include but are not limited to requiring that the applicant:

- (a) Eliminate any critical deficiencies;
- (b) Agree to a compliance schedule which carries forward into the next certification period no more than one key and two other deficiencies identified in previous inspection;
- (c) Address any new key or other deficiencies in a new or revised compliance schedule; and
- (d) Meet the requirements of certification described in the Department's administrative guidelines based on the NSSP Model Ordinance.

Following the refusal to renew the certification, a dealer must meet the requirements of initial certification prior to restoration to the ICSSL.

(10) The Department may refuse to issue or renew an ICSSL certification if the applicant fails to submit an approved correction plan in a timely manner.

(11) The suspension of a permit or of a specific activity of a wholesale shellfish dealer shall automatically result in the immediate suspension of such dealer's ICSSL certification, or certification for the specific activity that was suspended.

(12) The Department may suspend those activities related to shellfish on the dealer's permit whenever the dealer's ICSSL certification is suspended, revoked, or not renewed.

Supplemental Regulations for Meat and Poultry Slaughter and Processing

500.030: General Requirements and Exemptions

(A) All persons who operate a meat or poultry slaughter and/or processing facility shall comply with 105 CMR 500.030 through 500.031.

(1) Included are custom slaughter and custom processing operations, and persons who slaughter or process wild animals that have been raised commercially for wholesale, such as, but not limited to, rabbits, buffalo, deer, elk, and emus. These animals are included in the definition of livestock or poultry, and their products are included in the definition of meat or poultry.

(2) Wild-caught animals such as deer, moose, *etc.* may be processed at a custom facility after notification to the Department as required by 105 CMR 500.031(K)(9)(a).

(B) All persons who slaughter livestock shall comply with federal regulation 9 CFR Part 313: *Humane Slaughter of Livestock*. Ritual slaughter as defined in M.G.L. c. 94, § 139G and the handling or other preparation of livestock for ritual slaughter shall be exempt from this requirement.

(C) All persons who operate a meat or poultry slaughter and/or processing facility shall comply with all applicable federal regulations, including but not limited to 9 CFR Part 416: *Sanitation*.

(D) Pork. All facilities handling pork shall handle it in compliance with the methods prescribed in 9 CFR § 318.10: *Prescribed Treatment of Pork and Products Containing Pork to Destroy Trichinae*.

(E) No person shall slaughter or process livestock, wild-caught animals, or poultry, or operate a meat or poultry slaughter and/or processing facility, without a valid license granted by the Department, or in violation of any of the applicable requirements of 105 CMR 500.000.

(1) Any person applying to the Department for a license shall provide documentation showing either that he or she is currently being inspected by USDA's Food Safety and Inspection Service (FSIS) or is exempt from the requirement of such inspection. No license will be issued in the absence of such documentation.

(2) No person subject to inspection under FSIS may continue to operate if such inspection has been withdrawn by FSIS. Such withdrawal of inspection shall result in the summary suspension of the license, and any hearing requested shall be limited to the issue of whether FSIS withdrew inspection. An affidavit from FSIS shall be *prima facie* evidence of whether FSIS inspection was withdrawn.

(F) Exempt Activities. The slaughtering by an individual of livestock or poultry of his or her own raising on his or her own premises, and the preparation by him or her of the carcasses, parts thereof, and food products of such animals on his or her own premises exclusively for use by him or her and the members of his or her household and his or her nonpaying guests and employees, are exempt from regulation under 105 CMR 500.000, provided that such livestock or poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of food products that are sound, clean, and fit for human food.

(G) Duly authorized inspectors may inspect to confirm that the persons conducting operations that are exempt from regulation are in compliance with the appropriate conditions for exemption provided in 105 CMR 500.030(F).

(H) Exemptions Based on Religious Dietary Laws. Any person who slaughters or processes poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws may apply for exemption from specific provisions of 105 CMR 500.000 which are in conflict with such religious dietary laws.

(I) Notification to the Department. Any person subject to inspection by FSIS must notify the Department immediately when such inspection is withdrawn. After the grant of inspection is withdrawn, such person must notify the Department when the grant of inspection is reinstated.

500.031: Slaughter and Processing Facilities That Are Exempt from USDA Inspection

(A) Any person who operates a custom slaughter and/or processing facility, or a facility that is otherwise exempt from inspection by USDA, shall comply with the additional requirements in 105 CMR 500.031.

(B) Transportation Cages.

- (1) Live animal holding cages shall be thoroughly cleaned and sanitized after each use.
- (2) Live animal holding cages in facilities shall be equipped with waste material catch pans at the bottom of each cage.
- (3) Transportation cages shall be held in an area separate from the processing area within the facility.

(C) Diseased or Injured Animals.

- (1) A licensee may not slaughter an animal for human consumption that appears diseased.
- (2) A licensee shall immediately notify the state veterinarian in the Massachusetts Department of Agricultural Resources of the names and addresses of any individuals who have presented animals for slaughter that exhibit central nervous system abnormalities, signs of foot and mouth disease, or any other reportable animal disease. If such symptoms are encountered, the licensee shall follow the instructions of the state veterinarian with respect to holding the animal for evaluation.
- (3) A licensee may not process any meat or poultry from a carcass that appears diseased.
- (4) A licensee may not slaughter an injured animal unless the animal's owner certifies that the animal is otherwise healthy.
- (5) A licensee may not process any meat or poultry from a carcass that is injured unless the owner of the carcass certifies that the animal was injured shortly prior to slaughter and was otherwise healthy.

(D) Cooling Standards. Products that must be stored under refrigeration shall be handled in accordance with 105 CMR 500.005(G), except that cured products may be cooled in accordance with Food Safety and Inspection Service (FSIS) directives or guidelines.

(E) Inedible Material.

- (1) Receptacles used for handling inedible material shall be of such smooth and impervious material and construction that allows them to be easily cleaned, shall be maintained in a clean condition, shall be conspicuously and distinctively marked "INEDIBLE", and shall not be used for handling any edible product.
- (2) Receptacles for food shall not be used for any non-food materials.

(F) Denaturing.

- (1) Articles that are not intended for use as human food but that could be mistaken for human food shall be denatured prior to their removal from the premises. The denaturing material must be mixed with all of the carcasses or carcass parts to be denatured and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.
- (2) 105 CMR 500.031(F)(1) does not apply to the culling of diseased animals.

(G) Casings.

- (1) The only animal casings that may be used as containers of product are those from cattle, sheep, swine, or goats.
- (2) Casings for products shall be carefully inspected. Only those casings that have been carefully washed and thoroughly flushed with clean water immediately before stuffing are suitable for containers.

(H) Dry milk products which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when produced in a facility approved by USDA.

(I) Hides shall not be stored on the killing floor, nor stored in rooms or compartments used for edible products.

500.031: continued

(J) Poultry Requirements.

- (1) All poultry producers and sellers shall comply with the federal exemptions at 9 CFR § 381.10: *Exemptions for Specified Operations*.
- (2) Poultry shall be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and assure that breathing has stopped prior to scalding. Blood from the killing operation shall be confined to as small an area as possible.
- (3) Non-eviscerated poultry may not be sold, unless under a religious exemption in accordance with 105 CMR 500.030(H).
- (4) In the final washing of eviscerated poultry, the carcass shall be thoroughly rinsed with clean water under pressure.
- (5) All offal resulting from the evisceration operation shall be removed from the facility as often as necessary to prevent the development of an unsanitary condition. Offal shall be disposed of in a manner consistent with environmental laws and regulations and/or by a method approved by the Department.
- (6) Containers to be used for packaging poultry products shall be clean, free from substances and odors that would result in adulteration of the products, and of sufficient strength and durability to protect the products adequately during normal distribution.
- (7) Protective coverings shall be used for poultry products while they are in any facility or are being transported between facilities, which are adequate to protect the products against contamination by any foreign substances (including but not limited to dust, dirt, and insects).

(8) Temperatures and Chilling and Freezing Procedures.

- (a) Temperatures and procedures for chilling and freezing ready-to-cook poultry, including all edible portions thereof, shall insure the prompt removal of the animal heat, shall preserve the condition and wholesomeness of the poultry, and shall assure that the products are not adulterated.

(b) General Chilling Requirements.

1. All poultry that is slaughtered and eviscerated in the facility shall be chilled immediately after processing so that the internal temperature is reduced to 40°F or less within four hours, unless such poultry is to be frozen or cooked immediately at the facility. Poultry which is to be held at the facility in packaged form in excess of 24 hours shall be held under mechanical refrigeration at a temperature of 40°F or less.
2. Continuous chillers shall not be used unless a recording thermometer, with a 24-hour recording cycle, is provided to measure the temperature in the warmest part of the chilling system. The temperature recorder shall be readily accessible. The completed temperature charts shall be kept on file at the facility.
3. Previously chilled poultry carcasses and major portions shall be maintained constantly at 40°F or below until removed from the vats or tanks for immediate packaging.
4. Poultry which is to be held in chilling tanks in excess of 24 hours shall at the end of the 24-hour chilling period be removed from the tanks and repacked in clean ice and in clean tanks which are continually drained, or as an alternative, the tanks shall be drained and re-iced and placed in a cooler which will maintain all of the poultry in the tanks at a temperature of 40°F or below.
5. Ready-to-cook poultry shall be adequately drained after chilling, to remove ice and free water prior to packaging or packing.
6. When poultry is ice-packed in barrels or other containers, the barrels and containers shall be covered.

(c) Thawing Poultry in Water. When frozen ready-to-cook poultry is thawed in water, the thawing practices and procedures shall prevent the product from becoming adulterated.

(d) Air Chilling. Facilities that air chill raw poultry shall comply with USDA directives for ready-to-cook poultry.

(e) Freezing.

1. Ready-to-cook poultry which is to be or is labeled with descriptive terms such as "fresh frozen," "quick frozen," "frozen fresh," or any other term implying a rapid change from a fresh state to a frozen state shall be placed into a freezer within 48 hours after initial chilling.

500.031: continued

2. Ready-to-cook poultry shall be frozen in a manner so as to bring the internal temperature of the birds at the center of the package to 0°F or below within 72 hours from the time of entering the freezer.

3. Frozen poultry shall be held under conditions that will maintain the product in a solidly frozen state.

(9) Requirements for Use of Mobile Poultry Processing Unit.

(a) Any person who slaughters and/or processes poultry for sale using a mobile poultry processing unit (MPPU) shall comply with all written protocols of the Department for use of the unit.

(b) MPPUs are not considered facilities for the purposes of 105 CMR 500.000, but any person who operates a MPPU is required to be licensed.

(10) Any person who slaughters and/or processes poultry for sale in a small on-farm processing operation under a USDA exemption shall comply with all written protocols of the Department for such activities.

(K) Additional Requirements for Custom Slaughter and/or Processing Facilities.

(1) Persons who operate a custom meat or poultry slaughter and/or processing facility shall comply with all federal requirements applicable to such operations, including but not necessarily limited to those specified in 9 CFR 303.1: *Exemptions*.

(2) A licensee of a custom slaughter and/or processing facility, who makes available to customers live animals for slaughtering at the facility, must maintain a certificate attesting to the health of the animals, in addition to a record of the source from which the animals were obtained. This includes animals secured from live animal auctions, whether the animals are donated to or made available for purchase to the customer. Such records must be kept on file at the facility and shall be made available to the customer and inspectors upon request.

(3) Live animals purchased at live animal auctions without a health certificate shall be slaughtered within three days.

(4) Custom slaughter facilities may not release certain portions of slaughtered cattle considered to be Specified Risk Materials (SRM) that may present a risk of transmitting Bovine Spongiform Encephalopathy (BSE). These parts are considered "inedible" and are:

(a) For all cattle: tonsils.

(b) For cattle 30 months of age and older: the head including the skull, and the vertebral column.

(5) The licensee shall at all times keep products for sale separate and apart from custom slaughtered and custom processed products.

(6) Custom prepared products or their containers shall be plainly marked "Not for Sale."

(7) The licensee shall keep records sufficient to carry out a product recall pursuant to 105 CMR 500.005(K), showing the numbers of animals, dates of slaughter, and kinds of animals slaughtered on a custom basis; the quantities and types of products prepared on a custom basis; and the names, addresses, and telephone numbers of the owners of the animals.

(8) Articles resulting from custom slaughter or custom processing that are not intended for use as human food but that could be mistaken for human food shall be promptly denatured as provided in 105 CMR 500.031(F), or otherwise identified, and not removed from the facility until so denatured or identified, unless they are delivered to the owner of the articles.

(9) Processing of Wild Game. A licensee who custom processes wild game for the game owner shall comply with all of the following.

(a) The licensee shall notify the Department that he or she is engaged in or intends to engage in the processing of wild game.

(b) The operator shall accept only legally harvested, clean, and wholesome wild game carcasses for custom processing.

(c) The operator, when custom processing wild game, shall comply with processing, labeling, and record-keeping requirements applicable to the custom processing of other animals. Among other things, the operator shall label all of the resulting wild game products, "Not for Sale." Wild game products shall be clearly identified by species.

(d) The operator shall process wild game only at times when the operator is not slaughtering or processing other animals.

(e) The operator shall clean and sanitize equipment used to process wild game before using that equipment to slaughter or process animals for sale.

(f) The operator shall keep wild game and wild game products separate from all other meat, poultry, meat food products, and poultry food products in the facility.

Supplemental Fluid Milk and Milk Products Regulations

500.060: General Requirements

(A) Requirements for pasteurization of dairy products shall be established as administrative guidelines by the Department, based on the Grade "A" Pasteurized Milk Ordinance (PMO) published by the United States Department of Health and Human Services. All pasteurization plants in Massachusetts, as well as all facilities in Massachusetts that produce milk products, butter, or cheese, shall comply with the administrative guidelines. Excluded from the pasteurization requirements is the production of cheese made from unpasteurized milk, which must be aged a minimum of 60 days.

(B) No person shall operate a pasteurization plant without a valid license granted by the board of health or in violation of any of the requirements specified in 105 CMR 500.000.

500.061: Laboratory and Analyst Certification

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, Grade A condensed or dry milk products, and Grade A condensed or dry whey. Such certification shall be accomplished in accordance with administrative guidelines of the Department based on the standards and procedures described in *Evaluation of Milk Laboratories, Recommendations of the United States Department of Health and Human Services, Public Health Service/Food and Drug Administration*.

500.062: Examination of Milk and Milk Products for Vitamin and Mineral Fortification

(A) Sampling. Each pasteurization plant that adds vitamins or minerals to milk or milk products shall have at least two assays made per year, at approximately six month intervals. It shall be the responsibility of the pasteurization plant to provide for the submission and shipment of samples and payment for testing to a laboratory approved by the Department pursuant to 105 CMR 500.062(C).

(B) Approved Methods for Laboratory Testing. Samples for assay shall be analyzed at a laboratory approved by the Department using methods prescribed by administrative guidelines of the Department based on the *Association of Official Analytical Chemists' Official Methods of Analysis*, 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 500.062(A) shall be forwarded to the Department by the 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 be forwarded to the Department by such laboratory within ten days of obtaining test results.

(C) Approval of Milk Laboratories. Any person who desires to have his or her laboratory approved by the Department as a milk laboratory 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 that the tests will be conducted in accordance with administrative guidelines of the Department based on methods prescribed by the *Association of Official Analytical Chemists' Official Methods of Analysis*, 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".

500.062: continued

(D) Enforcement.

- (1) Whenever vitamin or mineral assay results indicate that fortification levels are not within the fortification levels required by 21 CFR § 131.110: *Milk*, 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 shall be resubmitted by the pasteurization 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 the approved laboratory. Results of these tests shall also be forwarded to the Department by the laboratory within ten days of obtaining test results.
- (2) Whenever the pasteurization plant fails to comply with requirements set forth in 105 CMR 500.062(D)(1), the Department may initiate proceedings to suspend or revoke the license.

500.063: Grade A Milk and Milk Products Which May Be Sold from Outside Massachusetts

Grade A milk and milk products from pasteurization plants outside Massachusetts may be sold or served within Massachusetts if such Grade A milk and milk products comply with the standards set forth in the PMO.

500.064: Review of Plans for Construction or Remodeling of a Pasteurization Plant, 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 Department for approval before such work is begun. No work shall be started until approval is granted.

(B) After the work has been completed, the Department shall inspect the pasteurization plant prior to the start of operations to ascertain compliance with the approved plans and specifications and with the requirements of 105 CMR 500.000.

500.065: Certification for Interstate Shipment

(A) In certifying pasteurization plants for listing on the Interstate Milk Shippers List (IMS List), the Department shall follow the procedures in administrative guidelines of the Department based on:

- (1) *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*, published by the U. S. Department of Health and Human Services, the U. S. Public Health Service, the U. S. Food and Drug Administration, and the National Conference on Interstate Milk Shipments; and
- (2) *Methods of Making Sanitation Ratings of Milk Shippers*, published by the U.S. Public Health Service and the U.S. Food and Drug Administration.

(B) Only those pasteurization plants that voluntarily request listing on the IMS list, that meet the standards specified in the Department's administrative guidelines based on the PMO for inclusion on the IMS List, and that are certified for listing by the Department shall be allowed to ship Grade A milk or milk products interstate.

(C) Every two years, the Department shall rate pasteurization plants for inclusion on the IMS List.

(D) The Department shall certify for listing on the IMS List only those pasteurization plants that meet the Department's administrative guidelines based on the PMO.

(E) Inspection reports and Notices of Violation/Orders to Correct shall constitute *prima facie* evidence of the conditions stated therein.

500.065: continued

(F) Enforcement Procedures Related to IMS Listing.

- (1) The Department shall follow the procedures in its administrative guidelines specified in 105 CMR 500.065(A) when withdrawing a pasteurization plant's certification for listing on the IMS List.
- (2) Pasteurization plants that are removed, either voluntarily or involuntarily, from the IMS List shall promptly notify their customers in writing that they are no longer involved in the interstate shipment of Grade A milk or milk products.

Supplemental Regulations for Manufacturers of Frozen Desserts, Frozen Dessert Mixes, Butter, and Cheese

500.080: Exemption for Retail Manufacture of Non-milk-based Frozen Desserts

(A) A person who operates a retail machine for the manufacture of non-milk-based frozen desserts only, including but not limited to so-called slush or water ice, shall obtain a permit pursuant to 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments*. Such a permit, when valid, shall be deemed to satisfy the requirements of 105 CMR 500.000, and no separate license pursuant to 105 CMR 500.000 shall be required.

(B) If such person already has a valid permit pursuant to 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments* because he or she operates a food establishment, no separate permit for non-milk-based frozen desserts shall be required.

500.081: General Requirements

(A) Regulated Activities.

- (1) Persons who engage in any of the following activities shall comply with 105 CMR 500.081 through 500.083, as appropriate, in addition to 105 CMR 500.004 through 500.008.
 - (a) Manufacturing frozen desserts or frozen dessert mix within Massachusetts;
 - (b) Manufacturing frozen desserts or frozen dessert mix outside Massachusetts and selling such product(s) within Massachusetts;
 - (c) Manufacturing butter within Massachusetts for wholesale; or
 - (d) Manufacturing cheese within Massachusetts for wholesale.
- (2) Out-of-state Frozen Dessert License Applicants. With its application for a license, an out-of-state applicant for a license to manufacture and sell frozen desserts in Massachusetts shall also submit a copy of its license, permit, or certification received from the out-of-state regulatory agency having jurisdiction.

(B) License. No person shall engage in any activity listed in 105 CMR 500.081(A)(1) without a valid license or in violation of any of the requirements specified in 105 CMR 500.000. The following licenses are required.

- (1) A person who manufactures frozen desserts or frozen dessert mix within Massachusetts for sale at wholesale or retail must hold a license (which may be called a permit) issued by the board of health pursuant to M.G.L. c. 94, § 65H.
- (2) A person who manufactures frozen desserts or frozen dessert mix outside Massachusetts and sells such products in Massachusetts must hold a license issued by the Department pursuant to M.G. L. c. 94, § 65H.
- (3) A person who manufactures butter or cheese in Massachusetts for sale at wholesale in a facility separate from a pasteurization plant (*i.e.* does not hold a license under M.G.L. c. 94, § 48A) must hold a license issued by the Department pursuant to M.G. L. c. 94, § 305C.

(C) Pasteurization.

- (1) Manufacturers of frozen desserts, frozen dessert mixes, butter, and cheese shall comply with the relevant sections of the Department's administrative guidelines based on the PMO, except that manufacturers of cheese made from unpasteurized milk shall comply with all relevant sections of the guidelines except the pasteurization requirements.

500.081: continued

(2) Any milk-based ingredient used in the manufacture of frozen desserts shall be pasteurized in compliance with the guidelines.

(D) Requirements for Ingredients.

(1) All raw milk and cream shall be obtained from a farm or facility licensed or permitted by the appropriate governmental authority in the jurisdiction.

(2) No milk or cream from a source outside the United States, subject to the Federal Import Milk Act, 21 U.S.C. § 141 *et seq.*, shall be used in the manufacture of frozen desserts, frozen dessert mixes, butter, or cheese unless the importer has documentation to show that the exporter is in compliance with 21 CFR Part 1210: *Regulations Under the Federal Import Milk Act*. The manufacturer shall maintain adequate documentation of such compliance for at least two years.

(3) Manufacturers that receive any milk or milk product in bulk form shall pasteurize it before using it in the manufacturing process, even if it has been previously pasteurized, except that this requirement shall not apply to milk or milk products received in:

(a) A tanker that provides written documentation to the facility that:

1. The tanker is dedicated to fluid milk products;
2. The tanker has been properly washed and sanitized; and
3. The load has been previously pasteurized; or

(b) A single service container of five gallons or less whose contents have been pasteurized; or

(c) Any other container and/or system approved by the Department following submission of a written plan by the facility.

(4) Fats and oils other than from milk used in frozen desserts shall conform to the applicable provisions of the United States Food, Drug and Cosmetic Act.

(5) Dry whole milk, nonfat dry milk, dry whey, or dry buttermilk, when used as an ingredient in a frozen dessert, shall be USDA Extra Grade or its equivalent.

(E) Reprocessing and Resale.

(1) Spilled products and ingredients shall be discarded.

(2) Product intended for reprocessing shall be handled in sanitary covered containers and stored at or below 45°F (7.2°C) or shall be piped directly back to vats.

(3) Frozen dessert mix that has been strained to remove nuts, fruit, or other ingredients shall be re-pasteurized. If such mix contained a major food allergen, it shall be used only as mix for products that contain the same allergen.

(4) Products that have left the possession of the manufacturer shall not be reprocessed.

(F) Daily Cleaning and Sanitizing.

(1) Processing and Filling Equipment. Any manufacturer that wishes to operate processing or filling equipment for longer than one production day between cleaning and sanitizing the equipment shall apply to the Department for a variance pursuant to 105 CMR 500.212, and shall explain in the variance application how product safety will be maintained.

(2) Silos and Holding Tanks.

(a) Any manufacturer that wishes to use any silo or holding tank containing pasteurized or unpasteurized ingredient or product for longer than the time allowed by the Department's administrative guidelines based on the PMO between cleaning and sanitizing shall apply to the Department for a variance pursuant to 105 CMR 500.212, and shall explain in the variance application how product safety will be maintained.

(b) Any silos or holding tanks put into service after September 26, 2003 shall be equipped with a seven-day temperature recording device.

(3) Soft-serve Machines. The operator of any soft-serve machine shall comply with the machine manufacturer's instructions with respect to cleaning and sanitizing.

(G) Temperatures for Raw and Finished Products.

(1) All milk and milk products used as ingredients in frozen desserts, frozen dessert mixes, butter, or cheese shall be received, stored, and shipped so as to ensure that the internal temperature does not exceed 45°F (7.2°C).

(2) All finished frozen dessert products, excluding products produced in a soft-serve machine, shall be received, stored, and shipped so as to ensure that the internal product temperature does not exceed 10°F.

500.081: continued

(3) All finished butter and pasteurized cheese products shall be received, stored, and shipped so as to ensure that the internal temperature does not exceed 45°F (7.2°C).

(H) Aged Cheese. Non-pasteurized cheese shall be aged for a minimum of 60 days.

500.082: Testing Requirements; Enforcement

(A) Raw Milk to be Used in Frozen Desserts, Frozen Dessert Mixes, Butter, or Cheese.

(1) Drug Residues.

(a) All manufacturers shall test for drug residues, or have evidence of a previous test for drug residues, on all incoming unpasteurized milk and milk products received for processing into frozen desserts, frozen dessert mixes, butter, or cheese.

(b) Drug residue tests shall be performed as required by the Department's administrative guidelines based on the PMO.

(c) The manufacturer shall not use any item tested until it receives a negative test result, provided that when drug residues have been found in a second sample of raw milk or a raw milk product, the manufacturer shall destroy such milk or milk product.

(d) Any positive drug residue test shall be reported to the Department of Agricultural Resources.

(e) Whenever a drug residue test is confirmed positive, the manufacturer shall investigate to determine the cause, and shall correct the cause in accordance with the guidelines.

(2) Pesticide Residues.

(a) Pesticide residue tests are performed by federal agencies on a non-routine basis.

(b) Whenever a pesticide residue test is positive, the manufacturer shall investigate to determine the cause, and shall correct the cause. No product shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the levels established by law for such residues.

(B) Finished Products Testing Requirements for Manufacturers of Frozen Desserts.

(1) Phosphatase.

(a) Phosphatase tests are performed by the Department on samples that are collected routinely.

(b) Whenever a phosphatase test is positive, the manufacturer shall investigate to determine the cause. Where the cause is improper pasteurization, it shall be corrected and any product involved shall not be offered for sale.

(2) All manufacturers manufacturing finished frozen dessert products by means other than a soft-serve machine shall have the tests specified in 105 CMR 500.083(F) performed by a laboratory approved by the Department of each of the following categories of finished products at least once a month:

(a) Plain frozen dessert (vanilla, chocolate, coffee, *etc.*);

(b) Fruits and variegated (strawberry, frozen pudding, raspberry royale, *etc.*);

(c) Nuts and candy (maple walnut, butter crunch, *etc.*);

(d) Sherbet;

(e) Novelties (spumoni, dixies, sandwiches, *etc.*);

(f) Seasonal products (products manufactured during only part of the year); and

(g) Frozen yogurt, except that if live cultures have been added to the product after pasteurization, the test for bacterial limit shall not be required.

If the flavors listed in each of these categories can be practically rotated, the tests shall be made on that basis.

(3) New Products. Any new frozen dessert product, including a new flavor of any frozen dessert, shall be placed in the appropriate category specified in 105 CMR 500.082(B)(2) and shall have priority for testing.

(4) All manufacturers of frozen desserts produced in a soft-serve machine shall have the tests of its finished product specified in 105 CMR 500.083(F) performed by a laboratory approved by the Department at least once a month.

(5) Copies to be Submitted by In-state Manufacturers. The manufacturer shall ensure that copies of all test results for required tests are submitted directly to the board of health by the laboratory within three business days of completion of the tests.

500.082: continued

(6) Notification Regarding Laboratory. Each manufacturer of a frozen dessert or frozen dessert mix shall notify the board of health in writing of the name and address of the laboratory where the tests required by 105 CMR 500.083 are done. When the manufacturer ceases to use a particular laboratory, he or she shall immediately notify the board of health in writing of the name and address of the new laboratory that is to be used.

(C) Sampling and Testing after a Bacterial Violation is Found: Frozen Desserts Produced by Means Other than a Soft-Serve Machine. Whenever any sample tested pursuant to 105 CMR 500.082(B)(1), (2) or (3) is found to be in violation of the bacterial limit or coliform standard in 105 CMR 500.083(F), the manufacturer shall re-sample and retest each subsequent production run of the finished product originally found in violation (*e.g.* vanilla, chocolate, *etc.*) until three consecutive non-violative samples are obtained.

(D) Enforcement of Bacterial Standards: Frozen Desserts and Frozen Dessert Mixes.

(1) Whenever two of the last four consecutive tests for bacterial limit counts or coliform determinations (except those for aseptically processed products), taken on separate days (different production days), exceed the limit of the standard specified in 105 CMR 500.083(D), (E), or (F), the board of health or the Department, as appropriate, shall send a written notice thereof to the licensee. This notice shall also inform the licensee of the provisions of 105 CMR 500.082(D)(2), and shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard.

(2) Whenever a standard specified in 105 CMR 500.083(D), (E), or (F) has been violated by three of the last five consecutive tests for bacterial limit or coliform determinations (except those for aseptically processed products), taken on separate days (different production days), the board of health or the Department, as appropriate, shall immediately suspend the license or one or more particular operations, or the sale of one or more particular products, without prior notice or hearing, in accordance with 105 CMR 500.207(B).

(3) When the license or operation(s) are suspended as provided in 105 CMR 500.082(D)(2), the following procedures shall be followed.

(a) The manufacturer shall provide to the board of health and the Department documentation showing:

1. The cause of the violative condition; and
2. The plan of correction used to correct the violative condition.

(b) After receipt of the documentation specified in 105 CMR 500.082(D)(3)(a):

1. The Department shall collect samples and conduct laboratory analyses to determine if the condition(s) have been corrected, and
2. An inspection shall be made. If it is determined that the condition(s) responsible for the violation(s) has been corrected, the board of health or Department shall reinstate the license, or allow the resumption of operation(s), or the sale of suspended product(s).

(E) Violation of Standards: Soft-serve Machines. Whenever any sample from a soft-serve machine tested pursuant to 105 CMR 500.082(B)(2)(a) is found to be in violation of the bacterial limit or coliform standard in 105 CMR 500.083(F), the machine operator shall thoroughly clean, rinse, and sanitize the machine and shall test the first product produced by the machine after cleaning. The machine may be operated until the result of the confirmatory test is received. If such test shows a violation, production must stop and further cleaning, sanitizing, and testing must be done. No product may be sold or distributed in any way until the result of the subsequent test meets the standards in 105 CMR 500.083(F).

500.083: Chemical, Physical, Bacteriological, and Temperature Standards

The items listed in 105 CMR 500.083: *Table 1* shall comply with the standards specified.

TABLE 1

(A) Grade "A" raw milk for pasteurization for use for butter or cheese (not frozen desserts)	Drug residues	No positive results as specified in administrative guidelines of the Department
	Pesticide residues	No positive results
	Freezing point	0.530 H maximum
(B) Grade "A" raw milk for pasteurization for use for frozen desserts	Bacterial limits	Not to exceed 100,000 per ml for individual supplies. Not to exceed 300,000 per ml for commingled milk.
	Somatic cell count	Not to exceed 750,000 per ml
	Drug residues	No positive results as specified in administrative guidelines of the Department
	Pesticide residues	No positive results
(C) Butter, whipped butter	% Butterfat	Not less than 80%
	Temperature	Maintained at a temperature of 45°F (7.2°C) or less when in storage
	Proteolytic count	Not more than 50 per gram
	Yeast and mold	Not more than ten per gram
	Coliform count	Not more than ten per gram
	Keeping quality	Satisfactory after seven days at 70°F (21°C)
(D) Pasteurized milk, cream, and other fluid dairy products for use for frozen desserts	Bacterial limit	Not to exceed 20,000 per ml
	Coliform count	Not to exceed ten per gram, except in the case of bulk milk transport tank shipments not to exceed 100 per ml.
	Storage temperature	No higher than 45°F (7.2°C)
(E) Frozen dessert mix	Bacterial limit	30,000 per ml
	Coliform count	Not to exceed ten per gram, except in the case of bulk milk transport tank shipments not to exceed 100 per ml.
	Storage temperature	No higher than 45°F (7.2°C), except that sterile or aseptic mix has no storage temperature requirement.
(F) Frozen desserts	Bacterial limit	30,000 per ml
	Coliform count	Other than soft-serve: not to exceed 20 per gram Soft-serve: not to exceed 50 per gram
	Storage temperature	No higher than 10°F (-12°C)
	Milkfat	Standards listed in 21 CFR Part 135
(G) Private water supplies for milk pasteurization plants; Recirculated cooling water (sweet water);Glycol for cooling	Coliform count	than 1.1 per 100 ml as MPN or equivalent method less than 1 per 100 ml

Supplemental Regulations for the Manufacture, Collection, Bottling, and Labeling of Bottled Water and Carbonated Non-alcoholic Beverages

500.090: General Requirements

(A) No person within Massachusetts shall manufacture or bottle carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption without a license issued by the board of health or in violation of the terms of the license or any of the requirements specified in 105 CMR 500.000.

(B) No person engaged outside Massachusetts in the business of manufacturing or bottling carbonated non-alcoholic beverages or water, whether carbonated or non-carbonated, for human consumption shall sell any such product in Massachusetts without a license issued by the Department or in violation of the terms of the license or any of the requirements specified in 105 CMR 500.000.

(C) No person shall use water from a particular water source in bottling bottled water or carbonated non-alcoholic beverages unless that source and any treatment of that source have a current approval from the Department or the relevant out-of-state jurisdiction.

(D) No person shall sell or exchange, deliver, advertise, or offer for sale or exchange any bottled water or carbonated non-alcoholic beverage unless the manufacturer and bottler of such product hold a valid license from the board of health or the Department.

(E) All persons who manufacture or bottle bottled water, whether carbonated or non-carbonated, for human consumption shall comply with all applicable federal regulations, including but not limited to the following sections of the federal regulation 21 CFR Part 129: *Processing and Bottling of Bottled Drinking Water*:

- (1) Subpart A - *General Provisions*;
- (2) Subpart B - *Buildings and Facilities*, sections 129.20, 129.35(a)(4)(iii), and 129.37;
- (3) Subpart C - *Equipment*; and
- (4) Subpart E - *Production and Process Controls*.

(F) All persons who manufacture or bottle carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption shall comply with all applicable federal regulations, including but not limited to the following sections of federal regulation 21 CFR Part 165: *Beverages*:

- (1) Subpart A, section 165.3 - *Definitions*, for both bottled water and carbonated non-alcoholic beverages; and
- (2) Subpart B - *Requirements for Specific Standardized Beverages*, except that bottled water that does not comply with a standard of identity in 21 CFR § 165.110(a) may not be marketed in Massachusetts, unless approved by the Department.

(G) Multi-use Equipment. Water intended for bottling water or carbonated non-alcoholic beverages shall not be stored, transported, processed, or bottled through equipment or lines used for any dairy product, except that filling equipment may be used for dairy products in accordance with the following requirements.

- (1) When filling equipment designed for cleaning in place is utilized for dairy products or non-beverage foods, such equipment shall be thoroughly cleaned and sanitized in place in accordance with procedures specified by the manufacturer and in 21 CFR Part 129: *Processing and Bottling of Bottled Drinking Water* prior to being used for bottled water or carbonated non-alcoholic beverages.
- (2) Fillers not designed for cleaning in place shall be completely disassembled for cleaning and sanitizing prior to being used for bottled water or carbonated non-alcoholic beverages.

(H) Ozone.

- (1) Where ozone is used as a germicidal agent, all gaskets, o-rings, and similar flexible material shall be made of silicone rubber, Teflon, or other ozone resistant material. These flexible parts shall be replaced whenever they show evidence of surface deterioration.
- (2) If ozone is used as an antimicrobial disinfectant in the bottling process, it shall be used as specified in 21 CFR Part 184: *Direct Food Substances Affirmed as Generally Recognized as Safe*.

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(I) Additional Labeling Requirements for Bottled Water. In addition to the labeling requirements of 105 CMR 500.006(A), all bottled water shall comply with the following labeling requirements.

- (1) Source. The label shall state:
 - (a) The type of water source (such as well, spring);
 - (b) The location of the water source: municipality, state, and country if not the United States;
 - (c) When bottled water comes from a community water system, as defined in 40 CFR § 141.2, except when it has been treated to meet the definition(s) in 21 CFR § 165.110 (a)(2)(iv) (purified water/purified drinking water) or 21 CFR § 165.110(a)(2)(vii) (sterile water) and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, in type size at least $\frac{1}{2}$ the size of the statement of identity but in no case less than one sixteenth of an inch; and
 - (d) If more than one water source is used in the final product, the label shall clearly state the type and location of all water sources used.
- (2) Spring. The term "spring", "springs" or "spring water" shall not be used as a product name or a brand name on a label unless the water source meets the definition of spring water in 21 CFR § 165.110(a)(2)(vi).

500.091: Water Source Protection, Treatment, and Modification for Bottled Water and Carbonated Non-alcoholic Beverages

(A) In-state Sources.

- (1) Each water source shall comply with 310 CMR 22.00: *Drinking Water*, with any applicable Massachusetts Department of Environmental Protection (DEP) water supply health advisories or guidelines, and, if applicable, with M.G.L. c. 21G.
- (2) The Department and DEP shall cooperate in the approval, inspection, and enforcement of requirements for in-state water sources, pursuant to the terms of the current Memorandum of Understanding (MOU) between the Department of Public Health and the Department of Environmental Protection for In-state Bottled Water Source Review.
- (3) Each water source shall be located, developed, and protected to ensure that it is not subject to natural or artificial contamination. If necessary, source water may be treated in order to control natural or artificial contamination. Source water treatment must be approved in accordance with 105 CMR 500.091(A)(4) and (5).
- (4) Before a water source is used or substantially modified, or the source water is treated or the treatment is substantially modified, or a new source is used in addition to the existing approved source(s), the source owner shall apply to the Department for approval and shall submit information as required by the application form, including but not limited to:
 - (a) The type of source (e.g. well, spring);
 - (b) A detailed location of the source;
 - (c) The owner(s) of the source;
 - (d) Information about the use and treatment of the source and/or the modification of the source or treatment;
 - (e) If the source is a public water system, the information specified in 105 CMR 500.093(A)(1)(c); and
 - (f) If the source is not a public water system, the information specified in 105 CMR 500.093(A)(1)(a), and subject to the requirements of 105 CMR 500.093(A)(1)(b).
- (5) The Department will forward that portion of the application relating to the water source to DEP. Based on DEP's recommendation and in accordance with current law, the Department shall notify the owner whether the following are approved:
 - (a) The water source;
 - (b) Substantial modification to the water source;
 - (c) Treatment to bring source water into compliance with the quality standards in 105 CMR 500.092(A); and/or
 - (d) Substantial modification to source water treatment.If the Department determines that approval is not appropriate, it shall notify the owner of the modifications that are necessary in order for approval to be granted.

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(6) Prior to the sale of products using any new or substantially modified source or new or substantially modified treatment, the bottler shall submit the following information to the Department:

- (a) One label for each container size and brand name of the product that is proposed to be sold; and
- (b) If the source is not a public water system, or if the source is a public water system that the bottler treats beyond the definition of minimal treatment, *i.e.*, beyond mechanical filtration and/or disinfection, the results of a complete chemical, physical, microbiological, and radiological analysis of the source water and of each of the different finished products bottled by the facility, as specified in 105 CMR 500.093(A). The analyses shall have been completed within the 12 months prior to the first use of the new or modified source water or treatment, with the exception of the microbiological analysis, which shall have been performed within the four weeks prior to the first such use.

(7) The bottler shall not sell products manufactured with water from the new or substantially modified source or new or substantially modified treatment until written approval is received from the Department.

(8) The bottler may use water from a particular water source in bottling bottled water or carbonated non-alcoholic beverages only when that source and any treatment of that source have a current approval from the Department.

(B) Enforcement Actions with Respect to a Water Source.

- (1) The Department may issue an Order to Cease and Desist or summarily suspend approval of the water source if there is a reasonable likelihood that continued use of the water source presents an imminent danger to the public health. An Order to Cease and Desist shall be as specified in 105 CMR 500.206, and summary suspension shall be as specified in 105 CMR 500.207(B), except that all references to "license" and "licensee" shall be replaced by "source approval" and "source owner;" and all references to "facility" shall be replaced by "water source."
- (2) The Department may refuse to grant, suspend with notice, or revoke approval of a water source if the water source fails to comply with any DEP requirement or with any applicable requirement of 105 CMR 500.000. Such refusal, suspension, or revocation shall be as specified in 105 CMR 500.207(A) or (C), except that all references to "license" and "licensee" shall be replaced by "source approval" and "source owner;" and all references to "facility" shall be replaced by "water source."
- (3) The Department has the authority to commence enforcement proceedings against a water source pursuant to 105 CMR 500.206 through 500.208 in the case of violations with respect to the use or substantial modification of the water source, or treatment or substantial modification of treatment of source water.
- (4) If the approval of the water source is subject to condition(s), the Department may enforce the conditions by issuing an order or by commencing an administrative enforcement action.

(C) Out-of-state and Foreign Sources.

- (1) Out-of-state and foreign water sources shall be licensed or approved by the government agency having jurisdiction, if such jurisdiction issues such licenses or approvals. A copy of the current such license or approval shall be provided to the Department by the bottler upon application and reapplication for a license, and upon substantial modification of the source or source treatment, or upon the addition of a new source. Additional information, including but not limited to hydro-geological reports on source development, site plans, and the like may also be required.
- (2) All bottlers who use an out-of-state or foreign water source shall provide documentation to the Department from the appropriate government agency regarding the type of water source to be used in finished products, as specified in 21 CFR 165.110: *Bottled Water* (*e.g.* well, spring, *etc.*). In foreign countries where no such government approval process is available, the company shall provide hydro-geological reports, photographs, and any other documentation requested, in English, to facilitate determination of the type of source as specified in 21 CFR 165.110. The Department will determine the type of source after review of the information provided.

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(3) Prior to the sale of products using any new or substantially modified source or new or substantially modified treatment, the bottler shall submit to the Department the information specified in 105 CMR 500.091(A)(4) and (6).

(4) The bottler shall not sell products manufactured with water from the new or substantially modified source or new or substantially modified treatment until written approval is received from the Department.

(D) Maintenance of Records. At all times, the facility shall maintain current records of approval of the source water by the government agency having jurisdiction.

500.092: Quality Standards for Bottled Water and Carbonated Non-alcoholic Beverages

(A) Source Water. All source water shall comply with applicable requirements of 310 CMR 22.00: *Drinking Water*, promulgated by DEP, and with any additional maximum contaminant levels promulgated by EPA and in effect. Source water may be treated to reduce the level of a contaminant or drinking water constituent.

(B) Finished Products: Bottled Water.

(1) The finished product shall conform to the standards of quality in 21 CFR § 165.110(b).
(2) Finished products, the quality of which is below that prescribed by any standard of quality in 21 CFR § 165.110(b) (*i.e.* substandard products), shall not be sold or distributed in any manner in Massachusetts.

500.093: Sampling and Testing Requirements for Bottled Water and Carbonated Non-alcoholic Beverages

(A) Sampling and Testing Procedures.

(1) Source Water. 105 CMR 500.093(A)(1) applies to both bottled water and carbonated non-alcoholic beverages, except that 500.093(A)(1)(d) applies only to bottled water.

(a) The raw water from the source shall be sampled immediately after it is withdrawn from the source, and analyzed to characterize its microbiological, physical, radiological, and chemical quality. If any of the analyses show the water not to be in compliance with the quality requirements specified in 105 CMR 500.092(A), the water shall be treated to meet the requirements of 105 CMR 500.092(A) and shall be tested after treatment. Sampling and analysis shall be performed as often as necessary, but at a minimum frequency of:

1. Once each year for chemical and physical contaminants;
2. Once every four years for radiological contaminants, or as otherwise specified by the Department; and
3. Once each week for microbiological contaminants.

(b) All analyses shall be conducted by an approved water-testing laboratory in accordance with the testing and methodological requirements specified by EPA's National Primary and Secondary Drinking Water Regulations (40 CFR Parts 141 and 143).

(c) Facilities that use a public water system for source water, without treatment or with only minimal treatment, may satisfy the testing requirements of 105 CMR 500.093(A)(1)(a) and (b) by substituting public water system testing results, or copies of certificates showing full compliance with relevant provisions of the EPA regulations in 40 CFR Parts 141: *National Primary Drinking Water Regulations* and 143: *National Secondary Drinking Water Regulations*. Any additional treatment of the source water from a public water system beyond the definition of minimal treatment, *i.e.*, beyond mechanical filtration and/or disinfection, shall require source water analysis pursuant to 105 CMR 500.093(A)(1)(a) and (b); and for bottled water only, submission of results pursuant to 105 CMR 500.093(A)(1)(d).

(d) Bottled Water Only: Each facility shall submit a signed copy of the results from the approved water-testing laboratory of all analyses of its source water as specified in 105 CMR 500.093(A)(1)(a) and (b), or copies of certificates as allowed by 105 CMR 500.093(A)(1)(c), to the Department at the same time as it submits its initial application for a license, and annually thereafter, as follows:

1. Testing for chemical and physical contaminants performed within the preceding 12 months;

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2. Testing for radiological contaminants performed within the preceding 12 months, for any year in which radiological testing is required; and
3. Testing for microbiological contaminants performed within the preceding four weeks.

(2) **Finished Products: Bottled Water**

- (a) Samples of each type of finished bottled water product produced shall be taken by the facility and analyzed by an approved water-testing laboratory in the manner and frequency specified in 21 CFR § 129.80: *Processes and Controls*, and consistent with "Quality Standards for Bottled Water", Massachusetts Department of Public Health, Food Protection Program.
- (b) In addition, if any flavor or color is added to the product during the manufacturing process, a representative sample shall be taken immediately prior to the addition of such flavor or color, at the frequency specified in 21 CFR § 129.80: *Processes and Controls*, and the sample shall be analyzed by an approved water-testing laboratory in the manner and frequency specified in 21 CFR § 129.80.
- (c) The methods of analysis shall be any method approved by FDA.
- (d) The facility shall submit a signed copy of the results from the approved water-testing laboratory of the analyses of its finished products performed in accordance with 105 CMR 500.093(A)(2)(a) through (c) to the Department. Such results shall be submitted at the same time as it submits its initial application for a license, and annually thereafter, as follows:
 1. Testing for chemical, physical, and radiological contaminants performed within the preceding 12 months; and
 2. Testing for microbiological contaminants performed within the preceding four weeks.

(3) **Finished Products: Carbonated Non-alcoholic Beverages**

- (a) Samples of each type of finished carbonated non-alcoholic beverage product shall be taken and analyzed as frequently as necessary to ensure that no product is adulterated.
- (b) Routine test results need not be submitted to the Department, but all results shall be maintained by the facility as required by 105 CMR 500.093(D).

(B) Additional Testing of Bottled Water and Carbonated Non-alcoholic Beverages.

- (1) Notwithstanding any other provisions of 105 CMR 500.000, the Department may require any bottler of bottled water or carbonated non-alcoholic beverages or any applicant for a license to:
 - (a) Test and submit results to the Department for any substance at any time when the Department has reason to believe that the substance may be present in a water source used by the bottler or in a finished product and may threaten public health, or
 - (b) Make an assessment of the ongoing potential for contamination of a water source used by the bottler.
- (2) Whenever a bottler or license applicant has reason to believe that a substance may be present in a water source or in a finished product and may threaten public health, the bottler or license applicant shall:
 - (a) Notify the Department within 24 hours;
 - (b) Test the source water or finished product for the substance at a frequency determined by the Department;
 - (c) Submit all test results to the Department, and direct the laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results; and
 - (d) Follow the Department's instructions as to whether and under what conditions bottling operations may continue until the problem is resolved.

(C) Unexpected Noncompliance with Quality Standards: Bottled Water or Carbonated Non-alcoholic Beverages.

(1) **In-state Facilities.**

- (a) **Source Water.** When an in-state facility receives any test result indicating that its water source is not in compliance with any Maximum Contaminant Level listed in 310 CMR 22.00: *Drinking Water*, or with any other Maximum Contaminant Level promulgated by EPA and in effect, it shall:

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1. Notify the Department within 24 hours;
2. Test the source water at a frequency determined by the Department;
3. Submit all test results to the Department, and direct the laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results; and
4. Follow the Department's instructions as to whether and under what conditions bottling operations may continue until the problem is resolved.

(b) Finished Products: Bottled Water. When an in-state facility receives any confirmed test result indicating that any of its finished products are not in compliance with any standard of quality in 21 CFR § 165.110(b), it shall:

1. Immediately cease all operations until the Department determines that the finished product is in compliance with all applicable quality standards;
2. Notify the Department within 24 hours;
3. Conduct appropriate tests at a frequency determined by the Department; and
4. Submit all test results to the Department, and direct any laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results.

(2) Out-of-state Facilities: Bottled Water. When an out-of-state facility receives any confirmed test result indicating that any of its finished products are not in compliance with any standard of quality in 21 CFR § 165.110(b), it shall notify the Department within 24 hours.

(D) Maintenance of Test Results by Facilities Producing Bottled Water or Carbonated Non-alcoholic Beverages. Results of all sampling and analysis shall be maintained for five years in a separate file at the facility and shall be made available to inspectors of the Department, DEP as the Department's designee, and/or the board of health during an inspection or upon request.

500.094: Bulk Storage and Transportation of Water

All bottled water and carbonated non-alcoholic beverage facilities shall comply with the following requirements in addition to the transportation requirements in 105 CMR 500.007.

(A) General. A bottled water or carbonated non-alcoholic beverage facility shall not accept water for use in its products unless the facility and the bulk water transporter, as appropriate, comply with the following requirements.

- (1) Bulk storage tanks and related equipment shall be cleaned, sanitized, and inspected internally for integrity on a routine basis in compliance with the sanitary standards in 21 CFR Parts 110: *Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food* and 129: *Processing and Bottling of Bottled Drinking Water*. A record of all cleaning and sanitizing showing the date, time, place, and signature or initials of the person doing the work shall be maintained with the storage tank. If someone other than an employee of the licensee does the work, a copy of the record shall be given to the licensee and kept at the facility for at least six months. The facility shall provide these records to the Department upon request.
- (2) Equipment used for transport of bulk water shall not be used, and shall not have been used previously, for any non-food product. Such equipment shall not be used for any dairy product or non-beverage food except in an emergency. If the equipment is used for any food or beverage other than bulk potable water, it shall be cleaned and sanitized as required by 21 CFR Parts 110: *Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food* and 129: *Processing and Bottling of Bottled Drinking Water* immediately before the water is loaded.

(B) Responsibility of Licensee. The licensee shall assure that its bulk water supplier and transporter comply with the appropriate sanitary requirements in 21 CFR Parts 110: *Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food* and 129: *Processing and Bottling of Bottled Drinking Water*.

Administration and Enforcement

500.200: General Administration

(A) The following provisions shall govern the administration and enforcement of 105 CMR 500.000, except when an applicable statute requires a different procedure.

(B) The Department may publish interpretations of 105 CMR 500.000 and guidelines as it deems necessary to promote uniform application of 105 CMR 500.000, and may make them available to those persons subject to 105 CMR 500.000.

(C) In addition to the specific enforcement provisions in 105 CMR 500.021(G), 500.065, 500.082, and 500.093, the regulatory agency may enforce 105 CMR 500.000 by issuing a Notice of Violation/Order to Correct Violations and/or an Order to Cease and Desist operation of a facility and/or a specific operation within a facility, or by commencing an enforcement action pursuant to 105 CMR 500.207 and 500.208.

500.201: Licensure

(A) License and Permit Requirements; Applicable Regulatory Agency. The following types of food-related operations require a license or permit from the following regulatory agencies. In some circumstances, a person may require more than one license or permit.

- (1) A person who operates a residential kitchen that prepares food for wholesale sale: a license issued by the Department pursuant to M.G.L. c. 94, § 305C.
- (2) A person who operates as a retail seafood dealer or a wholesale seafood dealer or who operates a wholesale seafood truck: a permit issued jointly by the Department and the Division of Marine Fisheries pursuant to M.G.L. c. 130, § 80.
- (3) A person who cooks, smokes, or otherwise processes seafood, or combines seafood with non-seafood ingredient(s), for sale at wholesale: a license issued by the Department pursuant to M.G. L. c. 94, § 305C.
- (4) A person who slaughters livestock or poultry, processes meat or poultry for sale at wholesale, custom slaughters livestock or poultry, or custom processes meat or poultry: a license issued by the Department pursuant to M.G. L. c. 94, § 120.
- (5) A person who operates a milk pasteurization plant: a license (which may be called a permit) issued by the board of health pursuant to M.G.L. c. 94, § 48A.
- (6) A person who manufactures butter or cheese in Massachusetts for sale at wholesale in a facility separate from a pasteurization plant (*i.e.* does not hold a license under M.G.L. c. 94, § 48A): a license issued by the Department pursuant to M.G. L. c. 94, § 305C.
- (7) A person who manufactures frozen desserts or frozen dessert mix within Massachusetts for sale at wholesale or retail: a license (which may be called a permit) issued by the board of health pursuant to M.G.L. c. 94, § 65H.
- (8) A person who manufactures frozen desserts or frozen dessert mix outside Massachusetts and sells such products in Massachusetts: a license issued by the Department pursuant to M.G. L. c. 94, § 65H.
- (9) A person who, within Massachusetts, manufactures or bottles carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption: a license (which may be called a permit) issued by the board of health pursuant to M.G.L. c. 94, § 10A.
- (10) A person who, outside Massachusetts, manufactures or bottles carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption and sells such products in Massachusetts: a license issued by the Department pursuant to M.G. L. c. 94, § 10A.
- (11) A person who manufactures juice or apple cider for sale at wholesale: a license issued by the Department pursuant to M.G. L. c. 94, § 305C.
- (12) A person who manufactures or processes any food not specifically named in 105 CMR 500.201(A)(1) through (11), including dietary supplements, for sale at wholesale: a license issued by the Department pursuant to M.G. L. c. 94, § 305C.
- (13) A person who operates a cold storage or refrigerating warehouse: a license issued by the Department pursuant to M.G. L. c. 94, § 66.
- (14) A person who operates a food warehouse: a license issued by the Department pursuant to M.G. L. c. 94, § 305C.

500.201: continued

(15) A person who transports or causes to be transported any bakery product into Massachusetts for the purpose of sale: a license issued by the Department pursuant to M.G.L. c. 94, § 305E.

Table 2 summarizes these requirements.

TABLE 2

Statute	Regulated Activity	License or Permit	Issuing Agency
M.G.L. c. 94, § 305C	Residential kitchen that prepares food for wholesale sale	License	DPH
M.G.L. c. 130, § 80	Retail seafood dealer	Permit (joint)	DPH and Division of Marine Fisheries
M.G.L. c. 130, § 80	Wholesale seafood dealer	Permit (joint)	DPH and Division of Marine Fisheries
M.G.L. c. 130, § 80	Wholesale seafood truck	Permit (joint)	DPH and Division of Marine Fisheries
M.G.L. c. 94, § 305C	Process, <i>etc.</i> seafood for sale at wholesale	License	DPH
M.G.L. c. 94, § 120	Slaughter or custom slaughter livestock or poultry; process or custom process meat or poultry	License	DPH
M.G.L. c. 94, § 48A	Operate a milk pasteurization plant	License (may be called a permit)	Local board of health
M.G.L. c. 94, § 305C	Manufacture butter or cheese for sale at wholesale in a facility separate from a pasteurization plant	License	DPH
M.G.L. c. 94, § 65H	Manufacture frozen desserts or frozen dessert mix within MA for sale at wholesale or retail	License (may be called a permit)	Local board of health
M.G.L. c. 94, § 65H	Manufacture frozen desserts or frozen dessert mix outside MA and sell them in MA	License	DPH
M.G.L. c. 94, § 10A	Manufacture or bottle within MA carbonated non-alcoholic beverages or bottled water for human consumption	License (may be called a permit)	Local board of health
M.G.L. c. 94, § 10A	Manufacture or bottle carbonated non-alcoholic beverages or bottled water for human consumption outside MA and sell them in MA	License	DPH
M.G.L. c. 94, § 305C	Manufacture juice or apple cider for sale at wholesale	License	DPH

500.201: continued

Statute	Regulated Activity	License or Permit	Issuing Agency
M.G.L. c. 94, § 66	Operate a cold storage or refrigerating warehouse	License	DPH
M.G.L. c. 94, § 305C	Operate a food warehouse	License	DPH
M.G.L. c. 94, § 305E	Transport or cause to be transported any bakery product into MA for purpose of sale	License	DPH
M.G.L. c. 94, § 305C	Manufacture or process any food not specifically named above, including dietary supplements	License	DPH

(B) No person, unless exempted pursuant to 105 CMR 500.000, shall conduct an activity requiring a license, permit, approval, or certification pursuant to 105 CMR 500.000 without a valid license, permit, approval, or certification, or in violation of the terms of a valid license, permit, approval, or certification or the applicable requirements of 105 CMR 500.000.

(C) No person, unless exempted, shall sell, exchange, deliver, advertise, offer, expose for sale or exchange, attempt to deliver, or have in his or her possession with intent to do so, any food for human consumption unless the manufacturer or processor thereof holds a license or permit issued pursuant to 105 CMR 500.000 then in full force.

(D) A person who desires to conduct an activity named in 105 CMR 500.201(A) shall submit an application for a license or permit to the appropriate regulatory agency, together with the fee required by statute and any other information required by the regulatory agency. Such application shall be on a form prescribed by the regulatory agency.

(E) A new applicant for a license or permit from the Department shall notify the local board of health in the city or town where the facility is located of his or her intent to operate and of the type of business.

(F) Only a person who complies with the requirements of 105 CMR 500.000 shall be entitled to receive and retain a license, permit, approval, or certification. A license, permit, approval, or certification shall be valid only for the licensee or permit holder and for the location indicated on it.

(G) A license, permit, approval, or certification shall remain in effect for the term specified, unless it is surrendered, suspended, or revoked.

(H) A license or permit may be renewed by applying at least 30 days prior to the expiration date. Application for renewal shall be made in writing on a form prescribed by the regulatory agency.

(I) **All Licenses and Permits are Non-transferable.**

- (1) No licensee or permit holder shall transfer or assign a license or permit in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any company.
- (2) No person shall conduct an activity named in 105 CMR 500.201(A) pursuant to a license or permit transferred or assigned by any person.
- (3) No licensee or permit holder shall transfer an operation to a new location without obtaining a new license or permit.

500.201: continued

(J) Notification to the Regulatory Agency.

- (1) Mailing Address. Each applicant, licensee, and permit holder shall provide the regulatory agency with its complete and correct mailing address, and shall notify the regulatory agency within seven calendar days of the change of its mailing address. The last address provided to the regulatory agency shall be deemed the appropriate address for the service of all orders and notices from the regulatory agency.
- (2) Change of Ownership. A licensee or permit holder shall notify the regulatory agency prior to, or within ten days after, a change of ownership, and shall surrender the license or permit upon change of ownership. The new owner shall submit to the regulatory agency an application for a new license or permit, and shall not operate until such license or permit is issued.
- (3) Change of Name. A licensee or permit holder shall notify the regulatory agency at least 30 days prior to any change of the name of the business. The licensee or permit holder shall submit to the regulatory agency an application for an amended license or permit, together with written documentation stating the change of name.
- (4) Change of Location. A licensee or permit holder shall notify the regulatory agency at least 30 days prior to a change of location of the business, and shall surrender its license or permit upon closure of the business at the former location. The licensee or permit holder shall submit to the regulatory agency an application for a new license or permit, and shall not operate until such license or permit is issued.
- (5) Remodeling. A licensee or permit holder shall promptly notify the regulatory agency any time that a facility is being remodeled. Upon notification, the regulatory agency may inspect the facility to verify compliance with 105 CMR 500.000.
- (6) Imminent Danger. A licensee or permit holder shall notify the regulatory agency immediately when an imminent danger to the public health is present in the facility.
- (7) Change in Operations. A licensee or permit holder shall notify the regulatory agency of any change in the types of products that it manufactures or distributes.

(K) No person shall transport or cause to be transported any bakery product into Massachusetts for the purpose of sale without obtaining a license from the Department, pursuant to M.G.L. c. 94, § 305E.

- (1) After receipt of an application for a license, the Department shall review the application and any documents filed with it. To determine the extent of the facility's compliance with 105 CMR 500.000, the Department may accept reports of the responsible authorities in the jurisdiction where the facility is located. When information reveals that the applicable requirements of 105 CMR 500.000 have been met, the Department shall issue a license to the applicant.
- (2) Each license granted by the Department pursuant to 105 CMR 500.201(K) shall apply to one facility only, and shall be valid throughout Massachusetts.

500.202: Operating Without a License, Permit, Approval, or Certification

(A) The regulatory agency may inspect any facility which it has reason to believe contains an operation subject to regulation pursuant to 105 CMR 500.000.

(B) The regulatory agency may issue an Order to Cease and Desist to any person engaged in an activity subject to regulation pursuant to 105 CMR 500.000 who is operating without a required license, permit, approval, or certification.

(C) The regulatory agency may deny an application for a license, permit, approval, or certification when the applicant was previously engaged in an activity subject to regulation pursuant to 105 CMR 500.000 without a required license, permit, approval, or certification.

(D) If allowed by statute, the Department may impose civil monetary penalties against a facility subject to licensure that is found to be operating without the required license, permit, approval, or certification.

(E) The regulatory agency may petition the Superior Court to enjoin the operation of a facility operating without a required license, permit, approval, or certification.

500.203: continued

(F) The regulatory agency may take such other steps as required to bring a person operating without a required license, permit, approval, or certification into compliance, or to terminate the operation of the facility or any portion of the facility, in order to protect the health and safety of the public.

500.203: Inspections

(A) Inspections; Applicable Regulatory Agency. The following types of food-related operations are routinely subject to inspection by the following regulatory agencies.

- (1) A person who operates a residential kitchen that prepares food for wholesale sale: inspection by the Department.
- (2) A person who operates as a retail seafood dealer: inspection by the board of health or the Department.
- (3) A person who operates as a wholesale seafood dealer or who operates a wholesale seafood truck: inspection by the Department.
- (4) A person who cooks, smokes, or otherwise processes seafood, or combines seafood with non-seafood ingredient(s) for sale at wholesale: inspection by the Department.
- (5) A person who slaughters livestock or poultry, processes meat or poultry for sale at wholesale, custom slaughters livestock or poultry, or custom processes meat or poultry: inspection by the Department.
- (6) A person who operates a milk pasteurization plant: inspection by the Department.
- (7) A person who manufactures butter or cheese in Massachusetts for sale at wholesale in a facility separate from a pasteurization plant: inspection by the Department.
- (8) A person who manufactures frozen desserts or frozen dessert mix within Massachusetts for sale at wholesale: inspection by the Department.
- (9) A person who manufactures frozen desserts or frozen dessert mix within Massachusetts for sale at retail: inspection by the board of health.
- (10) A person who, within Massachusetts, manufactures or bottles carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption: inspection by the Department.
- (11) A person who manufactures juice or apple cider for sale at wholesale: inspection by the Department.
- (12) A person who manufactures or processes any food not specifically named in 105 CMR 500.203(A)(1) through (11) for sale at wholesale: inspection by the Department.
- (13) A person who operates a cold storage or refrigerating warehouse: inspection by the Department or the local board of health.
- (14) A person who operates a food warehouse: inspection by the Department.

(B) Notwithstanding 105 CMR 500.203(A), the Department may request the applicable board of health, and the applicable board of health may request the Department, to undertake an inspection of a food-related operation on its behalf. Such an inspection shall have the same force and effect as an inspection conducted by the regulatory agency that routinely inspects that type of operation.

(C) To carry out its responsibilities under 105 CMR 500.000 and applicable statutes and to protect the health and well-being of the people of Massachusetts, the regulatory agency, or an authorized agent or representative of the regulatory agency, is authorized, as often as is deemed necessary for the enforcement of 105 CMR 500.000, to enter, examine, photograph, and survey any facility engaged in an activity subject to regulation pursuant to 105 CMR 500.000. Duly authorized inspectors may also enter and inspect any place where food is being prepared to ascertain whether any of the provisions of applicable statutes or 105 CMR 500.000, including but not limited to those that apply to exempted persons, have been violated.

(D) Inspections may be random systematic inspections or in response to a specific complaint or request. An inspection initiated from a specific complaint or request is not limited to that complaint or request. At the time of the inspection, the inspector may record all violations.

500.203: continued

(E) Agents of the regulatory agency, after identifying themselves, may enter all areas of the facility, at any time, for the purpose of making an inspection to ascertain whether the facility is in compliance with 105 CMR 500.000, including unannounced inspections, which do not require prior notification to the facility. Individuals engaged in regulated activities shall provide access to regulatory agency inspectors at all times for inspection of the premises.

(F) Agents of the regulatory agency may examine all records of the facility to determine which are subject to enforcement under 105 CMR 500.000 and all applicable statutes. Agents may copy all records they deem relevant.

(G) The person in charge of the facility at the time of the inspection shall furnish the agent of the regulatory agency with all requested records and shall provide the agent with access to all areas of the facility.

(H) If the person in charge at the time of the inspection refuses entry to an agent of the regulatory agency, refuses to permit an authorized inspection, refuses access to records, or interferes with the regulatory agency, or any agent thereof, in the performance of its duties, the regulatory agency may:

- (1) Seek an administrative search warrant to search/inspect the premises. The warrant application shall apprise the applicant, licensee, permit holder, or owner of the facility concerning the nature of the inspection and the justification for it. The regulatory agency may seek the assistance of police authorities in executing the warrant; and/or
- (2) Take steps to refuse to issue, refuse to renew, suspend, or revoke the license, permit, approval, or certification, or to impose administrative penalties or fines, in accordance with applicable statute; and/or
- (3) Issue an Order to Cease and Desist operations.

500.204: Notice of Violations/Order to Correct

(A) Whenever the regulatory agency finds upon inspection, investigation of a complaint, or through information in its possession that an applicant, licensee, or permit holder is not in compliance with any of the provisions of 105 CMR 500.000, the regulatory agency shall notify such person of each violation or deficiency. The notice shall include a statement of the violations or deficiencies found; the provisions of the law relied upon; the level of severity of the violation or deficiency, when appropriate; a reasonable period of time for correction; and notice that a violation or deficiency may result in a refusal to issue or renew or a suspension or revocation of a license, permit, or approval; a modification or limitation of a license, permit, or approval; an order to cease and desist; and/or the imposition of fines and/or administrative penalties, as applicable.

(B) The reasonable period of time for correction shall be within the discretion of the regulatory agency to establish in each instance, and shall be based on an evaluation of the type and the severity of each violation or deficiency.

(C) The inspection report may, if so stated, constitute the Notice of Violations/Order to Correct all violations or deficiencies indicated, or the regulatory agency may issue a separate Notice/Order. Both the inspection report and the Notice of Violations/Order to Correct shall constitute *prima facie* evidence of the violations stated therein.

(D) If critical violations are found, or if after review or reinspection the regulatory agency finds that the violations have not been corrected, the regulatory agency may issue a prescriptive order stating specific actions that the facility must take to correct the violations. The regulatory agency shall document the conditions that necessitate the specific actions.

(E) Service of the Notice of Violations/Order to Correct.

- (1) Service shall be in person to the person in charge at the time of the inspection; or by certified mail, return receipt requested, to the address on file with the regulatory agency; or by any officer of the Commonwealth authorized to make service.

500.204: continued

- (2) If served personally, notice is deemed to be served on the date when the Notice of Violations/Order to Correct is delivered personally.
- (3) If served by certified mail, return receipt requested, notice is deemed to be served on the second business day after it is mailed.
- (4) Notice is deemed served if the applicant, licensee, permit holder, or person in charge has actual notice.

(F) The applicant, licensee, or permit holder shall be responsible for the correction of all violations or deficiencies and compliance with any order issued pursuant to 105 CMR 500.000 and applicable statutes.

(G) The completed inspection report form and other related enforcement documents are public records as defined in M.G.L. c. 4, § 7, clause 26th, unless a specific exemption applies in a particular case.

(H) All inspection report forms and other related enforcement documents shall be maintained by the regulatory agency for a minimum of seven years, or longer if otherwise required by law.

500.205: Plan of Correction

(A) The applicant, licensee, or permit holder, within the time specified in the Notice of Violations/Order to Correct, shall file a written plan of correction, certified under the pains and penalties of perjury.

(B) Each plan of correction shall:

- (1) State the name of the applicant, licensee, or permit holder and the name of the individual and address for receipt of notices;
- (2) Reference each violation or deficiency cited, and for each indicate:
 - (a) The specific corrective action completed and the date the work was completed; and/or
 - (b) Where corrective action was not yet completed, the specific corrective action planned and the timetable and date for completion, which is in accordance with the date indicated in the Notice of Violations/Order to Correct; and
- (3) Include the date and the signature of the applicant, licensee, or permit holder or his or her official designee, sworn to under the pains and penalties of perjury.

(C) If the applicant, licensee, or permit holder cannot complete the corrective action within the time frame designated in the Notice of Violations/Order to Correct, such person must petition the regulatory agency in writing for an extension of the time to correct. Any petition to extend the time to correct must be submitted to the regulatory agency prior to the date indicated in the Notice of Violations/Order to Correct for the violation or deficiency to be corrected. An untimely petition for extension will not be considered unless good cause can be shown for the failure to file in a timely manner. A petition for an extension of time shall include the reason(s) that the correction cannot be timely completed (*e.g.* the work requires a permit which will not be issued within the time period granted), including documentary evidence in support and a specific time by which the facility will complete corrections. The regulatory agency shall notify the applicant, licensee, or permit holder whether an extension of the time is granted and the duration of the extension, if it is granted.

(D) The regulatory agency may reinspect a facility to determine whether the violations have been corrected.

(E) If upon review of the plan of correction and/or upon reinspection the regulatory agency finds that an applicant, licensee, or permit holder remains noncompliant with applicable laws and regulations, the regulatory agency may:

- (1) Initiate enforcement procedures as set forth in 105 CMR 500.207; or
- (2) Request that the applicant, licensee, or permit holder amend and resubmit the plan of correction within ten calendar days of the issuance of the notice or such other time as the regulatory agency may specify for resubmission; or

500.205: continued

(3) Issue a prescriptive order that requires specific actions as described in 105 CMR 500.204(D).

500.206: Order to Cease and Desist

(A) An Order to Cease and Desist may be issued to the licensee, permit holder, person in charge, or operator upon belief that:

- (1) An operator is conducting a food operation without the required license, permit, approval, or certification; or
- (2) A licensee or permit holder is conducting its operation in violation of the law, regulations, and/or standards applicable to it; or
- (3) A licensee or permit holder refuses access to the premises and/or records to authorized enforcement agents; or
- (4) A licensee or permit holder is operating in a manner that may pose an imminent danger to the public health; or
- (5) The licensee or permit holder has violated an embargo order; or
- (6) The licensee or permit holder has failed to comply with an Order to Correct within the time specified; or
- (7) The licensee or permit holder is operating in a manner that is unsafe, unsanitary, or otherwise below the accepted standards for the type of operation for which the license, permit, or approval was issued and summary closure is authorized by statute on these grounds.

(B) Service of Orders to Cease and Desist shall be on the licensee, permit holder, person in charge, or operator by:

- (1) Personal delivery by an agent of the regulatory agency; or
- (2) Posting in a conspicuous place at the licensed facility; or
- (3) Simultaneously mailing, by first class and certified mail return receipt requested; or
- (4) By any officer of the Commonwealth authorized to make service.

Notice is deemed to be served if the licensee, permit holder, person in charge, or operator has actual notice of the Order to Cease and Desist.

(C) Violations of Orders to Cease and Desist shall be enforced in Superior Court in the county where the operation is located, or in the Suffolk Superior Court by agreement of the parties.

500.207: Grounds for Administrative Enforcement Action

(A) Grounds for Refusal to Issue a License, Permit, or Certification.

- (1) The regulatory agency may refuse to issue a license, permit, or certification based on any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to refuse to issue a license or permit.
 - (a) Failure to submit a timely application in accordance with the regulatory agency's procedures;
 - (b) Failure to submit the required fee;
 - (c) Failure to comply with any applicable statute, with any applicable provision of 105 CMR 500.000, or with any lawful order of the regulatory agency or the Commissioner;
 - (d) Denial of entry to agents of the regulatory agency, or any attempt to impede the work of a duly authorized agent or representative of the regulatory agency;
 - (e) Providing a false or misleading statement to the regulatory agency, or keeping or submitting any misleading or false records or documents pertaining to the subject business, or failing to keep records required to be kept;
 - (f) The applicant operated the business or any business without a required license or permit or after the expiration of the same;
 - (g) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the business has been convicted of, pled guilty or *nolo contendere* to, or has, in a judicial proceeding, admitted facts sufficient to find that he or she is guilty of a crime relating to the procuring, possessing, processing, storage, distribution, or sale of food in connection with the business;

500.207: continued

- (h) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the business has engaged in conduct that endangers the public health;
- (i) A business owned or operated by the applicant is, or was, the subject of a proceeding(s) which is still ongoing or resulted in the suspension, denial, or revocation of a license or permit, or refusal to renew the same;
- (j) Failure to comply with all Massachusetts laws relating to taxes, reporting of employees and contractors, and withholding and remitting of child support as required by M.G.L. c. 62C, § 49A;
- (k) Failure to pay administrative penalties or fines assessed by the regulatory agency in a timely manner; or
- (l) Failure to comply with local regulations, bylaws, or ordinances related to the operation of the business.

(2) Notice of Refusal to Issue a License or Permit.

- (a) The notice shall be in writing and shall specify the specific reason(s) for which the license or permit is being denied, the applicable provisions of law, and the procedures for requesting any hearing to which the applicant may be entitled.
- (b) The notice shall be served on the applicant using the same procedures specified in 105 CMR 500.206(B) for service of an Order to Cease and Desist.

(3) Hearing. To obtain a hearing, the applicant shall follow the procedures set forth in 105 CMR 500.208(B).

(B) Summary Suspension without a Prior Hearing.

- (1) The regulatory agency may, without a prior hearing, suspend a license, permit, or certification, or one or more particular operations in a facility, if it finds that the licensee or permit holder is operating the facility in a manner which is endangering or may cause imminent danger to the public health.
- (2) A summary suspension order shall be in writing and shall be immediately provided to the licensee, permit holder, or person in charge of the facility, and a copy shall be posted at the facility. The order shall state:
 - (a) The reason(s) for the summary suspension;
 - (b) The violation(s) leading to the determination that the facility is operating in a manner which is endangering or may cause imminent danger to the public health, and the applicable provisions of law;
 - (c) That all operations or one or more operations of the facility shall immediately cease and desist; and
 - (d) That an opportunity for a hearing shall be afforded if timely requested.
- (3) The order of summary suspension shall be effective upon posting of the order at the facility by an authorized agent of the regulatory agency. If the person whose name appears on the license or permit is not present at the time of such posting, or if the licensee or permit holder is a corporation or other firm, a copy of the order of summary suspension shall also be served using the same procedures specified in 105 CMR 500.206(B) for service of an Order to Cease and Desist.
- (4) The regulatory agency may end the summary suspension at any time if reasons for the suspension no longer exist.
- (5) The inspection report and the Notice of Violations/Order to Correct shall constitute *prima facie* evidence of the conditions listed therein.

(C) Suspension, Revocation, or Refusal to Renew a License, Permit, or Certification, and/or Imposition of Administrative Penalties, after Opportunity for a Hearing.

(1) Suspension.

- (a) After providing an opportunity for a hearing, the regulatory agency may suspend a license, permit, or certification, or one or more particular operations or activities of the facility, if the facility or the operation/activity does not comply with any one or more of the requirements of 105 CMR 500.000. Each day during which each noncompliance occurs or continues shall constitute a separate violation.
- (b) The suspension shall continue until the regulatory agency determines that the required corrections have been made.

500.207: continued

(2) Revocation. After providing an opportunity for a hearing, the regulatory agency may revoke a license, permit, or certification, or terminate one or more particular operations of the facility, if any one or more of the following grounds exists. Each of the following grounds shall constitute full and adequate grounds for such revocation.

- (a) A serious violation or repeated violations of any of the requirements of 105 CMR 500.000 or of any relevant statute. Each day during which each violation occurs or continues shall constitute a separate violation;
- (b) Interference with the regulatory agency or any of its authorized agents in the performance of its duties including, but not limited to, refusal to provide access to inspect any part of the premises;
- (c) The licensee or permit holder, or if the licensee or permit holder is a corporation, a corporate officer or the owner of the facility has been convicted of, pled guilty or *nolo contendere* to, or has, in a judicial proceeding, admitted facts sufficient to find that he or she is guilty of a crime relating to the procuring, possessing, processing, storage, distribution, or sale of food in connection with the business;
- (d) Keeping or submitting any misleading or false records or documents required by 105 CMR 500.000 or related law, or failing to keep records required to be kept;
- (e) Failure to pay administrative penalties or fines assessed by the regulatory agency in a timely manner;
- (f) Failure to immediately report to the regulatory agency:
 - 1. When an imminent danger to the public health is present in the facility;
 - 2. An outbreak of illness within the facility that may affect the safety of the food product; or
 - 3. An outbreak of illness that may have been caused by a food product from the facility; or
- (g) Failure to provide regulatory agency access to any and all records required to be kept by the licensee or permit holder.

(3) Refusal to Renew. The regulatory agency may refuse to renew a license, permit, or certification if the facility does not comply with any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds for such refusal to renew.

- (a) Any of the grounds specified in 105 CMR 500.207(A);
- (b) Any of the grounds specified in 105 CMR 500.207(B); or,
- (c) Any of the grounds specified in 105 CMR 500.207(C)(1) or (2).

(D) Administrative Penalties. The Department may assess administrative penalties, pursuant to M.G.L. c. 94, §305C, in *lieu* of, or in addition to, suspending, revoking, refusing to issue, or refusing to renew a license, or other enforcement procedures.

(1) Administrative penalties may be imposed against any person for one or more of the following grounds:

- (a) Failure to correct a violation or deficiency that constitutes a critical violation in a timely manner. Penalties shall accrue from the date set for correction in the Notice of Violations/Order to Correct, until the violation or deficiency is corrected;
- (b) The occurrence of a second critical violation for the same deficiency within any 12-month period. Penalties shall accrue from the date set for correction in the Notice of Violations/Order to Correct for the second critical violation or deficiency, until the violation or deficiency is corrected;
- (c) Denial of entry to agents of the Department or any attempt to impede the work of a duly authorized agent or representative of the Department, including impeding the taking of photographs. Penalties shall accrue from the date of the denial of entry or other impediment, for each day until agents of the Department are granted unimpeded access;
- (d) Failure to comply with an Order to Cease and Desist from the Department. Penalties shall accrue from the date of the issuance of the Order to Cease and Desist, until there is full compliance with the order;
- (e) False certification of correction pursuant to 105 CMR 500.205(A);
- (f) The operation of a facility without a license, for which penalties shall accrue for every day of operation without a license; or
- (g) Failure to comply with any other requirement of 105 CMR 500.000.

500.207: continued

(2) Determining the Monetary Amount of an Administrative Penalty.

(a) Maximum Penalty. The maximum administrative penalty for a single violation of any rule or regulation shall not exceed the amount specified in M.G.L. c. 94, § 305C.

(b) Level of Administrative Penalty.

1. The penalty shall be \$500.00 for each day that a person fails to comply with an order to correct a critical violation.

2. The penalty shall be \$100.00 for each day that a person fails to comply with an order to correct a non-critical violation.

3. The penalty for a false certification of correction shall be \$200.00 for each violation falsely certified.

4. The penalty for the denial of entry to or impeding the work of a duly authorized agent or representative of the Department shall be \$500.00 for each time entry is denied or work is impeded.

5. The penalty shall be \$500.00 for each day that a person fails to comply with an Order to Cease and Desist from the Department.

6. The penalty shall be \$500.00 for each day that a person operates a facility without a license.

(c) Repeated Noncompliance. Each day during which each noncompliance occurs or continues shall constitute a separate violation/offense and shall be subject to a separate penalty, not to exceed \$500.00 per day, per violation. If noncompliance continues for any part of a day, that day shall be included in the calculation.

(d) Calculating the Duration of Continued and/or Repeated Noncompliance. Noncompliance shall be calculated commencing from the dates described in 105 CMR 500.207(D)(1). Penalties shall be assessed for each day of noncompliance, commencing on the date described in 105 CMR 500.207(D)(1) and continuing until the day when the person comes into compliance, or as established by the final agency decision. However, nothing in 105 CMR 500.207(D)(2)(d) prevents the person from accruing further penalties regarding the same violations commencing on the day following the date established by the final agency decision, which would form the basis of a future enforcement action.

(E) Surrender of License and Voluntary Closures.

(1) The licensee or permit holder must surrender the license or permit to the regulatory agency if there is a transfer of ownership, or if there is a cessation of operations at the facility for other than routine vacation or maintenance closures.

(2) The licensee or permit holder may voluntarily surrender the license or permit to the regulatory agency for any lawful reason.

500.208: Procedures for Administrative Enforcement Action

(A) Notice of Agency Action.

(1) Whenever the regulatory agency determines to suspend with notice, revoke, refuse to issue, or refuse to renew a license, permit, or certification or to assess civil monetary penalties, it shall issue a Notice of Agency Action. The Notice of Agency Action shall be in writing and shall specify:

(a) The specific reasons(s) for which the particular Agency Action is to be taken, and the applicable provisions of law;

(b) When the particular Agency Action will take effect; and

(c) The procedure for requesting a hearing, unless no hearing is required pursuant to M.G.L. c. 30A, § 13 or other applicable state or federal law.

(2) The Notice of Agency Action shall be served on the licensee, permit holder, person in charge, or operator using the same procedures specified in 105 CMR 500.206(B) for service of an Order to Cease and Desist.

(B) Hearings.

(1) The person to whom an Order of Summary Suspension, Order to Cease & Desist, or Notice of Agency Action is directed may request a hearing before the regulatory agency. Such request must be received by the regulatory agency within the time specified in the Order or Notice.

500.208: continued

- (2) The failure to request a hearing within the time specified constitutes a waiver of the right to a hearing.
- (3) A hearing based on an Order of Summary Suspension or Order to Cease & Desist should be conducted within 96 hours after the regulatory agency receives the request for a hearing, or within such other time period as is specified by applicable statute. If such time period expires on a weekend day or holiday, the hearing may be held on the next business day. The parties may agree to extend such time period.
- (4) A hearing based on a Notice of Agency Action shall be commenced within a reasonable time after the regulatory agency receives the request for a hearing.
- (5) Failure to hold a hearing within the time periods specified is procedural and shall not affect the validity of the proceedings or constitute a defense to a violation.
- (6) The applicant, licensee, or permit holder shall be given the opportunity for an administrative fair hearing to contest whether the proposed action should be taken. Any oral testimony given at a hearing shall be recorded verbatim (tape recording shall suffice).
- (7) The Notice of Violations/Order to Correct shall constitute *prima facie* evidence of the conditions listed therein.
- (8) The Department shall conduct hearings in accordance with M.G.L. c. 30A and all applicable provisions of 801 CMR 1.01: *Formal Rules*.
- (8) The hearing officer shall determine whether the Department met its burden of proof by a preponderance of the evidence, based on the relevant facts as they existed at or prior to the time the Department initiated the action.
- (9) If the hearing officer finds any ground for the action sought by the regulatory agency, the hearing officer shall render a written recommended decision affirming the action of the regulatory agency.

(C) Department Enforcement Actions: Final Agency Decision and Judicial Review.

- (1) In the case of enforcement actions initiated by the Department, the recommended decision of the hearing officer shall be reviewed by the Commissioner. After review and adoption or rejection, the Commissioner's decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.
- (2) Any applicant, licensee, permit holder, or other responsible person who fails to exercise his or her right to a hearing or withdraws the request for a hearing waives his or her right to review by the Commissioner. In such cases, the Department's findings shall become the final agency decision. The failure to request a hearing or the withdrawal of a request for a hearing shall be deemed a failure to exhaust administrative remedies.

500.209: Embargo

- (A) Pursuant to M.G.L. c. 94, § 189A, the Commissioner or his or her agent may place an embargo on any product which he or she finds or has probable cause to believe is adulterated or misbranded provided that:
 - (1) A written notice is issued to the licensee, permit holder, or the person in charge at the facility, or if no one is present at the facility, conspicuously posted at the facility; and
 - (2) The notice specifies the reason(s) for the embargo order.
- (B) The Commissioner or his or her agent shall affix a tag, label, or shall otherwise identify any product subject to the embargo order. The tag or label shall state that the 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 or her agent.
- (C) The Commissioner or his or her agent shall permit storage of the product under conditions specified in the embargo order, unless storage is not possible without imminent threat to the public health, in which case immediate destruction or isolation of the product may be ordered and accomplished.

500.209: continued

(D) If the product subject to embargo is found to be adulterated or misbranded, the Commissioner or his or her agent shall take such steps as they shall deem necessary, pursuant to M.G.L. c. 94, § 189A, to effect the condemnation and disposal or reconditioning of the product.

(E) If the product subject to embargo is found not to be adulterated or misbranded, it shall be released.

500.210: Criminal Penalties

Pursuant to applicable statutes, criminal penalties may be imposed.

500.211: Nonexclusivity of Enforcement Procedures

None of the enforcement procedures contained in 105 CMR 500.000 is mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so warrants.

500.212: Variance

(A) The Department may vary the application of any provision of 105 CMR 500.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided that the decision of the Department shall not conflict with the purpose of 105 CMR 500.000. The Department may place reasonable conditions on any variance.

(B) Copies of all variances shall be available to the public.

500.213: Severability

The provisions of 105 CMR 500.000 are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

105 CMR 500.00: M.G.L. c. 94, §§ 9F, 10E, 10I, 12, 48A, 65G through 65U, 66, 67, 73A, 88C, 119, 120, 124, 125, 126, 127, 139G, 192, 305A, 305B, 305C, and 305E; c. 111, §§ 3, 5, 6, 9, and 184A; and c. 130, § 80.