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105 CMR 561.000: FROZEN DESSERTS AND FROZEN DESSERT MIXES

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561.001: Purpose

The purpose of 105 CMR 561.000 is to establish standards for the manufacture of frozen desserts and frozen dessert mixes, and to establish standards of identity for frozen desserts. 105 CMR 561.000 shall be liberally construed and applied to promote the underlying purpose of protecting the public health.

561.002: Scope

105 CMR 561.000 applies to all persons within Massachusetts who manufacture frozen desserts or frozen dessert mix at wholesale or retail, and to all persons engaged in the manufacture of frozen desserts or frozen dessert mix outside Massachusetts who wish to sell such

products within Massachusetts, except that 105 CMR 561.000 does not apply to a person who operates a retail machine for the manufacture of non-milk-based frozen desserts, provided that such person has a valid permit under 105 CMR 590.000: *State Sanitary Code Chapter X: Minimum Sanitation Standards for Food Establishments.*

561.003: Definitions

Adequate or Approved Water Source means that the source of water used in the manufacture of frozen desserts or frozen dessert mixes, whether used in plant operations or as an ingredient of a product, shall be from an approved source meeting the quality standards in 105 CMR 561.006(A).

Allergen: *see* definition of "Known Allergen."

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

CFR means the Code of Federal Regulations.

Certified Laboratory means a laboratory certified pursuant to M.G.L. c. 111, § 184A.

Commissioner means the Commissioner of Public Health.

Department means the Massachusetts Department of Public Health.

Division means the Division of Food and Drugs of the Massachusetts Department of Public Health.

EPA means the U.S. Environmental Protection Agency.

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

Food Establishment means a food establishment as defined in 105 CMR 590.000.

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. 105 CMR 561.003: Frozen Dessert includes products made from the milk of cows, sheep, goats, and other dairy animals.

Frozen Dessert Freezing/Dispensing Machine means any equipment used in the conversion of milk-based frozen dessert mix into frozen desserts for sale at retail (hereinafter referred to as "soft-serve machine").

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

or milk shakes.

Imminent Health Hazard or Imminent Danger to the Public Health means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(1) the number of potential injuries, and

(2) the nature, severity, and duration of the anticipated injury. This definition may include but is not limited to:

(a) An extended loss of water supply such that it poses a danger to public health;

(b) The use of an unapproved source of water within a plant or food establishment or as an ingredient of a product;

(c) A failed sewer system or a sewage backup into the plant or food establishment where the manufacturing equipment is located;

(d) An extended power outage such that it poses a danger to public health;

(e) A violation of a pasteurization requirement, as specified in 105 CMR 561.024(F)(2);

(f) The plant or food establishment has been subject to one or more of the following: flood, fire, chemical exposure, natural disaster and/or other catastrophic event;

(g) An employee has been found to be infected with a communicable disease as described in 105 CMR 561.009; or

(h) Severe unsanitary conditions that threaten to contaminate the plant or food establishment, a part of the plant or food establishment, or a particular product.

The failure to include other violations, practices, circumstances or events in 105 CMR 561.003: Imminent Health Hazard or Imminent Danger to the Public Health shall not be construed as a determination that other violations, practices, circumstances or events are not or may not be considered an imminent health hazard.

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

Known Allergen means a food or ingredient containing peanuts, soy, milk, eggs, tree nuts, wheat, fish, shellfish, or any other food or ingredient designated in writing as a known allergen by the U.S. Food and Drug Administration.

Law includes federal, state and local statutes, ordinances and regulations.

License means a license or permit issued by a board of health authorizing a person within Massachusetts to manufacture frozen desserts or frozen dessert mixes, whether at wholesale or retail; and a license or permit issued by the Department authorizing a person outside Massachusetts to manufacture frozen desserts or frozen dessert mixes for sale in Massachusetts.

Licensee means any person who holds a license or permit to manufacture frozen desserts or frozen dessert mixes from a local board of health or from the Department.

Manufacturer means:

(1) Any person who manufactures frozen desserts or frozen dessert mixes, either by a continuous or batch process, for sale at wholesale; and

(2) Any person who manufactures milk-based frozen desserts from pasteurized mixes in a

food establishment, using either a batch process or a soft-serve machine, for sale at retail.

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.

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

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

(1) Engaging in any frozen dessert operation subject to regulation by 105 CMR 561.000 or applicable statute, without a license, whenever engaging in such an operation requires a license.

(2) Engaging in any activity prohibited by, or not in compliance with, 105 CMR 561.000, or any order, license or policy issued or adopted by the board of health or the Department pursuant to 105 CMR 561.000 or applicable statute.

(3) Failing to do, or failing to do in a timely manner, anything required by 105 CMR 561.000, or any order, license or policy issued or adopted by the board of health or the Department pursuant to 105 CMR 561.000 or applicable statute.

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

Person in Charge means the individual present in a plant or food establishment who is the supervisor or is otherwise responsible for the operation of the plant or food establishment at the time of inspection.

Plant or Frozen Dessert Plant means any facility in which frozen desserts or frozen dessert mixes are manufactured for shipment or sale at wholesale.

Product means any frozen dessert or frozen dessert mix.

Production Day means a period of 24 consecutive hours.

Retail means sale to the ultimate consumer.

Soft-Serve Machine: *see* definition of "Frozen Dessert Freezing/Dispensing Machine."

Wholesale means sale to other than the ultimate consumer.

570.004: Adoption of Federal Regulation 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 110: *Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food*, published by the United States Office of the Federal Register, National Archives and Records Administration, Washington, DC (2002), to the extent it is not inconsistent with specific provisions of 105 CMR 561.000.

561.005: Adoption of Federal Regulation 21 CFR Part 135: Frozen Desserts

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 135: *Frozen Desserts*, published by the United States Office of the Federal Register, National Archives and Records Administration, Washington, DC (2002), to the extent it is not inconsistent with specific provisions of 105 CMR 561.000.

561.006: Supplemental Regulations for All Frozen Desserts and Frozen Dessert Mixes, Whether or not they are Milk-based

The following requirements are in addition to those specified in 105 CMR 561.004 and 561.005.

(A) Source of Water. All water used in the manufacture of frozen desserts or frozen dessert mixes, whether used in plant or equipment operations or as an ingredient in any product, shall be from an approved water source 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 water source in Massachusetts:

(a) If used as an ingredient in any product, shall meet the standard in 105 CMR 561.006(A)(1), and

(b) If used solely in plant 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.

(B) Allergens.

(1) Whenever a manufacturer uses the same equipment for processing multiple products and makes a transition from processing a product containing a known allergen to a product containing no known allergen or a different known allergen, it shall ensure that all of the product-contact surfaces of the processing and filling equipment are fully flushed and rinsed in a manner sufficient to clear the lines of any residual allergen before the subsequent product is processed.

(2) Alternatively, products containing any known allergen may be processed on dedicated processing and filling equipment.

(C) Frozen and Refrigerated Products.

(1) Delivery and Transportation.

(a) Frozen and refrigerated packaged product delivery vehicles shall be equipped with a combination of insulation and mechanical refrigeration, capable of maintaining a product temperature of 0°F (-18°C) or lower for frozen products and 45°F (7.2°C) or lower for refrigerated products, while loaded with any frozen or refrigerated products.

(b) Frozen and refrigerated packaged product delivery vehicles shall be equipped with a thermometer or other appropriate means of temperature measurement, indicating air

temperature inside the vehicle.

(c) Any person who wishes to use a method of transportation for packaged products other than a mechanically refrigerated vehicle shall apply to the Department for a variance pursuant to 105 CMR 561.035, and shall explain in the variance application how safe temperatures will be maintained.

(d) The internal product temperature for any individual consignment of frozen products shall not exceed 10°F (-12°C), and for refrigerated products shall not exceed 45°F (7.2°C) during any loading, transportation or unloading of said consignment.

(e) Frozen and refrigerated products shall be loaded and unloaded as quickly as possible to insure a minimum of exposure to temperatures above 10°F (-12°C) or 45°F (7.2°C), whichever is appropriate.

(f) Equipment that has direct contact with ingredients shall not be used, and shall not have been used previously, for any non-food product.

(g) Frozen and refrigerated products shall be transported under sanitary conditions in accordance with good commercial practice.

(h) After loading, all access points to the contents of any tanker carrying fluid milk, cream, condensed milk or frozen dessert mix shall be sealed with a tamper-evident seal printed with a unique identifier. The seal may be removed only by the receiving entity, and the vehicle shall be resealed after each delivery.

(2) Handling Practices for Over-the-Road Transportation.

(a) Vehicles carrying packaged products shall be pre-cooled before loading.

(b) Frozen and refrigerated products destined for direct consumer use shall be securely packaged or wrapped in a sanitary manner before they are offered for transportation. Other frozen and refrigerated products shall be shipped in accordance with good sanitary practice.

(c) No frozen or refrigerated product shall be accepted for transportation when the internal product temperature exceeds 10°F (-12°C) for frozen products or 45°F (7.2°C) for refrigerated products.

(d) Frozen and refrigerated products shall be loaded within a vehicle of transportation so as to provide for free circulation of refrigerated air to the front, rear, top, bottom and both sides of the load, except for vehicles of envelope type construction wherein refrigerated air circulates within walls of said vehicles.

(e) Frozen and refrigerated products shall be handled expeditiously during any loading or unloading of said consignment, so as not to be unreasonably exposed to temperatures above 10°F (-12°C) or 45°F (7.2°C), as appropriate.

(f) The mechanical refrigerating unit of the vehicle shall be turned on, and the doors of the vehicle shall be kept closed during any time interval when loading or unloading operations cease or are interrupted.

(D) Product Recall.

(1) A manufacturer who knows or has reason to believe that circumstances exist that may adversely affect the safety of products, including but not limited to spills, accidents, natural disasters, or breakdowns in production, shall notify the Department immediately. Any in-state manufacturer shall also notify the board of health.

(2) Each plant operator shall develop and maintain on file a current written contingency plan for use in initiating and accomplishing a product recall in accordance with 21 CFR §§ 7.40 through 7.49, 7.53 and 7.55. The plan shall include procedures for the notification of

the Department, consumer notification, and recall of the product.

(3) The plant 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 use.

(4) The plant 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 a period of time that exceeds the shelf life and expected use of the product and is at least two years.

(5) The plant shall implement the recall procedures as necessary with respect to any product for which the manufacturer or the Department knows or has reason to believe that circumstances exist that may adversely affect its safety for the consumer.

(6) If the Department determines that the circumstances present an imminent health hazard 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 manufacturer:

(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 manufacturer shall be responsible for disseminating the notice in a manner designed to inform consumers who may be affected by the problem.

2. The manufacturer shall where appropriate provide the notice to radio and television media and/or to the newspaper(s) serving the affected public, and/or shall directly notify affected consumers when doing so effectively avoids or minimizes the risk to health.

If the manufacturer is participating in a recall in cooperation with FDA, this will be deemed sufficient to satisfy the manufacturer's obligations pursuant to this section 105 CMR 561.006(D)(6), provided that the manufacturer gives timely notice to the Department.

(7) Product recalls shall conform to the procedures and policies of 21 CFR Part 7.

(E) Sanitation Standard Operating Procedure (SSOP). Each plant operator shall develop and implement a written Sanitation Standard Operating Procedure (SSOP), and shall make it available to inspectors of the board of health and/or the Department during an inspection or upon request. The SSOP shall be updated as necessary and shall at a minimum address the following areas:

(1) Safety of the plant's operations water;

(2) Construction and condition of, and cleaning procedures for, the plant and all equipment, including but not limited to pipelines, silos, holding tanks, storage tanks, fillers and washing equipment;

(3) Prevention of cross-contamination;

(4) When a known allergen is an ingredient of any product, a schedule for the use of all equipment that comes in contact with the known allergen, including a schedule for cleaning and flushing/rinsing the equipment in a manner sufficient to clear the lines of any residual allergen;

(5) Production logs for each production run, including information on cleaning and sanitizing the equipment;

(6) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(7) Protection of packaging and product contact surfaces from contamination;

(8) Proper labeling of all toxic substances in the plant;

(9) Sanitization procedures;

(10) Employee health and hygiene;

(11) Employee training;
(12) Exclusion of pests; and
(13) Procedures for daily monitoring and recording compliance with the SSOP.

(F) Maintenance of Records. All records required to be kept pursuant to 105 CMR 561.000 shall be maintained on file for at least two years, and shall be made available to agents of the board of health or the Department upon request.

561.007: Supplemental Regulations for All Milk-based Frozen Desserts and Frozen Dessert Mixes

The following requirements for milk-based frozen desserts and frozen dessert mixes are in addition to the requirements specified in 105 CMR 561.006. They apply to all such products, regardless of what type of dairy animal is the source of the milk.

(A) Source of Ingredients. All raw milk and cream shall be obtained from a farm or plant licensed or permitted by the appropriate governmental authority in the jurisdiction.

(B) Pasteurization.

(1) Any milk-based ingredient used in the manufacture of frozen desserts shall be pasteurized in compliance with 105 CMR 561.000.

(2) When a plant performs pasteurization, it shall use an automatic recording thermometer chart.

(a) In batch pasteurization, the following information shall be entered on the chart.

1. Date;
2. Number or location of recorder when more than one is used;
3. A continuous record of the product temperature;
4. Extent of holding period, including filling and emptying times when required;
5. Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart;
6. Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
7. Amount and name of pasteurized milk or milk product represented by each batch or run on the chart;
8. Record of unusual occurrences;
9. Signature or initials of operator; and
10. Name of plant.

(b) In high-temperature, short-time pasteurizers and higher heat, shorter time pasteurizers, recording thermometer charts shall contain the information specified in 105 CMR 561.007(B)(2)(a), with the exception of 561.007(B)(2)(a) 4. and 5., and in addition shall include the following information.

1. A record of the time during which the flow-diversion device is in the forward-flow position;
2. The cut-in and cut-out milk temperatures, recorded daily by the operator, at the beginning of the run (high-temperature, short-time only); and
3. The information in 105 CMR 561.007(B)(2)(a)6. shall also be recorded immediately after a chart has been changed.

(3) Pasteurization shall be done at one of the following temperatures for the time specified.

Temperature	Time
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

Whichever combination of time and temperature is used, the ingredients or mixes, after pasteurization, shall be promptly cooled to and maintained at a temperature of 45°F or lower.

(4) Batch pasteurization: airspace heating

(a) Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and milk products at a temperature not less than 5° F (3° C) higher than the minimum required temperature of pasteurization, during the holding period.

(b) Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least 25 millimeters (one inch) below the bottom of the thermometer bulb when the vat is in operation.

(c) The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart.

(5) Manufacturers that receive frozen dessert mix in bulk form shall pasteurize the mix before using it in the manufacturing process, even if it has been previously pasteurized, except that this requirement shall not apply to mix received in:

(a) A tanker that provides written documentation to the plant 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 plant.

(C) Milk-based Ingredients from Outside the United States. 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 or frozen dessert mixes unless the importer has documentation to show that the exporter is in compliance with 21 CFR Part 1210. The manufacturer shall maintain adequate documentation of such compliance for at least two years.

(D) Reprocessing and Resale.

(1) Spilled frozen desserts and ingredients shall be discarded.

(2) Product intended for reprocessing shall be handled in sanitary covered containers and stored at or below 45°F 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 repasteurized. If such mix contained a known allergen, it shall be used only as mix for products that contain the same allergen.

(4) Frozen desserts that have left the possession of the manufacturer and been returned to the manufacturer shall not be resold until the manufacturer verifies that the products are safe for human consumption. Returned products that have been opened or are at or past the date specified on the package for sale of the product, shall not be resold but may be reprocessed.

(E) Daily Cleaning and Sanitizing.

(1) Processing and Filling Equipment.

(a) At a minimum, processing and filling equipment shall be cleaned and sanitized at least once during each production day.

(b) 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 561.035, and shall explain in the variance application how product safety will be maintained.

(2) Silos and Holding Tanks.

(a) At a minimum, silos and holding tanks containing unpasteurized ingredient or product shall be emptied, cleaned and sanitized at least once every 72 hours, and silos and holding tanks holding pasteurized ingredient or product shall be emptied, cleaned and sanitized at least once every 96 hours.

(b) 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 105 CMR 561.007(E)(2)(a) between cleaning and sanitizing shall apply to the Department for a variance pursuant to 105 CMR 561.035, and shall explain in the variance application how product safety will be maintained.

(c) Any new silos or holding tanks put into service after the effective date of 105 CMR 561.000 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.

(F) Testing Requirements.

(1) Raw Milk and Milk Products.

(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 or frozen dessert mixes. All drug residue tests shall be performed by a certified laboratory.

(b) The manufacturer shall not use any item tested until it receives a negative test result.

(2) Finished Products.

(a) All manufacturers manufacturing finished frozen dessert products by means other than a soft-serve machine shall have the tests specified in 105 CMR 561.007(G)(3): *Table 1* performed by a certified laboratory of each of the following categories of finished products at least once a month:

1. Plain frozen dessert (vanilla, chocolate, coffee, *etc.*)
2. Fruits and variegated (strawberry, frozen pudding, raspberry royale, *etc.*)
3. Nuts and candy (maple walnut, butter crunch, *etc.*)
4. Sherbet
5. Novelties (spumoni, dixies, sandwiches, *etc.*)

6. Seasonal products (products manufactured during only part of the year)
7. Frozen yogurt, except that if live cultures have been added to the product after pasteurization, the standard plate count 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.

(b) All manufacturers of frozen desserts produced in a soft-serve machine shall have the tests specified in 105 CMR 561.007(G)(3): *Table 1* performed by a certified laboratory of its finished product at least once a month.

(c) 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 561.007(F)(2)(a) and shall have priority for testing.

(3) Copies to be Submitted.

(a) In-state Manufacturers. Copies of all test results for required tests shall be submitted directly to the board of health by the certified laboratory within three business days of completion of the tests.

(b) Out-of-state Manufacturers. Upon application or re-application for a license, an out-of-state manufacturer shall submit copies of results of all required tests performed on finished products within the previous 30 days to the Department.

(4) Notification Regarding Certified Laboratory. Each manufacturer of a frozen dessert or frozen dessert mix shall notify the board of health (the Department, if an out-of-state manufacturer) in writing of the name and address of the certified laboratory where the tests required by 105 CMR 561.007(G)(3): *Table 1* are done. When the manufacturer ceases to use a particular laboratory, he or she shall immediately notify the board of health (the Department, if an out-of-state manufacturer) in writing of the name and address of the new laboratory that is to be used.

(G) Standards for Raw and Finished Products.

(1) All milk and milk products used as ingredients in a frozen dessert, including a frozen dessert mix, shall be received, stored and shipped so as to ensure that the internal temperature does not exceed 45° F.

(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.

(3) Bacterial and other Standards. The items listed in 105 CMR 561.007(G)(3): *Table 1* shall not exceed the following standards.

Table 1

Item	Standard PlateCount	Coliform	Drugs
Raw Milk and Milk Products	100,000 for individual producer milk 300,000 for commingled milk*	-	0**
Finished Products Produced by means other than a Soft-Serve	50,000/g	20/g	-

Machine			
Finished Products Produced in a Soft-Serve Machine	50,000/g	50/g	-
Aseptically Processed Finished Products	"Commercial Sterility" as defined in 21 CFR 113.3(e)(1)	-	-

*Not a mandated test, but this standard applies to any test conducted by either the manufacturer or the regulatory agency.
**No detectable drug residue.

(H) Violation of Standards: Products Produced by Means Other than a Soft-Serve Machine.

(1) Sampling and Testing after a Bacterial Violation is Found. Whenever any sample tested pursuant to 105 CMR 561.007(F) is found to be in violation of any standard plate count or coliform standard in 105 CMR 561.007(G)(3), the manufacturer shall resample 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.

(2) Enforcement of Bacterial Standards.

(a) Whenever two of the last four consecutive standard plate 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 561.007(G)(3), the board of health shall, and the Department may, send a written notice thereof to the licensee. This notice shall also inform the licensee of the provisions of 105 CMR 561.007(H)(2)(b), and shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard.

(b) Whenever the standard specified in 105 CMR 561.007(G)(3) has been violated by three of the last five consecutive standard plate counts or coliform determinations (except those for aseptically processed products), taken on separate days (different production days), the board of health shall, and the Department may, 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 561.030(A).

(c) In the case of plants producing aseptically processed products, when an inspection of the plant and its records reveals that the process used does not comply with the process specified in 21 CFR Part 113, the violation shall be considered an imminent health hazard, and the board of health shall, and the Department may, immediately suspend the license of the plant or suspend the operation of the process, without prior notice or hearing, in accordance with 105 CMR 561.030(A).

(3) Sampling and Testing after a Drug Residue Violation is Found. Whenever a drug residue is detected in raw milk or a raw milk product, the manufacturer shall arrange for confirmatory testing of a second sample of the same product by an appropriate certified laboratory. If the suspect raw product has been processed into finished product, the finished product shall be held until the result of the confirmatory test is received.

(a) If no drug residues are found in the second sample, the raw or finished products may be used or sold.

(b) If the second sample is found to contain a drug residue, all remaining raw product

and all finished products into which the violative raw product was processed shall be destroyed.

(I) Violation of Standards: Soft-Serve Machines. Whenever any sample from a soft-serve machine tested pursuant to 105 CMR 561.007(F) is found to be in violation of any standard plate count or coliform standard in 105 CMR 561.007(G)(3), the machine operator shall thoroughly clean, rinse, and sanitize the machine and shall arrange for testing of 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 561.007(G)(3).

561.008: Labeling and Standards of Identity

(A) General Labeling Requirements.

(1) All frozen desserts and frozen dessert mixes shall comply with the requirements for "natural" labeling of products provided in 105 CMR 520.116, and, if the products are open dated, shall comply with the applicable requirements of 105 CMR 520.119.

(2) All such products shall also comply with the applicable requirements of the federal Food Labeling regulations, 21 CFR Part 101. Among other things, this Part includes the federal regulations governing nutrition labeling, nutrient content claims, and health claims. When the Department receives a complaint alleging a violation of any provision of 21 CFR Part 101 with respect to a product that is at any time in the course of interstate commerce, the Department may refer the complainant to the FDA.

(B) Coding of Packages. All packages of frozen desserts shall be labeled with an identification code number, and/or with coding sufficient to comply with 105 CMR 561.006(D)(3).

(C) Standards of Identity. Frozen dessert labeling shall comply with the standards of identity in 21 CFR Part 135. When the Department receives a complaint alleging a violation of any provision of 21 CFR Part 135 with respect to a product that is at any time in the course of interstate commerce, the Department may refer the complainant to the FDA.

561.009: Prevention of Disease Transmission by Employees

(A) The procedures specified in 105 CMR 590.017 (Prevention of Foodborne Disease Transmission by Employees) shall apply to all employees in any food establishment where milk-based frozen desserts are manufactured and sold.

(B) In accordance with 21 CFR 110.10, it is the responsibility of the plant operator to protect the integrity of frozen dessert products by:

(1) Developing and implementing a plan for employee health and hygiene (as part of the SSOP developed pursuant to 105 CMR 561.006(E)) 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.

(C) When the licensee, person in charge, or manager of a plant knows or has reasonable cause to believe that an employee has contracted a disease transmissible through food or has become a carrier of such a disease, he or she shall immediately notify the board of health.

(D) When the board of health or the Department knows or has reasonable cause to believe that an employee has contracted a disease transmissible through food or has become a carrier of such a disease, it is authorized to:

(1) Secure a confidential medical history of the suspected employee and make other investigations as deemed appropriate; and

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

(E) The board of health shall immediately notify the Director of the Food Protection Program in the Division of suspected disease transmission, and shall keep the Director informed until any investigation is completed.

(F) The Commissioner or his or her designee, on his or her own initiative or at the request of a local board of health, may require any employee 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.

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

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

(1) Restriction of particular employees' services to specific areas and tasks in the plant that present no risk of transmitting the disease;

(2) Excluding particular employees from the plant; or

(3) Closing the plant by summarily suspending the permit in accordance with 105 CMR 561.030(A).

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

(1) *Salmonella Typhi*
(2) *Shigella* spp.
(3) *Escherichia coli* O157:H7 and other *Enterohemorrhagic E. coli* (EHEC)
(4) Hepatitis A virus
(5) *Entamoeba histolytica*
(6) *Camplylobacter* spp.
(7) *Vibrio* spp.
(8) *Cryptosporidium* spp.
(9) *Giardia* spp.
(10) *Hemolytic Uremic* Syndrome

(11) Salmonella spp. (*non-typhi*)
(12) *Yersinia enterocolitica*
(13) *Cyclospora cayetanensis*

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

561.020: General Administration

(A) Enforcement Policy. The following provisions shall cover the administration and enforcement of 105 CMR 561.000.

(B) The purpose of the enforcement program is to promote the protection of the public health by:

(1) Ensuring compliance with regulations and conditions of holding a license;
(2) Obtaining prompt correction of violations and adverse quality conditions that may affect public health;
(3) Deterring future violations and occurrences of conditions adverse to public health; and
(4) Encouraging improvement of good manufacturing practices for individual licensees, and by example, for the industry, including prompt identification and reporting of potential health or sanitation problems.

(C) The Department may from time to time publish interpretations of 105 CMR 561.000 and guidelines as necessary to promote uniform application of 105 CMR 561.000, and may make them available to those persons holding licenses under 105 CMR 561.000. The Department may advise licensees or local boards of health on particular questions regarding the interpretation of 105 CMR 561.000.

(D) The board of health or the Department may enforce 105 CMR 561.000 by issuing an order to correct violations or by commencing an enforcement action pursuant to 105 CMR 561.030 and 561.031.

561.021: Licenses

(A) In-state Manufacturers.

(1) Unless exempted by statute or by 105 CMR 561.000, no person shall engage within Massachusetts in the business of manufacturing frozen desserts or frozen dessert mixes, whether at wholesale or retail, without a valid license from the board of health of the city or town where the business is located. No person shall engage in such business in violation of the terms of a valid license or the requirements of 105 CMR 561.000.

(2) Exemption. 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 561.000, and no separate license pursuant to 105 CMR 561.000 shall be required. If such person already has a valid permit pursuant to 105 CMR 590.000 because he or she operates a food establishment, no separate permit pursuant to 105 CMR 590.000 shall be required.

(B) Out-of-state Manufacturers. No person engaged outside Massachusetts in the business of manufacturing frozen desserts or frozen dessert mixes shall sell any such product within Massachusetts without a valid license from the Department. No person shall engage in such business in violation of the terms of a valid license or the requirements of 105 CMR 561.000.

(C) No person shall sell or exchange, deliver, advertise, offer, or expose for sale or exchange, or attempt to deliver, or have in his possession with intent to do so, any frozen dessert or frozen dessert mix unless the manufacturer thereof is the holder of a current license issued pursuant to 105 CMR 561.021.

(D) Application Process.

(1) In-state Manufacturers. A person who desires to manufacture frozen desserts or frozen dessert mixes within Massachusetts shall submit an application for a license to the board of health of the city or town where the business is or is to be located, on a form provided by the board of health and prescribed by the Department.

(2) Out-of-state Manufacturers. A person who is engaged outside Massachusetts in the business of manufacturing frozen desserts or frozen dessert mixes and who wishes to sell such products in Massachusetts shall submit an application for a license to the Department, on a form provided by the Department. With the application, an out-of-state applicant shall also submit a copy of its license, permit or certification received from the regulatory agency having jurisdiction, a copy of an inspection report of the plant by such agency completed within the past six months, and copies of results of all tests required by 105 CMR 561.007(G)(3) on finished frozen dessert products, performed within the previous 30 days.

(E) Only a person who complies with the requirements of 105 CMR 561.000 shall be entitled to receive and retain a license.

(1) A license issued by a board of health shall be valid only for the licensee indicated on the license and only for the location indicated on the license.

(2) A license issued by the Department shall be valid throughout Massachusetts.

(F) A license shall remain in effect for the period of time specified by statute.

(G) A licensee may renew a license by applying to the board of health or Department at least 30 days prior to the expiration of the license. Application for renewal shall be made in writing on a form provided by the board of health or Department.

(H) No licensee shall transfer or assign a license in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any company. No licensee shall operate pursuant to a license transferred or assigned by a prior licensee.

(I) Operating Without a License.

(1) The board of health or Department may inspect any facility for which it has a reasonable belief contains a wholesale or retail manufacturing operation for frozen desserts or frozen dessert mixes.

(2) The board of health or Department may deny an application for a license when the

applicant was previously operating a frozen dessert or frozen dessert mix manufacturing operation, or any type of food processing operation, without a required license.

(3) Operation of a manufacturing operation that is subject to a license pursuant to M.G.L. c. 94, § 65H, without a license, shall subject a person to a fine of not more than the amount specified by statute. The Superior Court shall have jurisdiction to enjoin the operation of a manufacturing operation, or enjoin the sale of products from a manufacturing operation, that does not have a license.

(4) The board of health or Department may take such other steps as required to bring a manufacturing operation operating without a license into compliance or to terminate the operation of the manufacturing operation, in order to protect the health and safety of the public.

561.022: Notification to the Board of Health and the Department

(A) Mailing Address. Each applicant and licensee shall provide the board of health or Department with its complete and correct mailing address. Each applicant and licensee shall notify the board of health or Department within seven calendar days of the change of its mailing address. The address provided to the board of health or Department shall be deemed the appropriate address for the service of all orders and notices from the board of health or Department.

(B) Change of Ownership or Business Location. A licensee shall notify, and relinquish its license to, the board of health or Department immediately upon a change of ownership or business location. The new owner in a change of ownership, or the licensee in the case of a new location, shall submit to the board of health or Department an application for a new license, and shall not operate until said license is issued.

(C) Change of Name. A licensee shall notify the board of health or Department at least 30 days prior to any change of the name of the business. A change of name only shall require the licensee to submit to the board of health or Department an application for an amended license, together with written documentation reflecting the change of name.

(D) Remodeling of an In-state Plant. Before initiating the work, a licensee shall notify the board of health and the Department in writing of any proposed changes to an in-state plant that could affect the integrity of products, including but not limited to a change in any production line, storage tank, filling equipment, and washing equipment. After receiving notification, the board of health or Department may inspect the plant to verify that the proposed changes will comply with 105 CMR 561.000.

(E) Non-Renewal of In-state License. If a license for an in-state plant is not renewed, the board of health shall notify the Department to that effect.

561.023: Inspections

(A) To carry out properly their responsibilities under 105 CMR 561.000 and applicable statutes and to protect properly the health and well-being of the people of the Commonwealth, the appropriate board of health and the Department, or an authorized agent or representative of the

board of health or Department, are authorized, as often as is deemed necessary for the enforcement of 105 CMR 561.000, to enter, examine, or survey any plant or food establishment containing a wholesale or retail operation for manufacturing frozen desserts or frozen dessert mixes. Upon reasonable belief that a person is engaged in such an operation without a license, the appropriate board of health and the Department are authorized to inspect the location.

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

(C) Agents of the board of health or the Department, after identifying themselves, may enter all areas of the plant or food establishment, at any reasonable time, for the purpose of making an inspection to ascertain whether the plant or food establishment is in compliance with 105 CMR 561.000. Any reasonable time includes unannounced inspections, which do not require prior notification. Access shall be provided to board of health or Department inspectors at any reasonable time for inspection of the premises.

(D) Agents of the board of health or Department may examine all records of the plant or food establishment to determine which are subject to enforcement under 105 CMR 561.000 and all relevant statutes. Agents may copy all relevant records.

(E) The licensee, applicant, or the person in charge at the time of the inspection shall furnish the agent of the board of health or Department with all requested records and shall provide the agent with access to all areas of the plant or food establishment.

(F) If the licensee, applicant, or the person in charge at the time of the inspection refuses entry to an agent of the board of health or Department, refuses to permit an authorized inspection, or interferes with the board of health or Department or any agent thereof, in the performance of its duties, the board of health or Department may:

(1) Seek in a court of competent jurisdiction an administrative search warrant to search/inspect the premises. The warrant application shall apprise the applicant, licensee, or owner concerning the nature of the inspection and justification for it, and the board of health or the Department may seek the assistance of police authorities in presenting the warrant; and/or

(2) Take steps to summarily suspend, refuse to issue or renew, suspend or revoke the license or to impose fines in accordance with M.G.L. c. 94, §§ 65R or 305A.

(G) When an inspection is made, the findings shall be recorded on a printed inspection report form, which shall summarize the requirements of 105 CMR 561.000. Boards of health may obtain a prototype of an inspection form from the Department. A board of health may use this form or, subject to approval by the Department, any form consistent with the prototype. Each board of health that has a licensee within its jurisdiction shall submit the form it adopts to the Department.

561.024: Notice of Violations/Order to Correct

(A) Whenever the board of health or Department finds upon inspection, investigation of a

complaint or through information in its possession that an applicant or licensee is not in compliance with any of the provisions of 105 CMR 561.000, the board of health or Department shall notify the applicant or licensee of each violation. The notice shall include a statement of the violations found; the provisions of the law relied upon; the level of severity of the violation, when appropriate; a reasonable period of time for correction; and notice that the failure to correct a violation may result in a refusal to issue or renew or a suspension or revocation of a license, and/or the imposition of fines.

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

(C) The inspection report shall constitute the Notice of Violations and the Order to Correct all violations so indicated.

(D) The applicant or licensee shall be responsible for the correction of all violations and the compliance with any order issued pursuant to 105 CMR 561.000 and applicable statutes.

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

(1) Service shall be in person to the applicant or licensee or the person in charge at the time of the inspection, or by certified mail, return receipt requested.

(2) If served personally, notice is deemed to be issued on the date when the report is delivered personally.

(3) If served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.

(F) Procedures for Pasteurization Violations. In addition to the procedures set forth in 105 CMR 561.024 (A) through (E), the following procedures shall apply in the case of violation(s) of pasteurization requirements.

(1) If the inspection reveals a violation of a requirement set forth in 105 CMR 561.007(B), a second inspection shall be conducted after a time deemed necessary by the board of health or Department to remedy the violation. Such period shall not be shorter than three days, except in cases of public health emergency, in which case the reinspection may be conducted as soon as the board of health or Department deems necessary. Any violation of the same requirement on such second inspection may result in a Notice of Action to suspend the license pursuant to 105 CMR 561.030(C).

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

(a) Improper pasteurization, whereby every particle of milk or frozen dessert mix may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or

(b) A cross connection whereby direct contamination of pasteurized milk, frozen dessert mix, or product(s) is occurring; or

(c) Conditions whereby direct contamination of pasteurized milk, frozen dessert mix, or product(s) is occurring, the board of health or Department shall take immediate action to prevent further processing of such milk, frozen dessert mix or frozen dessert product(s) until such violations of critical processing element(s) have been corrected. Should

correction of such critical processing element(s) not be accomplished immediately, the violation(s) shall be considered an imminent health hazard, and the board of health or Department shall immediately suspend the license of the plant or suspend the operation of the process, without prior notice or hearing in accordance with 105 CMR 561.030(A), and may also institute court action.

561.025: Plan of Correction

(A) The applicant or licensee, within ten calendar days of issuance of the Notice of Violations/Order to Correct or within such shorter time as specified in the Notice, shall:

(1) Correct all violations and file a certification of correction with the board of health or Department, and/or

(2) For those items not certified as corrected, file a written plan of correction with the board of health or Department.

(B) Each plan of correction and each certification shall:

(1) State the name of the applicant or licensee and the name of the individual and address for receipt of notices;

(2) Reference each violation cited, and for each indicate:

(a) The specific corrective action completed and the date the work was completed; and

(b) When 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 signature of the applicant or licensee or his or her official designee, sworn to under the pains and penalties of perjury.

(C) If the applicant or licensee cannot complete the corrective action within the time frame designated in the Notice of Violations/Order to Correct, the applicant or licensee must petition the board of health or Department in writing for an extension of the time to correct. Any petition to extend the time to correct must be submitted to the board of health or Department prior to the date indicated in the Notice of Violations/Order to Correct for the violation to be corrected. An untimely petition for extension will not be considered unless good cause can be established for the failure to timely file. 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 corrections will be completed. The board of health or Department shall notify the applicant or licensee whether an extension of the time is granted and the duration of the extension, if it is granted.

(D) The board of health or Department may conduct a reinspection to determine whether the corrections were completed.

(E) If upon review of the plan of correction and/or upon reinspection the board of health or Department finds that an applicant or licensee remains noncompliant with applicable laws and regulations, the board of health or Department may initiate administrative enforcement action as set forth in 105 CMR 570.030 and 561.031, or it may request that the applicant or licensee amend and resubmit the plan of correction within ten calendar days of the issuance of the notice

or such other time as the board of health or Department may specify for resubmission.

561.030: Grounds for Administrative Enforcement Action

(A) Summary Suspension without a Prior Hearing.

(1) A board of health may immediately suspend a license issued by it or one or more particular operations of its licensee, and the Department may immediately suspend any license or one or more particular operations of any licensee, without a prior hearing, if:

(a) An imminent health hazard is found to exist;

(b) Three of the last five standard plate counts or coliform determinations have been in violation of the standard; or

(c) An agent of the board of health or the Department is refused entry to the premises or is prevented from conducting an authorized inspection.

(2) A summary suspension order shall be in writing and shall be immediately provided to the licensee or to the person in charge of the premises and a copy shall be posted on the premises. The order shall state:

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

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

(c) That all manufacturing operations or one or more manufacturing operations shall immediately cease and desist; and

(d) That a hearing shall be afforded pursuant to the procedures established in 105 CMR 561.031(C).

(3) The Order of Summary Suspension shall be effective upon posting of the order on the premises by an authorized agent of the board of health or Department, or in the case of an out-of-state plant, upon service of the order. If the person whose name appears on the license is not present at the time of such posting, or if the licensee is a corporation or other firm, a copy of the Order of Summary Suspension shall also be served in accordance with 105 CMR 561.031(B).

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

(B) Refusal to Issue a License after Opportunity for a Hearing. After providing an opportunity for a hearing, the board of health or Department may refuse to issue a license 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:

(1) Failure to submit an application or supporting documents in accordance with required procedures;

(2) Failure to submit the required fee;

(3) Failure to comply with any provision of 105 CMR 561.000;

(4) Denial of entry to agents of the board of health or Department, refusal to provide access to inspect any part of the premises, or any attempt to impede the work of a duly authorized agent or representative of the board of health or Department;

(5) Providing a false or misleading statement to the board of health or Department, or keeping or submitting any misleading or false records or documents required by 105 CMR 561.000 or related law;

(6) The applicant operated the plant or any other plant, food processing facility, food

establishment or soft-serve machine without a license or after the expiration of a license;
(7) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the plant, food establishment or soft-serve machine 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 manufacturing, processing, storage, distribution or sale of food in connection with a business;
(8) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the plant, food establishment or soft-serve machine has engaged in conduct that endangers the public health;
(9) A plant, food processing facility, food establishment or soft-serve machine 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 refusal to renew the license;
(10) Failure to pay any federal, state or local taxes as required by law, pursuant to M.G.L. c. 62C, § 49A;
(11) Failure to pay fines levied in accordance with M.G.L. c. 94, §§ 65R, 305A or 305C; or

(12) Failure to comply with local regulations/ordinances related to the operation of the plant, food establishment or soft-serve machine.

(C) Suspension of License or Operations after Opportunity for a Hearing.
(1) After providing an opportunity for a hearing, a board of health may suspend a license issued by it or one or more particular operations of its licensee, and the Department may suspend any license or one or more particular operations of any licensee, if the licensee or operation(s) does not comply with any one or more of the requirements of 105 CMR 561.000.
(2) The suspension shall continue until the board of health or Department determines that the required corrections have been made.

(D) Revocation of License after Opportunity for a Hearing.
(1) After providing an opportunity for a hearing, the Department may revoke a license issued by it or terminate one or more of its licensee's particular operations, and a board of health may revoke a license issued by it or terminate one or more of its licensee's particular operations, based upon any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to revoke a license or to terminate operation(s):
(a) A serious violation or repeated violations of any provision of 105 CMR 561.000 or of any provision of the license;
(b) Denial of entry to agents of the board of health or Department, refusal to provide access to inspect any part of the premises, or any attempt to impede the work of a duly authorized agent or representative of the board of health or Department;
(c) Providing a false or misleading statement to the board of health or Department, or keeping or submitting any misleading or false records or documents required by 105 CMR 561.000 or related law;
(d) The licensee or, if the licensee is a corporation, a corporate officer or the owner of the plant, food establishment or soft-serve machine 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 manufacturing of frozen desserts or frozen

dessert mixes;

(e) The licensee or, if the licensee is a corporation, a corporate officer or the owner of the plant, food establishment or soft-serve machine has engaged in conduct that endangers the public health;

(f) Failure to pay any federal, state or local taxes as required by law, pursuant to M.G.L. c. 62C, § 49A;

(g) Failure to pay fines levied in accordance with M.G.L. c. 94, §§ 65R or 305A; or

(h) Violation of any provision of M.G.L. c. 94, §§ 65G through 65U.

(2) The revocation of a license or termination of operation(s) shall be effective for a period of one year from the date of the final order, unless the order states otherwise.

(E) Refusal to Renew a License after Opportunity for a Hearing. After providing an opportunity for a hearing, the board of health or Department may refuse to renew a license if the licensee does not comply with any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to refuse to renew a license:

(1) Any of the grounds specified in 105 CMR 561.030(A);
(2) Any of the grounds specified in 105 CMR 561.030(B);
(3) Any of the grounds specified in 105 CMR 561.030(C); or
(4) Any of the grounds specified in 105 CMR 561.030(D).

561.031: Procedures for Administrative Enforcement Action

(A) Notice of Action.

(1) Whenever the board of health or Department determines to suspend with notice, revoke or refuse to issue or renew a license, it shall issue a Notice of Action. The Notice shall be in writing and shall specify:

(a) The specific reason(s) for which the particular administrative action is to be taken, and the applicable provisions of law;

(b) That the particular administrative action will occur at the end of a specified reasonable time set by the board of health or Department; and

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

(2) The Notice shall be served on the licensee in accordance with 105 CMR 561.031(B).

(B) Service of Orders and Notices of Action.

(1) Orders of Summary Suspension and Notices of Action with respect to any other administrative action shall be served on the licensee or his or her authorized agent as follows:

(a) By certified mail, return receipt requested; or

(b) In hand service.

(2) If served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.

(3) If served personally, notice is deemed to be issued on the date when the order or notice is delivered personally.

(4) If, and only if, the methods of service specified in 105 CMR 561.031(B)(1) are unsuccessful, service may be made:

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

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

(C) Hearings.

(1) Procedures Applicable to all Hearings.

(a) The person to whom an Order of Summary Suspension or Notice of Action was directed may request a hearing before the agency that issued it (*i.e.* the board of health or Department). Such request shall be in writing and must be received by the board of health or Department within ten days of the issuance of the order or notice.

(b) The failure to timely request a hearing constitutes a waiver of the right to a hearing.

(c) Any settlement of any enforcement action commenced under 105 CMR 561.000 shall be final and shall not be subject to judicial review.

(d) A hearing based on an Order of Summary Suspension shall be conducted within 96 hours after the board of health or Department receives the request for a hearing. If the 96-hour period expires on a weekend day or holiday, the hearing may be held on the next business day. If the parties agree to postpone the beginning of the hearing beyond 96 hours, the hearing may be postponed.

(e) A hearing based on a Notice of Action to suspend, revoke or refuse to issue or renew a license shall be commenced within a reasonable time period after the board of health or Department receives the request for a hearing.

(f) Failure to hold a hearing within the time periods specified herein shall not affect the validity of the proceedings.

(g) The applicant or licensee shall be given an opportunity to be heard and to show why the proposed action should not be taken. Any oral testimony given at a hearing shall be recorded verbatim (tape recording shall suffice).

(h) In the case of summary suspension, the standard for decision shall be whether the board of health or Department proved by a preponderance of evidence that there existed, immediately prior to or at the time of the suspension, an imminent health hazard.

(i) In the case of a Notice of Action to suspend, revoke or refuse to issue or renew a license, the standard of decision shall be whether the board of health or Department proved by a preponderance of the evidence that the license should be suspended, revoked, denied or not renewed, based on relevant facts as they existed at or prior to the time the board of health or Department initiated the action.

(j) The Notice of Violations/Order to Correct shall constitute *prima facie* evidence of the conditions listed therein.

(2) Hearings by the Department: Additional Provisions.

(a) The Department shall conduct all adjudicatory proceedings in accordance with M.G.L. c. 30A and all applicable provisions of 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.

(b) At the conclusion of the hearing, if the hearing officer finds any single ground for summary suspension, denial, suspension, revocation, or refusal to renew a license, the hearing officer shall render a recommended decision affirming the decision of the Department.

(c) Public Health Council and Judicial Review.

1. The recommended decision of the hearing officer shall be reviewed by the Commissioner and the Public Health Council. After review, their 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, 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 administrative review by the Public Health Council. In such cases, the Commissioner shall issue 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.

(3) Hearings by the Board of Health: Additional Provisions.

(a) A board of health that sets a hearing on a specified date rather than requiring the licensee to request a hearing, satisfies the hearing requirement provided that it gives adequate notice of the hearing date.

(b) After the hearing, the board of health shall make a final decision based upon the complete hearing record, and shall inform the petitioner in writing of the decision. Any single ground for summary suspension, denial, suspension, revocation, or refusal to renew a license, constitutes adequate grounds for affirming the notice.

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

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

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

(D) License or Operations: Reinstatement after Suspension.

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

(2) When the suspension has been due to a violation of any of the bacteriological or coliform standards (105 CMR 561.030(A)(1)(b)), an inspection shall be made within one week after the receipt of an application for reinstatement. The board of health or Department may conduct this inspection. If it is determined that the condition(s) responsible for the violation(s) has been corrected, the board of health or Department shall issue a temporary license, or allow the resumption of operation(s), or the sale of suspended product(s). The board of health or Department shall then take samples at a rate of not more than two per week on separate days within a three-week period. The board of health or Department shall reinstate the license forthwith, but in any event, within seven calendar days after the licensee is found to be in compliance with the appropriate standards.

(3) When the suspension has been due to a violation of a requirement other than one of those specified in 105 CMR 561.031(D)(2), the application for reinstatement shall indicate that the violation(s) has been corrected. Within one week of the receipt of such application, an inspection shall be made, and as many additional inspections thereafter as are deemed necessary, to determine that compliance with 105 CMR 561.000 has been achieved. The board of health or Department may conduct these inspections. The board of health or Department shall reinstate the license or allow the resumption of operation(s) forthwith, but in any event within seven calendar days after it determines that compliance has been achieved.

561.032: Embargo

(A) Pursuant to M.G.L. c. 94, § 189A, the Commissioner or his or her agent or the board of health may place an embargo on any product which it finds or has probable cause to believe is adulterated or misbranded provided that:

(1) A written notice is issued to the licensee or to the person in charge at the plant or food establishment; and

(2) The notice specifies in detail the reason(s) for the embargo order.

(B) The Commissioner or his or her agent or the board of health shall tag, label, or 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 or the board of health.

(C) The Commissioner or his or her agent or the board of health shall permit storage of the product under conditions specified in the embargo order, unless storage is not possible without risk to the public health, in which case immediate destruction shall be ordered and accomplished.

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

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

561.033: Criminal Penalties

Pursuant to the applicable provisions of M.G.L. c. 94, §§ 65R or 305A, criminal penalties may be imposed.

561.034: Nonexclusivity of Enforcement Procedures

None of the enforcement procedures contained in 105 CMR 561.000 is mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

561.035: Variance

(A) Upon application, the board of health or Department, within their respective jurisdictions (with the exception of variances considered by the Department pursuant to 105 CMR 561.006(C)(1)(c), 105 CMR 561.007(E)(1)(b) or 561.007(E)(2)(b)), may vary the application of any provision of 105 CMR 561.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice. The decision of the board of health or Department shall be in writing, shall state the reasons why the variance was granted or denied, and shall not conflict with the spirit of 105 CMR 561.000.

(B) A copy of each variance granted by the board of health shall be conspicuously posted for 30 days following its issuance, and shall be available to the public at all reasonable hours in the office of the city or town clerk or the office of the board of health while it is in effect. Notice of the grant of each variance shall be filed with the Department, which shall approve, disapprove, or modify the variance within 30 days from receipt thereof. If the Department fails to comment within 30 days, its approval will be presumed. No work shall be done under any variance until the Department approves it or 30 days elapse without its comment, unless the board of health or the Department certifies in writing that an emergency exists.

(C) A copy of any variance shall be available to the public.

561.036: Severability

The provisions of 105 CMR 561.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

105 CMR 561.000: M.G.L. c. 94, §§ 65G through 65U, 192, 305A, 305B; c. 111, § 5.

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