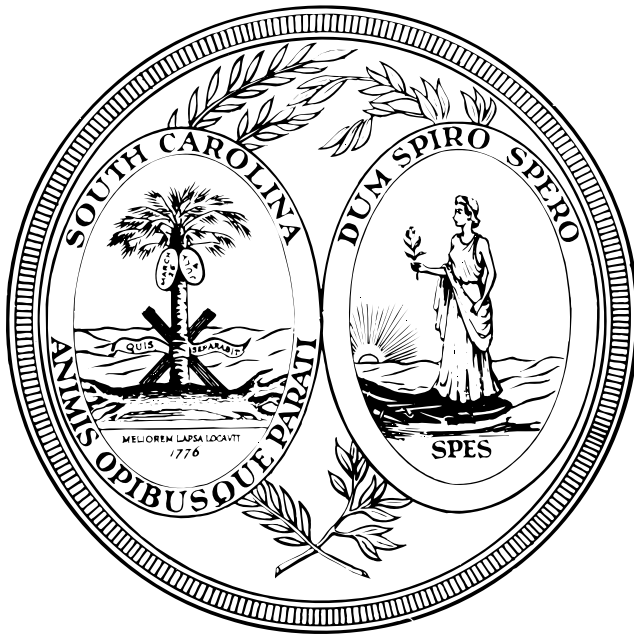


FROZEN DESSERTS

Regulation 61-36



South Carolina Department of Health and Environmental Control
2600 Bull Street, Columbia, South Carolina 29201
Revised - May 28, 2004

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Sections I - XVI
Revised: May 28, 2004

SECTION I. DEFINITIONS

The following definitions shall apply in the interpretation and the enforcement of this Regulation:

ADULTERATED FROZEN DESSERTS - a frozen dessert is deemed to be adulterated if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health;
2. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal regulation, or in excess of such tolerance if one has been established;
3. Consists, in whole or in part, of any substance unfit for human consumption;
4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;
5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
6. Has any substance added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;
7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342) will be considered as a violation of this Regulation.

AND/OR - “and” shall apply where appropriate, otherwise “or” shall apply.

ASEPTICALLY PROCESSED MIX – a frozen dessert mix that is hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of this Regulation so as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

ASEPTIC PROCESSING – a process whereby the mix has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and the provisions of Section VII (B), Item 16, of this Regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

DEPARTMENT - the authorized representative of the South Carolina Department of Health and Environmental Control.

DRUG – shall mean:

1. Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
2. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
3. Articles (other than food) intended to affect the structure of any function of the body of man or other animals; and
4. Articles intended for use as a component of any articles specified in clauses 1, 2, or 3, but does not include devices or their components, parts, or accessories.

FOUNTAIN FREEZER - a freezer which is installed and used for freezing frozen desserts which are held in the freezer under refrigeration until they are served for immediate consumption.

FROZEN DESSERTS - frozen desserts as used in this regulation shall be defined in S.C. Code Ann. Section 39-37-10 (1976, as amended). They shall also include mixes used for frozen dessert manufacturing and products such as gelato and sorbetto made in semblance of those products defined in Section 39-37-10.

FROZEN DESSERTS MANUFACTURER - any person, except frozen dairy foods retailer, who manufactures, processes, or freezes any frozen desserts for distribution or sale.

FROZEN DESSERTS PLANT - any place or premises except frozen dairy foods retailers where frozen desserts are manufactured, processed, or frozen for distribution or sale.

FROZEN DESSERTS RETAILER - any person who sells, serves, dispenses or processes by fountain freezing, frozen desserts at retail which have been processed in an approved frozen desserts plant.

HERMETICALLY SEALED CONTAINER - a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

MIX - the unfrozen combination of ingredients of frozen desserts except such fruits, nuts, flavors, color, and other ingredients as may be exempted by the Department. Mix shall be pasteurized.

NOVELTIES – Frozen desserts, either alone or in combination with other foods such as cookies, wafers, cones, coating, confections, etc., which are packaged in single-serving units.

PASTEURIZATION - the process of heating every particle of mix in properly designed and operated equipment to one of the temperatures given in the following table, and held continuously at or above that temperature for at least the corresponding specified time:

TEMPERATURE / TIME
155 degrees F / 30 Minutes
175 degrees F / 25 Seconds
180 degrees F / 15 Seconds
191 degrees F / 1.0 Second
194 degrees F / 0.5 Second
201 degrees F / 0.1 Second
204 degrees F / 0.05 Second
212 degrees F / 0.01 Second

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the United States Food and Drug Administration (FDA) to be equally efficient and which is approved by the Department.

PERSON - any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

OFFICIALLY DESIGNATED LABORATORY - a commercial laboratory authorized to do official work by the Department, or a milk industry laboratory officially designated by the Department for the examination of producer samples of Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.

OFFICIAL LABORATORY - a biological, chemical, or physical laboratory which is under the direct supervision of the Department.

SANITIZATION - the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the Department.

STERILIZED - the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

ULTRA-PASTEURIZED - mix that has been thermally processed at or above 138°C (280°F) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

SECTION II. ADULTERATED OR MISBRANDED FROZEN DESSERTS

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- A. No person shall within the State of South Carolina, or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any frozen dessert which is adulterated or misbranded. Any frozen dessert which may contain any unwholesome substance, or which if defined in this Regulation does not conform with the definition, shall be deemed adulterated and/or misbranded.
 - B. Any adulterated or misbranded frozen dessert may be impounded by the Department and disposed of in accordance with applicable laws or regulations.
 - C. Frozen desserts shall be examined by the Department as often as may be necessary to determine freedom from adulteration or misbranding. The Department may, upon written notice to the owner or person in charge, place a hold order on any frozen dessert which it determines or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, frozen desserts shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice or tag placed on frozen desserts by the Department, and neither such frozen desserts nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department, except on order by a court of competent jurisdiction.
 - D. When frozen desserts are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis provides the product to be free from adulteration.

SECTION III. COMPLIANCE PROCEDURES

A. PERMIT:

1. It shall be unlawful for any person who does not possess a permit from the Department to bring into, send into, or receive into South Carolina or its jurisdiction, for sale, or to sell, or offer for sale therein, or to have in storage any frozen dessert defined in this Regulation: Provided, that grocery stores, restaurants, soda fountains, and similar establishments where frozen desserts are served or sold at retail, but not processed, other than fountain freezing of approved pasteurized mix, may be exempt from the requirements of this section.
2. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Every frozen dessert manufacturer shall have a permit. Permits shall not be transferred with respect to persons and/or locations.

B. SUSPENSION OF PERMIT:

1. The Department shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this Regulation; or whenever the permit holder has interfered with the Department in the performance of its duties: Provided, that the Department shall, in all cases except where the frozen desserts involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the permit holder, manager or other duly authorized representative, a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in questions and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the Department before making any order of suspension effective. A suspension shall remain in effect until the violation has been corrected to the satisfaction of the Department.
2. When the permit suspension is due to violations other than bacterial, coliform, cooling temperature standards or adulteration by drugs, the permit holder, manager or other duly authorized representative, is notified of the intent to suspend the permit in fifteen days unless a written request for a hearing is filed by the permit holder within such fifteen day period with the Department. If the hearing upholds the findings of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.
3. The Department may without warning, notice, or hearing suspend a permit to operate a frozen dessert plant when it is determined that the operation of the frozen dessert plant constitutes an imminent health hazard, e.g., violations of bacterial, coliform, cooling temperatures, or adulteration by growth inhibitors (drugs) or other deleterious substances. Following immediate permit suspension, all manufacturing operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within fifteen days. If no written request for a hearing is filed within fifteen days, the suspension is sustained. During the process, the permit shall remain suspended unless the imminent health hazard has been corrected.
4. Hearings on suspension of permits provided for in this section shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 *et. seq.*, (1976, as amended) and applicable regulations.
5. Any frozen dessert or mix manufacturer whose permit has been suspended may make written application for the reinstatement of his permit.
6. Within one week of receiving the written application, the Department shall make inspections and/or collect samples for analysis to determine the applicant's establishment is in substantial compliance with this Regulation. If conditions warrant, the permit will be reinstated.

C. REVOCATION OF PERMIT:

1. The Department may revoke a permit after an opportunity for a hearing has been provided for repeated critical violations of any of the requirements of this regulation, or for interference with the Department of the performance of duty. Notwithstanding any other provisions of this regulation, the permit shall be revoked if the Department is threatened with bodily harm or physical interference in the performance of inspectional duties.
2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the fifteen days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within such fifteen day period.
3. When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, the Department may deny a new permit based upon past history.
4. The revocation of a permit, provided for in this chapter, shall be conducted in accordance with the South Carolina Administrative Procedures Act.
5. A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the frozen dessert plant's permit holder.
6. The hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 et. seq. (1976, as amended), and applicable regulations.

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SECTION IV. LABELING

All cans, packages, and other containers enclosing mix and frozen desserts or their ingredients derived from milk or edible food fats, except those filled from labeled bulk containers in retail dispensing, shall be plainly labeled or marked with: (1) the name of the contents; and (2) the name and address of the plant at which the contents were placed in the container. A frozen desserts manufacturing plant may be identified by a code when the Department is given advance notice of the coding. The label shall be in letters of an approved size, kind, and color and shall contain no marks or words which are misleading. All finished product labeling (name of product, ingredients, nutrition facts, net contents, etc.) shall conform to applicable federal and state labeling laws.

SECTION V. INSPECTION OF FROZEN DESSERT PLANTS

- A. Each frozen desserts manufacturer whose frozen desserts are intended for consumption within South Carolina or its jurisdiction shall be inspected by the Department prior to the issuance of a permit.

- B. Following the issuance of a permit, the Department shall inspect each frozen dessert manufacturer at least once every three months.
- C. If a violation of any requirement set forth in Section VI or Section VII is found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three days; this second inspection shall be used to determine compliance with the requirements of Section VI or VII. Any violation of the same requirement of Section VI or VII on such second inspection shall call for permit suspension in accordance with Section III and/or court action.
- D. Provided, that when the Department finds that a critical processing element violation involving:
1. Proper pasteurization, whereby every particle of mix or frozen desserts may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or
 2. A cross connection exists whereby direct contamination of pasteurized mix or frozen dessert is occurring; or
 3. Conditions exist whereby direct contamination of pasteurized mix or frozen desserts is occurring, the Department shall take immediate action to prevent further processing of such mix or frozen dessert until such violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the Department shall take prompt action to suspend the permit as provided for in Section III of this Regulation.
- E. Provided, that in the case of a mix plant producing aseptically processed mix, when an inspection of the mix plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to the public health and the Department shall take immediate action to suspend the permit of the plant for the sale of aseptically processed mix in conformance with Section III of this Regulation.
- F. One copy of the inspection report shall be handed to the operator, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department.
- G. Every frozen desserts plant operator shall, upon request of the Department, permit access of officially designated persons to all parts of his establishment or facilities to determine compliance with the provisions of this Regulation. A plant operator shall furnish the Department, upon request, for official use only, a true statement of the actual quantities of frozen desserts purchased and sold, and a list of all sources of such frozen desserts, records of inspections, tests, and pasteurization time and temperature records.
- H. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this Regulation which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of frozen desserts, or results of inspections or tests thereof) to use such information to his own advantage or to reveal it to any unauthorized person.

SECTION VI. THE EXAMINATION OF FROZEN DESSERTS

A. SAMPLING CRITERIA:

1. During any consecutive six months, at least four samples of pasteurized mix and a variety of different flavors, types and sizes of containers of frozen desserts and frozen dessert novelties defined in this Regulation, except aseptically processed mix, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, from every frozen desserts plant by the Department.
2. Samples of frozen desserts shall be taken while in the possession of the manufacturer and/or distributor at any time prior to delivery to the store or consumer.
3. Samples of frozen desserts from stores, cafes, soda fountains, restaurants, and other places where frozen desserts are sold may be examined as often as the Department may require.

B. SAMPLING ENFORCEMENT:

1. Whenever two of the last four consecutive bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for frozen desserts, the Department shall send a certified or hand delivered written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within twenty-one days of the sending of such notice, but not before the lapse of three days. Immediate suspension of permit in accordance with Section III, and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures.
2. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any mix or frozen desserts involved shall not be offered for sale.
3. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no frozen desserts shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.
4. Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provision of Section II of this Regulation.

5. Whenever a container or containers of aseptically processed mix is found to be unsterile due to under-processing, the Department shall consider this to be an imminent hazard to public health and shall suspend the permit of the mix plant for the sale of aseptically processed mix. No aseptically processed mix or frozen desserts made from the mix, shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products, including frozen desserts, manufactured from the lot found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department.

C. SAMPLING METHODS:

Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the *Standard Methods for the Examination of Dairy Products* of the American Public Health Association, and the certification of sample collectors, and examinations shall be evaluated in accordance with the United States Public Health Service/FDA *Evaluation of Milk Laboratories*. Aseptically processed mix packaged in hermetically sealed containers shall be tested in accordance with the FDA's *Bacteriological Analytical Manual*. Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Department requires.

SECTION VII. FROZEN DESSERT PLANTS

A. TEMPERATURE, BACTERIOLOGICAL AND CHEMICAL REQUIREMENTS:

1. All frozen desserts shall be produced, processed, and pasteurized, ultra-pasteurized, aseptically processed and frozen to conform with the following temperature, bacteriological, and chemical standards and the sanitation requirements of this section:
 - a. Raw Milk and Milk Products for Pasteurization, Ultra-Pasteurization, and Aseptic Processing:
 - (1) Temperature - Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milking does not exceed 10°C (50°F).
 - (2) Bacterial Limits - Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization.
 - (3) Somatic Cell Count - Individual producer milk not to exceed 750,000 per mL. Goat milk not to exceed 1,000,000 per mL.
 - (4) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

b. Pasteurized Frozen Desserts and Heat-Treated, Bulk-Shipped Milk Products:

- (1) Temperature – Cooled to 7°C (45°F) or less and maintained there at.
- (2) Bacterial limits* - 30,000 per mL.
- (3) Coliform - Not to exceed 10 per mL: provided that, in the case of bulk milk transport tank shipments, where contents are to be repasteurized, shall not exceed 100 per mL.
- (4) Phosphatase** - Less than 500 milliunits/L by the Fluorometer or Clarion ALP or equivalent.
- (5) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

c. Aseptically Processed Mix:

- (1) Temperature - None.
- (2) Bacterial limits - No growth by test specified in Section VI.
- (3) Drugs - No positive results on drug residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade A PMO as amended.

*Not applicable to cultured products.

**Not applicable to bulk shipped heat-treated milk products.

2. No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing, freezing, processing methods integral therewith, and appropriate refrigeration (freezing) shall be applied to mix and frozen desserts for the purpose of removing or deactivating microorganisms: Provided, that in the bulk shipment of cream, skim milk, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 125°F but less than 161°F for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and/or lowfat milk are labeled heat-treated.

B. SANITATION OF FROZEN DESSERT PLANTS

1. Floors - Construction: The floors of all rooms in which frozen desserts, or their ingredients are processed, handled or stored, including cold storage rooms, or in which containers, equipment and utensils are washed or stored shall be constructed of concrete or other equally impervious and easily cleaned material and shall be kept in good repair. Floors in all areas in which frozen desserts or their ingredients are processed or in which containers, equipment and utensils are washed shall be properly sloped and equipped with trapped drains.
2. Walls and Ceilings - Construction: Walls and ceilings of room in which frozen desserts or their ingredients are processed, handled, or stored, or in which containers, utensils, and equipment are washed shall have a smooth, water resistant, washable, light-colored surface in good repair.

3. Doors and Windows: Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather. Outside openings shall be protected against the entrance of insects by tight-fitting, self-closing doors, closed windows, screening, effective air curtains or other means.

4. Lighting and Ventilation:

- a. All rooms in which frozen desserts or their ingredients are handled, processed, or stored, and/or in which containers, equipment, and utensils are washed shall be well lighted and ventilated. At least twenty foot candles of light are needed in working areas. Dry storage and cold storage rooms need at least five foot candles of light.
- b. Pressurized ventilating systems shall have a filtered air intake.

5. Separate Rooms:

- a. There shall be separate rooms for:
 - (1) The pasteurizing, processing, cooling, freezing and packaging of mix and frozen desserts.
 - (2) Cleaning and sanitizing facilities for tank trucks in plants receiving mix or milk products in such tanks.
 - (3) Receiving cans of mix in plants receiving such cans.
- b. Rooms in which mix or frozen desserts are handled, processed, or stored, or in which containers, utensils, and equipment are washed or stored shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.
- c. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged mix and frozen desserts.

6. Toilet-Sewage Disposal Facilities:

Every frozen desserts plant shall be provided with toilet facilities conforming with state and local plumbing laws, regulations and codes. Toilet rooms shall not open directly into any room in which frozen desserts, their ingredients, equipment, or containers are processed, handled or stored. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in wastewater system approved by the Department. A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms used by employees.

7. Water Supply:

- a. Water for frozen dessert plant purposes shall be from a supply properly located, protected and operated, and shall be easily

accessible, adequate and of a safe, sanitary quality.

- b. Samples for bacteriological testing of individual water supplies shall be taken by the Department upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Examinations shall be conducted in an official laboratory, and records maintained.
8. Hand-washing Facilities: Convenient hand-washing facilities shall be provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or approved hand drying devices. Hand-washing facilities shall be kept in a clean condition and in good repair.
9. Frozen Dessert Plant Cleanliness: All rooms in which frozen desserts are handled, processed, frozen or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, freezing, packaging and bulk milk product storage rooms.
10. Sanitary Piping:
- a. All sanitary piping, fittings and connections which are exposed to frozen desserts, or from which liquids may drip, drain or be drawn into frozen desserts, shall consist of smooth, impervious, corrosion resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized frozen desserts shall be conducted from one piece of equipment to another only through sanitary piping.
 - b. All sanitary piping, connections and fittings shall consist of:
 - (1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or
 - (2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or
 - (3) Heat resistant glass; or
 - (4) Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short flexible take down jumpers or connections where flexibility is required for essential or functional reasons.

11. Construction and Repair of Containers and Equipment:

- a. All multi-use containers and equipment with which frozen desserts or their ingredients come into contact shall be smooth, impervious, corrosion-resistant, and of non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which frozen desserts come in contact shall be nontoxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.
- b. All frozen dessert contact surfaces of multi-use containers and equipment shall consist of:
 - (1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or
 - (2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or
 - (3) Heat resistant glass; or
 - (4) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, and do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

NOTE: 3-A Sanitary Standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection, and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, United States Public Health Service/Food and Drug Administration, Department of Health and Human Services.

12. Cleaning and Sanitizing of Containers and Equipment:

- a. The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling, freezing and storage of frozen desserts shall be effectively cleaned after each use, at least daily, and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed mix beyond the final heat treatment process shall be sterilized before any aseptically processed mix is packaged and shall be re-sterilized whenever any unsterile product has contaminated it.
- b. Storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two hours, except that permission may be granted by the Department for storage of pasteurized mix longer than seventy-two hours, provided necessary plant quality controls are in place. Storage tanks which are used to store raw milk, mix or heat treated milk products longer than twenty-four hours shall be equipped with a seven-day temperature recording device.

- c. A temperature recording device, complying with the specifications in Appendix H, FDA Grade A PMO as amended, or a recording device which has been reviewed by FDA and found to provide sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Department shall be installed in the return solution or other appropriate areas to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions.
- d. Recording charts shall be identified, dated and retained for three months. The Department shall review the recording charts during each inspection.

13. Storage of Cleaned Containers and Equipment: After cleaning, all multi-use frozen dessert containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

14. Storage and Handling of Single-Service Containers, Utensils and Materials: Covers, caps, parchment papers, wrappers, can liners, and single-service sticks, spoons and containers for frozen desserts or their ingredients shall be purchased and stored only in sanitary containers; wrappings or cartons shall be kept therein in a clean, dry place until used, and shall be handled in a sanitary manner.

15. Protection from Contamination

- a. Frozen dessert plant operations, equipment and facilities shall be located and conducted to prevent any contamination of frozen dessert products, ingredients, equipment, containers and utensils. All frozen desserts or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than mix or frozen desserts in the plant shall be performed to preclude the contamination of such frozen desserts. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of frozen desserts or ingredients of such frozen desserts or the product-contact surfaces of all equipment, containers or utensils.
- b. Frozen desserts in broken and open containers may after delivery be returned to the plant for inspection but shall not be used for making frozen desserts.
- c. Whenever air under pressure is used for the agitation or movement of frozen desserts or other ingredients, or is directed at frozen dessert contact surfaces or other ingredients, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H, FDA Grade A PMO as amended. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with frozen desserts, it shall be of culinary quality and shall comply with the applicable standards of Appendix H, FDA Grade A PMO as amended.

16. Pasteurization-Aseptic Processing:

- a. All mix shall be pasteurized or aseptically processed as described in Section I of this Regulation.
- b. To insure that pasteurization temperature and time will be applied to every particle of mix, the system design, public health controls and testing shall comply with Section 7. Item 16p of the FDA Grade A PMO as amended.

17. Cooling:

- a. All milk and fluid milk products received at frozen dessert plants for use in frozen desserts shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until pasteurized. All pasteurized mix shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until frozen.
- b. All mix which is not frozen at the plant at which it was pasteurized shall be transported to the place of manufacturing or freezing in a sanitary manner and maintained at a temperature of 45°F or less until processed. Every room or tank in which milk products or mix are stored shall be equipped with an accurate thermometer, which shall comply with the specifications of Appendix H, FDA Grade A PMO as amended.
- c. Recirculated cooling agents (water or glycol) which are used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such cooling agents shall be tested semi-annually and shall comply with the bacteriological standards of Appendix G, FDA Grade A PMO as amended. Samples shall be taken by the Department and examination shall be conducted in an official laboratory. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use.

18. Packaging:

- a. Packaging, cutting, molding, dipping, and other preparation of frozen desserts or their ingredients shall be done in a sanitary manner using approved equipment.
- b. Filling equipment for frozen desserts shall have drip defectors on the filler valve to prevent condensate from entering the product or container. Shielding shall be provided over conveyors for cartons, lids, caps and filled containers until they are closed to prevent water condensate or other contamination from entering the product.
- c. The product contact surface of the container, including the pouring lip for mix containers, shall be covered by the closure/lid.

- d. Hand capping/packaging is not an acceptable practice. Hand capping/packaging may be approved only if suitable mechanical equipment for the capping/packaging of specific containers is not available or is not practical for use. If hand capping is approved, a Department approved procedure will be established which will eliminate all possibility of contamination.

19. Ingredients:

- a. All raw milk and milk products used in the manufacture of frozen desserts shall be from a Grade A domestic source as defined in the FDA Grade A Pasteurized Milk Ordinance as amended or from other supplies acceptable to the Department. All mix and frozen dessert ingredients shall be clean, have a fresh wholesome flavor and odor and a normal appearance, be of satisfactory quality and shall be processed in an approved, sanitary manner.
- b. The only ingredients which may be added after pasteurization are those flavoring and coloring ingredients which are:
 - (1) Subjected to prior heat treatment sufficient to destroy pathogenic microorganisms.
 - (2) Of 0.85% water activity or less,
 - (3) Of pH less than 4.7,
 - (4) Roasted nuts (added at the freezer),
 - (5) Contain high alcohol content,
 - (6) Bacterial cultures,
 - (7) Fruits and vegetables added at the freezer, or
 - (8) Subjected to any other process which will assure that the ingredient is free of pathogenic organisms.

20. Personnel - Cleanliness: Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. Employees shall not resume work after visiting the toilet room without thoroughly washing their hands. All persons while engaged in the processing, pasteurization, freezing, handling, storage or transportation of mix or frozen desserts, containers, equipment and utensils shall wear clean outer garments. All persons while engaged in the processing of mix and frozen desserts shall wear adequate hair covering and shall not use tobacco.

21. Vehicles: All vehicles used for the transportation of frozen desserts or their ingredients shall be so constructed and operated as to protect their contents from the sun and from contamination. Such vehicles shall be kept clean and no substance capable of contaminating mix or frozen desserts or their ingredients shall be transported therewith in such manner as to permit contamination. The name of the distributor shall be prominently displayed on the vehicles.

22. Surroundings:

- a. Frozen dessert plants shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents, or otherwise constitute a nuisance.
- b. Only insecticides and rodenticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

SECTION VIII. FROZEN DESSERTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Frozen desserts from points beyond the limits of routine inspection by the Department may be sold in South Carolina if they are manufactured under provisions substantially equivalent to the requirements of this Regulation; provided, that the Department shall be satisfied that the agency having jurisdiction over the manufacture of these products is properly enforcing such provisions.

SECTION IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION

Properly prepared plans for all frozen dessert plants regulated under this Regulation which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Department for written approval before work is begun.

SECTION X. PERSONNEL HEALTH

No person affected with any disease capable of being transmitted to others through the contamination of food shall work at any frozen desserts plant in any capacity which brings them into direct contact with finished products, such as pasteurized or aseptically processed mix or frozen desserts, or which brings them into direct contact with associated pasteurized or aseptically processed mix and frozen dessert product-contact surfaces.

SECTION XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of frozen desserts, or their ingredients, the Department is authorized to require any or all of the following measures:

- A. The immediate exclusion of that person from handling frozen desserts, or their ingredients;
- B. The immediate exclusion of the frozen desserts concerned from distribution and use;
- C. Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges.

SECTION XII. RECALLS

Each frozen desserts manufacturer should develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the frozen desserts manufacturer, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the frozen desserts manufacturer to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The frozen desserts manufacturer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIII. PENALTIES

Violations of this regulation shall be punishable in accordance with S.C. Code Ann. Section 44-1-150 (1976 as amended). Each day of continued violation shall be a separate offense.

SECTION XIV. REPEAL AND DATE OF EFFECT

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All previous amendments of this regulation are hereby repealed; this regulation shall be in full force and effect immediately upon adoption and its publication, as provided by law.

SECTION XV. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of this Regulation be declared unconstitutional or invalid for any reason, the remainder of said regulation shall not be affected thereby.

Bureau of Environmental Health
Division of Food Protection
Dairy Foods and Soft Drink/Bottled Water Protection Program



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