Florida Department of Agriculture and Consumer Services  
Division of Food Safety  
Bureau of Dairy Industry

WHOLESALE FROZEN DESSERT REQUIREMENTS  
Rev. 06/2018

Please note: These are basic requirements put together for processors who wish to submit an application to start operating as a wholesale manufacturer of frozen dessert or mix. The full set of regulations a processor will need to abide by can be found in the documents listed below:

- Grade “A” Pasteurized Milk Ordinance (PMO) 2015 Revision

Please note: The information found in this document is taken all the documents listed above. The information taken from the PMO is NOT taken exactly from text and information that does not pertain to frozen desserts was left out. If you have any additional questions, please feel free to contact the Bureau of Dairy Industry.

ISSUANCE OF LICENSE

The Florida Department of Agriculture & Consumer Services Bureau of Dairy Industry is pleased to forward you the requirements for manufacturing frozen dessert products for wholesale in the State of Florida. This agency is only responsible for licensing frozen dessert manufacturers that sell all or a portion of their product wholesale.

Florida’s Department of Agriculture & Consumer Services’ Bureau of Dairy Industry is the agency responsible for licensing your facility. An application must be completed, appropriate fees paid and labels for all products to be produced must be submitted to the Bureau of Dairy Industry, 3125 Conner Blvd., MS-C18, Tallahassee, FL 32399-1650. Prior to receiving your permit, a Sanitation & Safety Specialist will conduct an inspection of your facility to determine if you meet the requirements outlined in this booklet. If the conditions noted are unsatisfactory, you must correct the problem(s) prior to receiving an inspection for your license. Once you have received a satisfactory inspection, your labels have been approved and all applicable samples were satisfactory, the Bureau will issue your license.
PLANS FOR CONSTRUCTION AND RECONSTRUCTION  
(SECTION 12 – PMO)

Properly prepared plans for all frozen dessert plants regulated under this Ordinance, which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Regulatory Agency for written approval before work is begun. A copy of all plans shall be on file with the Bureau of Dairy Industry for review.

INSPECTIONS

The Bureau of Dairy Industry will inspect your facility at least once every three (3) months. Violations will be documented and you will be provided with a copy of the inspection report. If the following inspection reveals that you have not corrected those items previously debited, the Specialist will issue a Time Frame Correction Report noting a specific date by which the violation(s) are to be corrected. Failure to make the necessary corrections within this time frame may subject you to a monetary penalty or perhaps suspension or revocation of your permit. Prior to such action, you will be given an opportunity to appear before an administrative hearing officer to explain why the violations were not corrected.

WHEN IS PASTEURIZATION REQUIRED?  
(BUREAU OF DAIRY INDUSTRY DIRECTIVE)

If a pasteurized mix is used, bulky flavorings or ingredients may be added in a sanitary manner provided they are generally recognized as safe, have been previously pasteurized, or have been otherwise treated by heat or sanitizer during the manufacturing process so that they will not cause the finished product to be adulterated. Compliance with this requirement may be verified by any effective means. Added flavorings or ingredients may include but are not limited to: roasted nuts, fruits (fresh, pasteurized frozen or canned), pasteurized fruit juice, canned vegetables, pasteurized egg products, sweeteners, cocoa, candy, cookies, spices, herbs, spirits, peanut butter, cereals, syrups, and pasteurized milk & cream. Incorporating raw egg products or an ingredient that is intended to be cooked into a ready-to-eat food that will not be cooked or otherwise treated to eliminate microorganisms of public health concern can pose a serious food safety risk (i.e. cookie dough or cake batter). Additionally, if you are adding water to a pasteurized ice cream mix during processing, legal pasteurization of that product will be required. If you are unsure if your formula requires pasteurization, please ask the Bureau of Dairy Industry to provide you with additional information regarding this issue.
ITEM 1p. FLOORS - CONSTRUCTION

The floors of all rooms in which frozen desserts are handled, processed, packaged, or stored; or in which such containers, utensils and/or equipment are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped drains and kept in good repair. Provided, that cold-storage rooms used for storing frozen dessert products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits. Provided further, that storage rooms for storing dry ingredients, packaged dry ingredients, packaged dry milk or milk products, and/or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

PUBLIC HEALTH REASON

Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are; therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the milk plant.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) The floors of all rooms in which frozen desserts are handled, processed, packaged, or stored; or in which such containers, utensils, and/or equipment are washed, are constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality con. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

2) The floor surface is smooth and sloped, so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious.

3) The floors are provided with trapped drains. Cold-storage rooms used for storing frozen desserts need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients, dry packaged milk or milk products, and/or packaging materials need not be provided with drains.

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Floors shall be constructed of concrete or tile; slip proof and sloped to drain.
ITEM 2p. WALLS AND CEILINGS - CONSTRUCTION

Walls and ceilings of rooms in which frozen desserts are handled, processed, packaged, or stored; or in which such containers, utensils and/or equipment are washed, shall have a smooth, washable, light-colored surface and be in good repair.

PUBLIC HEALTH REASON

Properly finished walls and ceilings are more easily kept clean and are; therefore, more apt to be kept clean. A light-colored finish aids in the even distribution of light and the detection of unclean conditions.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) Walls and ceilings are finished with smooth, washable, light-colored impervious materials.
2) Walls, partitions, windows and ceilings are kept in good repair.

NOTE: Storage rooms used for the storage of packaged dry milk or milk products are exempt from the ceiling requirements of this Item.

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Walls shall be of smooth finish impervious to water.
Ceilings shall be of a smooth finish impervious to water.

ITEM 3p. 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.

PUBLIC HEALTH REASON

Freedom from insects in the processing facility reduces the likelihood of contamination of the milk, milk product or frozen dessert.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1) All openings to the outer air are effectively protected by:
   a. Screening; or
   b. Effective electric screen panels; or
c. Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; or  
d. Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or  
e. Any effective combination of a, b, c, or d or by any other method which prevents the entrance of insects.

2) All outer doors are tight and self-closing. Screen doors shall open outward.  
3) All outer openings are rodent-proofed to the extent necessary to prevent the entry of rodents.  
4) **NOTE:** The evidence of insects and/or rodents in the frozen dessert plant shall be considered under Item 9p.

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Door frames shall be of steel or steel alloy and window frames shall be constructed of a corrosive resistant metal.

**ITEM 4p. LIGHTING AND VENTILATION**

All rooms in which milk, milk products or frozen desserts are handled, processed, packaged, or stored; or in which milk or frozen dessert containers, utensils and/or equipment are washed shall be well lighted and well ventilated.

**PUBLIC HEALTH REASON**

Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1) Adequate light sources are provided (natural, artificial or a combination of both) which furnish at least twenty (20) foot-candles (220 lux) of light in all working areas. This shall apply to all rooms where milk, milk products or frozen desserts are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five (5) foot-candles (55 lux) of light.  
2) Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls and ceilings.  
3) Pressurized ventilating systems, if used, have a filtered air intake.
ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for:

1) The pasteurizing, processing, cooling, and packaging of frozen desserts.
2) The cleaning of milk cans and frozen dessert containers, bottles, cases and dry milk or milk product containers.
3) The fabrication of containers and closures for frozen dessert products.
4) Receiving cans of milk and milk products in frozen dessert plants receiving such cans.

Rooms in which milk, milk products and frozen desserts are handled, processed, stored, and packaged, or in which containers, utensils and/or equipment are washed or stored, shall not open directly into any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged frozen desserts.

PUBLIC HEALTH REASON

If the washing and sanitization of containers are conducted in the same room in which the pasteurizing, processing, cooling, packaging is done, there is opportunity for the pasteurized product to become contaminated. For this reason, separate rooms are required as indicated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) Pasteurizing, processing, reconstitution, cooling, and packaging of frozen desserts is conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, portable storage bins, bottles and cases, or the unloading and/or cleaning and sanitizing of milk product tank trucks or totes, provided that these rooms may be separated by solid partitioning doors that are kept closed.
2) Rooms in which frozen desserts are handled, processed or stored; or in which frozen dessert containers, utensils and/or equipment are washed or stored, do not open directly into any room used for domestic purposes.
3) All rooms shall be of sufficient size for their intended purposes.

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Equipment should be located at least 18 inches from walls and a minimum distance of 3 feet is suggested between pieces of equipment in order to give the operators of such equipment sufficient room to pass between pieces of equipment comfortably.

ITEM 6p. TOILET-SEWAGE DISPOSAL FACILITIES

Every frozen dessert plant shall be provided with toilet facilities conforming to the regulations of the State of Florida. Toilet rooms shall not open directly into any room in which frozen dessert
products are processed. 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 a sanitary manner.

PUBLIC HEALTH REASON

Human excreta are potentially dangerous and must be disposed of in a sanitary manner. The organisms causing typhoid fever, para-typhoid fever and dysentery may be present in the body discharges of active cases or carriers. Sanitary toilet facilities are necessary to protect the frozen dessert products, containers, utensils and equipment from fecal contamination, which may be carried by insects, hands or clothing. When the toilet facilities are of a satisfactory type, are kept clean and are in good repair, the opportunities for the spread of contamination by the above means are minimized. The provision of an intervening room or vestibule between the toilet room and any room in which frozen dessert products are processed makes it less likely that contaminated insects will enter these rooms. It will also minimize the spread of odors. The wastes resulting from the cleaning and rinsing of containers, utensils, equipment and floors, from flush toilets, and from washing facilities, should be properly disposed of so as not to contaminate frozen dessert containers, utensils or equipment, or to create a nuisance or a public health hazard.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) The frozen dessert plant is provided with toilet facilities conforming to the regulations of the State of Florida.
2) Toilet rooms do not open directly into any room in which frozen dessert products are processed or packaged.
3) Toilet rooms are completely enclosed and have tight-fitting, self-closing doors.
4) Dressing rooms, toilet rooms and fixtures are kept in a clean condition, in good repair and are well ventilated and well lighted.
5) Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.
6) All plumbing is installed to meet the applicable provisions of the State or local plumbing code.
7) Sewage and other liquid wastes are disposed of in a sanitary manner.
8) Non-water-carried sewage disposal facilities are not used.

ITEM 7p. WATER SUPPLY

Water for frozen dessert plants shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality. The water supply should be accessible in order to encourage its use in cleaning operations; it should be adequate so that cleaning and rinsing may be thorough; and it should be of a safe, sanitary quality in order to avoid the contamination of containers, utensils and equipment.
PUBLIC HEALTH REASON

The water supply should be accessible in order to encourage its use in cleaning operations; it should be adequate so that cleaning and rinsing may be thorough; and it should be of a safe, sanitary quality in order to avoid the contamination of containers, utensils and equipment.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) Water for frozen dessert plant purposes is from an adequate supply, properly located, protected and operated. It shall be easily accessible and of a safe, sanitary quality.
2) There is no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank, such as for boilers, unless protected by an air gap or effective backflow preventer, constitutes a violation of this requirement. An approved air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle. The distance of the air gap is to be measured from the bottom of the potable inlet supply pipe or faucet to the top of the effective overflow, i.e., flood level rim or internal overflow, of the vessel. In no case, may the effective air gap be less than one (1) inch (2.54 cm).
3) New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are disinfected before being placed in use. (Refer to Appendix D.) The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.
4) Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each six (6) months thereafter; and when any repair or alteration of the water supply system has been made. Samples shall be taken by the Regulatory Agency and examinations shall be conducted in an official laboratory (See Appendix G). To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.
5) Current records of water test results are retained on file with the Regulatory Agency or as the Regulatory Agency directs.

NOTE: City or county municipal water supplies are exempt from inspection or sampling unless there is some reason to suspect that the supply may be or may have been contaminated.

ITEM 8p. HANDWASHING FACILITIES

Convenient hand washing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Hand washing facilities shall be kept in a clean condition and in good repair.
**PUBLIC HEALTH REASON**

Proper use of hand washing facilities is essential to personal cleanliness and reduces the likelihood of contamination of milk and milk products.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1) Convenient hand washing facilities are provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices.
2) Hand washing facilities are convenient to all toilets and to all rooms in which frozen dessert plant operations are conducted.
3) Hand washing facilities are kept in a clean condition and in good repair.
4) Steam-water mixing valves and vats for washing bottles, cans and similar equipment are not used as hand washing facilities.

**ITEM 9p. FROZEN DESSERT PLANT CLEANLINESS**

All rooms in which frozen dessert products are handled, processed or stored; or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, packaging, and frozen dessert product storage rooms.

**PUBLIC HEALTH REASON**

Clean floors, free of litter, clean walls, ceilings and all other areas of the frozen desserts plant are conducive to clean product handling operations. Cleanliness and freedom from insects and rodents reduces the likelihood of contamination of the frozen dessert products. Excess or unused equipment or equipment not directly related to the frozen dessert plant operations can be detrimental to the cleanliness of the plant.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1) Only equipment directly related to processing operations or the handling of containers, utensils and equipment is permitted in the pasteurizing, processing, cooling, packaging, and frozen dessert product storage rooms.
2) All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment are clean.
3) No trash, solid waste or waste dry product is stored within the frozen dessert plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.
4) All rooms in which frozen dessert products are handled, processed or stored; or in which containers, utensils, and/or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.

5) Excessive product dust shall be kept under effective control by the use of exhaust and collective systems designed for in-plant dust control. Tailings and materials collected from exhaust collective systems shall not be used for human consumption.

ITEM 10p. SANITARY PIPING

NOTE: Any piping used to convey cleaning solutions for the purpose of cleaning and sanitizing milk product contact surfaces must meet the same requirements as that for acceptable milk product contact surfaces.

All sanitary piping, fittings and connections which are exposed to frozen dessert products or from which liquids may drip, drain or be drawn into such products shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material, which is approved for food product-contact surfaces. All piping shall be in good repair. Pasteurized milk, cream and frozen dessert products shall be conducted from one piece of equipment to another only through sanitary piping.

PUBLIC HEALTH REASON

Piping and fittings are sometimes so designed as to be difficult to clean, or they may be constructed of metal, which corrodes easily. In either case, it is unlikely that they will be kept clean. Sanitary piping is a term, which applies to properly designed and properly constructed piping. The purpose of the third sentence is to prevent exposure of the pasteurized products to contamination.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) All sanitary piping, fittings and connections, which are exposed to frozen dessert products or from which liquids may drip, drain or be drawn into such products, consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material.

2) All sanitary piping, connections and fittings consist of:
   a. Stainless steel of the AISI 300 series; or
   b. Equally corrosion-resistant metal which is non-toxic and nonabsorbent; or
   c. Heat resistant glass; or
   d. Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; are non-toxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the frozen dessert product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.
3) Sanitary piping, fittings and connections are designed to permit easy cleaning; kept in good repair; free of breaks or corrosion; and contain no dead ends of piping in which frozen dessert product may collect.

4) All interior surfaces of demountable piping, including valves, fittings and connections are designed, constructed and installed to permit inspection and drainage.

5) All mechanically cleaned sanitary pipelines and return-solution lines are rigid, self-draining and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of Item 2 above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in Item 2 above and designed, finished and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks or inclusions.

In the case of welded lines, all welds shall be inspected as they are made and such welds shall be approved by the Regulatory Agency.

Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings or other means or combinations that are adequate for the inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the pipeline.

Detailed plans for welded pipeline systems shall be submitted to the Regulatory Agency for written approval prior to installation. No alteration or addition shall be made to any welded sanitary pipeline system without prior written approval from the Regulatory Agency.

6) Pasteurized milk, cream and frozen dessert products are conducted from one piece of equipment to another only through sanitary piping.

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Note: This rule applies to facilities using piping to convey frozen dessert, ingredients and CIP solutions.

Stainless steel pipelines are properly identified. Identification shall be made with colored tape, plastic bands or a method which has been approved by the regulatory agency and which will remain in place and retain it's coloring under normal conditions of use. The following colors shall be used:

- RED – RAW MILK LINES
- BLUE – PASTEURIZED PRODUCT LINES
- GREEN – CLEANING SOLUTION LINES (SUPPLY & RETURN)
- YELLOW – WATER LINES (APPLICABLE TO STAINLESS STEEL LINES ONLY)

Direction of flow in each line shall also be indicated by an arrow on the pipe, tape, or plastic band. The proper placement of the colored bands and directional arrows on pipelines shall be determined by the regulatory agency to ensure easy identification of the product in the pipe and direction of flow.
ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

All multi-use containers and equipment that frozen dessert ingredients and products come into contact with shall be of smooth, impervious, corrosion-resistant, 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 that frozen dessert ingredients and products come in contact with shall be non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

PUBLIC HEALTH REASON

When equipment is not constructed and located so that it can be cleaned easily, and is not kept in good repair, it is unlikely that it will be properly cleaned. Single-service articles, which have not been manufactured and handled in a sanitary manner, may contaminate the frozen dessert product.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) All multi-use containers and equipment that frozen dessert ingredients and products come into contact with are of smooth, impervious, corrosion-resistant and non-toxic material.

2) All product-contact surfaces of multi-use containers and equipment consist of:
   a. Stainless steel of the AISI 300 series; or
   b. Equally corrosion-resistant metal which is non-toxic and nonabsorbent; or
   c. Heat resistant glass; or
   d. 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 non-toxic, fat resistant, relatively nonabsorbent and do not impart flavor or odor to the frozen dessert product; and which maintain their original properties under repeated use conditions.

3) All joints in containers, utensils and equipment are flush and finished as smooth as adjoining surfaces, or if the surface is vitreous, it must be continuous. Where a rotating shaft is inserted through a surface with which frozen dessert products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Grease and oil from gears, bearings, and cables shall be kept out of the frozen dessert products. Where a thermometer or temperature-sensing element is inserted through a surface, with which frozen dessert products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

4) All openings in covers of tanks, vats, separators, etc. are protected by raised edges, or otherwise, to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometers, or temperature sensing elements and other equipment extending into a tank, bowl, vat or similar equipment, unless a watertight joint is provided.
5) All surfaces with which milk or milk products come into contact are easily accessible or
demountable for manual cleaning or are designed for mechanical cleaning. Provided, that
flexible plastic or rubber tanker loading and unloading hoses with screw-type hose clamps
shall be considered in compliance, if an appropriate screwdriver or tool is readily available
for disassembly. All product-contact surfaces shall be readily accessible for inspection and
shall be self-draining.

6) There are no threads used in contact with frozen dessert products except where needed for
functional and safety reasons, such as in high speed blenders and pumps. Such threads shall
be of a sanitary type.

7) All multi-use containers and other equipment have rounded corners; are in good repair; and
free from breaks, crevices and corrosion. Milk cans shall have umbrella-type covers.

8) All single-service containers, closures, gaskets and other articles that frozen dessert products
come in contact with are non-toxic.

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, Food and Drug Administration, Public Health Service, Department
of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary
Standards complies with the sanitary design and construction standards of this Ordinance.

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

The product-contact surfaces of all multi-use containers, utensils and equipment used in the
transportation, processing, packaging, handling, and storage of frozen dessert products shall be
effectively cleaned and shall be sanitized before each use.

PUBLIC HEALTH REASON

Frozen dessert products cannot be kept clean and safe, if permitted to come into contact with
containers, utensils and equipment that have not been properly cleaned and sanitized.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) 1. All multi-use containers and utensils are thoroughly cleaned after each use and all
equipment is thoroughly cleaned at least once each day used.

2) 2. Pipelines and/or equipment designed for mechanical cleaning meet the following
requirements:
   a. An effective cleaning and sanitizing regimen for each separate cleaning circuit
      shall be followed.
   b. A temperature recording device, complying with the specifications in Appendix
      H., or a recording device which provides sufficient information to adequately
      evaluate the cleaning and sanitizing regimen and which is approved by the
      Regulatory Agency, shall be installed in the return solution line or other
appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions. For purposes of this Section, recording devices which produce records not meeting the specifications of Appendix H. may be acceptable if:

i. The device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle.

ii. The record shows a typical pattern of each circuit cleaned, so that changes in the cleaning regimen may be readily detected.

iii. Electronic storage of required cleaning records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available. Electronic records must meet the criteria of this Section and those provisions of Appendix H., which are determined to be applicable by the Regulatory Agency and FDA. Except that, electronic storage of required cleaning records, with or without hard copy, shall be acceptable, provided the computer and computer generated records are readily available and meet the criteria of this Section and the 21 CFR Part 11.

c. Cleaning charts and electronically stored records required by this Section shall be identified, dated and retained for three (3) months or until the next regulatory inspection, whichever is longer.

d. During each official inspection, the Regulatory Agency shall examine charts and records to verify the cleaning regimens.

3) Frozen dessert plants in which containers and equipment are washed and sanitized manually are equipped with a three (3)-compartment wash-and-rinse vat for this purpose.

4) A thorough inspection procedure shall be in effect to remove any containers, which show stress cracks, splitting, pitting, discoloration, or cloudiness, as well as any unremoved soil. This must be carried out with adequate light and be much more thorough than the customary cursory inspection given to glass bottles.

a. If a metal detection device is used, a standard must be available for use by the regulatory agency for testing the proper sensitivity functioning levels of the device.

b. The containers shall comply with the applicable construction requirements of Item 11p of this Ordinance. The closure for the container shall be single-service. Screw-type closures shall not be used.

c. The container shall not impart, into the product, pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the FFDCA and regulations issued there under.

**ITEM 13p. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT**

After cleaning, all multi-use frozen dessert product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.
PUBLIC HEALTH REASON

If containers and equipment are not protected from contamination, the value of sanitization may be partly or entirely nullified.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

All multi-use containers, utensils and equipment, after cleaning, are transported and/or stored on racks made of impervious food grade materials, or in clean cases elevated above the floor. Containers shall be stored inverted, if practicable, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

ITEM 14p. STORAGE OF SINGLE-SERVICE CONTAINERS, UTENSILS AND MATERIALS

Single-service caps, lids, cap and lid stock, plastic and paper packaging material, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with frozen dessert products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

PUBLIC HEALTH REASON

Soiled or contaminated caps, lids, cap and lid stock, plastic and paper packaging material, parchment paper, containers, gaskets and other single-service articles nullify the benefits of the safeguards prescribed throughout this Ordinance.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) Single-service caps, lids, cap and lid stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with frozen dessert products are purchased and stored in sanitary tubes, wrappings or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

2) Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once, unless other methods are employed to protect the containers from contamination.

3) Tubes or cartons are not refilled with spilled caps, gaskets or parchment papers.

4) Cartons or boxes from which contents have been partially removed are kept closed.

5) Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures or containers.
ITEM 15p. PROTECTION FROM CONTAMINATION

All mix must be legally pasteurized before processing into frozen desserts. Bulky flavorings and ingredients can be added under sanitary conditions to pasteurized mix. If fresh fruit is added, it is important to properly wash and treat the fruit with a mild chlorine solution to kill bacteria and pathogens. There are numerous sources of “ready to eat” fruit products available both fresh-frozen and canned. Attention should be paid to the source of these products as producers in other countries may not adhere to good manufacturing practices. If water is added to a pasteurized mix for processing, the water and the mix must be legally pasteurized prior to use.

Frozen dessert plant operations, equipment and facilities shall be located and conducted to prevent any contamination of frozen dessert products, ingredients, containers, utensils and equipment. All frozen dessert products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than frozen dessert products in the frozen dessert plant shall be performed to preclude the contamination of such frozen dessert products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of frozen dessert products, or ingredients of such frozen dessert products, or the product-contact surfaces of all containers, utensils and equipment.

PUBLIC HEALTH REASON

Because of the nature of frozen dessert products and their susceptibility to contamination by bacteria, chemicals and other adulterants, every effort should be made to provide adequate protection for the frozen dessert products at all times. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the frozen dessert product or equipment with which the frozen dessert product comes in contact.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

15p. (A)

1) Equipment and operations are so located within the frozen dessert plant as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2) Packaged frozen dessert products, which have physically left the premises or the processing plant are not re-processed.
3) All product-contact surfaces of containers, utensils and equipment are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to frozen dessert product storage tanks and pumps, vats, etc., shall be capped or otherwise properly protected.
5) Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when frozen dessert product is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

6) Ingredients added to frozen dessert products are handled in such a manner as to avoid contamination.

7) Whenever air under pressure is used for the agitation or movement of frozen dessert products, or is directed at a frozen dessert product-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H.

8) All multi-use cases used to encase packaged frozen dessert product containers are cleaned prior to their use.

9) All ingredients and non-product-contact materials used in the preparation or packaging of frozen dessert products are stored in a clean place and are so handled as to prevent their contamination.

10) Pasteurized frozen dessert products are not strained or filtered, except through a perforated metal strainer.

11) Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, related cleaning compounds and medicinal agents necessary for the maintenance of the milk plant are present in the milk plant.

12) Those poisonous or toxic materials that are necessary are not stored in any room where frozen dessert products are received, processed, pasteurized, condensed, dried or stored; or where containers, utensils or equipment are washed; or where single-service containers, closures, bags, or caps are stored.

13) Those poisonous or toxic materials that are necessary are stored in a separate area of the frozen dessert plant in prominently and distinctly labeled containers. Provided that, this does not preclude the convenient availability of detergents or sanitizers to areas where containers, utensils and equipment are washed and sanitized.

14) Only insecticides and rodenticides approved by the Regulatory Agency and/or registered with the EPA shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating frozen dessert products, containers, utensils and equipment.

15p.(B)

1) During processing, pipelines and equipment used to contain or conduct frozen dessert products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.

2) All frozen dessert products that have overflowed, leaked, been spilled or improperly handled are discarded.

3) Means are provided to prevent contamination of frozen dessert products, containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.

4) The processing of foods and/or drinks other than frozen dessert products are performed to preclude the contamination of such frozen dessert products.
5) No product is handled in the frozen dessert plant that may create a public health hazard. Permission to handle products other than those defined in Section 1 or to conduct operations in equipment or rooms, other than those for which they are designated, should be provisional and subject to revocation if found objectionable.

ITEM 16p. PASTEURIZATION

*If your process includes pasteurization of mix, please request the Bureau of Dairy Industry to provide you with additional requirements for this process.*

ITEM 17p. COOLING OF FROZEN DESSERT PRODUCTS

All frozen dessert products shall be maintained at 7°C (45°F) or less until processed. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less and maintained thereat until further processed. Every refrigerated room or tank, in which frozen dessert products and milk products are stored, shall be equipped with an accurate indicating thermometer. On delivery vehicles, the temperature of frozen dessert and milk products shall not exceed 7°C (45°F).

PUBLIC HEALTH REASON

When frozen dessert and milk products are not cooled within a reasonable time, after being received at the frozen dessert plant, its bacterial content will be materially increased.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) All raw milk or milk products are maintained at 7°C (45°F) or less until processed.
2) All pasteurized milk, milk products and frozen dessert mix shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat until further processed.
3) Each refrigerated room in which milk, milk products and frozen dessert mixes are stored is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.
4) Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.
5) On delivery vehicles, the temperature of frozen dessert products shall not exceed 7°C (45°F).
6) Recirculated cooling water, which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency...
and examination shall be conducted in an Official Laboratory. Recirculated cooling 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.

7) Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.

ITEM 18p. PACKAGING AND CONTAINER FILLING

Packaging and container filling of frozen dessert products shall be done in a sanitary manner preferably by approved mechanical equipment if available.

Manual packaging or filling of containers is discouraged due to the potential contamination of the product. However, it is recognized that the use of such mechanical means may be unavailable or not practical for certain bulk containers, small volume or hand crafted items. All manual packaging and filling methods must be approved by the Regulatory Agency.

PUBLIC HEALTH REASON

Manual packaging and container filling is very apt to result in the exposure of the frozen dessert products to contamination if not performed in a sanitary manner. Such contamination would nullify the effects of pasteurization.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) All mechanical packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the capping devices are not integral within the same system.
2) All pipes, connections, and similar appurtenances shall comply with Items 10p and 11p of this Section.
3) Packaging machine supply tanks and bowls are equipped with covers that are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.
4) A drip deflector is installed on each filler valve. Drip deflectors shall be designed and adjusted to divert condensation away from the open container.
5) Container in-feed conveyors to automatic packaging machines have overhead shields to protect the packages from contamination. These shields shall extend from the forming unit discharge to the filling unit and from the filling unit to the closure unit.

6) Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude the contamination of open containers.

7) Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

8) The filler pipe of all packaging machines have a diversion apron or other acceptable device, as close to the filler bowl as possible, to prevent condensation from entering the inside of the filler bowl.

9) Filling cylinders on packaging machines are protected from contamination by overhead shields. When lubricants are used on filler pistons, cylinders or other frozen dessert product-contact surfaces, the lubricant shall be food-grade and applied in a sanitary manner.

ITEM 19p. CAPPING, CONTAINER CLOSURE and SEALING

Capping, closing or sealing of frozen dessert product containers shall be done in a sanitary manner preferably by approved mechanical equipment if available. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

Manual capping, closing and sealing of containers is discouraged due to the potential contamination of the product. However, it is recognized that the use of such mechanical means may be unavailable or not practical for certain bulk containers, small volume or hand crafted items. All manual capping, closing and sealing methods must be approved by the Regulatory Agency.

PUBLIC HEALTH REASON

Improper closing or sealing and hand capping exposes the frozen dessert product to contamination if not performed in a sanitary manner. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling, and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap, including frozen dessert product that has been forced out by temperature expansion and may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the frozen dessert products have not been contaminated after packaging.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:
1) The capping, closing or sealing of frozen dessert product containers is done in a sanitary manner on approved mechanical capping, closing and/or sealing equipment or by manual methods approved by the Regulatory Agency. The term "approved mechanical capping, closing and/or sealing equipment" shall not exclude manually operated machinery.

2) All mechanical capping, closing or sealing mechanisms are designed to minimize the need for adjustment during operation.

3) All caps and closures are handled in a sanitary manner.

ITEM 20p. PERSONNEL - CLEANLINESS

Hands shall be thoroughly washed before commencing frozen dessert plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, storage, transportation, or packaging of frozen dessert products, containers, utensils and equipment shall wear clean outer garments. All persons, while engaged in the processing of frozen dessert products, shall wear adequate hair coverings and shall not use tobacco.

PUBLIC HEALTH REASON

Clean clothing and clean hands, including clean fingernails, reduce the possibility of frozen dessert products, containers, utensils and equipment becoming contaminated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) Hands are thoroughly washed before commencing frozen dessert plant functions and as often as may be required to remove soil and contamination.

2) Each employee washes their hands following a visit to the toilet room and prior to resuming work.

3) All persons while engaged in the handling, processing, storage, transportation, or packaging of frozen dessert products containers, utensils, and equipment wear clean outer garments.

4) The use of tobacco products is prohibited in all rooms in which frozen dessert products are handled, processed or stored, or in which frozen dessert product containers, utensils and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, frozen dessert, milk, and milk product storage, cooling and dry storage ingredients, single-service article storage and container/utensil wash-up areas. Any person engaged in the processing of frozen dessert products wears adequate hair coverings.

ITEM 21p. VEHICLES

All vehicles used for the transportation of frozen dessert products shall be constructed and operated so that the frozen dessert products are maintained at 7°C (45°F) or less and are protected from contamination.
PUBLIC HEALTH REASON

Frozen dessert products, as well as empty containers, should be protected against contamination at all times.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) All vehicles are kept clean.
2) Material that is capable of contaminating frozen dessert products is not transported with frozen dessert products.
3) Frozen dessert products are maintained at 7°C (45°F) or less.
4) Vehicles have fully enclosed bodies with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Frozen dessert plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

PUBLIC HEALTH REASON

The surroundings of a frozen dessert plant should be kept neat and clean to prevent attracting rodents, flies and other insects, which may contaminate the frozen dessert products. Insecticides and rodenticides, not approved for use in frozen dessert plants, or approved insecticides and rodenticides, not used in accordance with label recommendations, may contaminate the frozen dessert products processed by the plant.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1) There is no accumulation of trash, garbage or similar waste in areas adjacent to the frozen dessert plant. Waste material stored in suitable covered containers shall be considered in compliance.
2) Driveways, lanes and areas serving plant vehicular traffic are graded, drained and free from pools of standing water.
3) Only insecticides and rodenticides approved for use by the Regulatory Agency and/or registered with EPA shall be used for insect and rodent control.
LABELING

Ice cream and frozen desserts are required to be labeled under the provisions of the Federal Nutrition Labeling and Education Act of 1990 (NLEA). To be exempt from NLEA nutritional labeling requirements you must qualify and obtain an exemption from the Food and Drug Administration. Companies claiming a small business exemption must notify FDA that they meet the criteria before they begin marketing their products. This request must be made in writing annually. The FDA will send you an acknowledgement of receipt of your application.

Products labels that make specific nutrient claims are not exempt under any circumstance and must have appropriately formatted nutritional information. To apply for a small business exemption in Florida, please contact:

Compliance Branch
Food & Drug Administration
Maitland, FL
407-475-4734

Or, visit the FDA website:

www.FDA.GOV

Go to the A-Z search, select F; scroll down and click on forms; then click on foods; scroll down to form 3570 – Model Small Business Food Labeling Exemption Notice

The website has a wealth of information on labeling and what qualifies as a nutritional claim.

Chapter 5K-10 F.A.C

5K-10.003(3)

(b) Frozen Dessert plants shall meet the following requirements in order to secure and maintain a said license:

1. Submit, with the appropriate fee, a properly completed application on Form DACS-05016 Application for License as a Wholesale Manufacturer of Frozen Dessert and/or Mix (Rev. 10.07), hereby incorporated by reference. Copies may be obtained from the Department of Agriculture and Consumer Services, Division of Dairy Industry, 3124 Conner Boulevard, Tallahassee, Florida 32399-1650.

2. Submit labels for approval
   a. In-State Plant must submit, for approval, a label for each product to be produced.
   b. Out-of-State Plant must submit for approval, a label for each product distributed in Florida.

3. Appropriate Facility Inspection.
   a. In-State Plant must pass a sanitation inspection. Inspection criteria is that of the PMO.
   b. Out-of-State Plant must submit its most recent inspection report from its local regulatory agency and provide a list of its distribution points in Florida.
# LABELING REQUIREMENTS for FROZEN DESSERT PROCESSORS

*Updated March 2008*

## WHOLESALE LABELING

<table>
<thead>
<tr>
<th>WHOLESALE BULK</th>
<th>WHOLESALE NOVELTY</th>
<th>INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Containers used solely to transport bulk product to wholesale distributors.</td>
<td>Boxes or wraps used solely to transport individually packaged product to wholesale distributors.</td>
<td>Containers, boxes or wraps used solely to transport bulk or individually packaged product to institutions or food establishments.</td>
</tr>
</tbody>
</table>

### IDENTITY OF PRODUCT

Ice Cream, Gelato, Sherbet, Frozen Yogurt, Italian Ice, etc.  
**MUST LABEL** the individually packaged product.

### FLAVOR(S)

Vanilla, Chocolate, Strawberry, etc.  
**MUST LABEL** the individually packaged product.

### NET CONTENTS

Both standard & metric.  
**MUST LABEL** the box or wrap with the count and individual package size or each individual package.

### INGREDIENTS

In descending order of predominance by weight.  
**MUST LABEL** the container or make information available because retailer must display ingredients at point of purchase by the use of a counter card, pamphlet, etc.

### NUTRITION INFORMATION

Fat, Cholesterol, Sodium, etc.  
**REQUIRED**  
When a nutrient content claim is made, a nutrition label is required on the container clearly visible to the consumer or each individual package or made available to retailer so information can be displayed at point of purchase by the use of a counter card, pamphlet, etc.

*See “Labeling” section for possible exemptions if not making any nutritional claims.*
## LABELING REQUIREMENTS - FROZEN DESSERT PROCESSORS

(continued)

<table>
<thead>
<tr>
<th>WHOLESALE BULK</th>
<th>WHOLESALE NOVELTY</th>
<th>INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CODE DATE</td>
<td>MUST LABEL</td>
<td>MUST LABEL EITHER</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the container, box or wrap</td>
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<td></td>
<td></td>
<td>OR each individual package.</td>
</tr>
<tr>
<td>PLANT IDENTIFICATION</td>
<td>MUST LABEL</td>
<td>MUST LABEL EITHER</td>
</tr>
<tr>
<td>Name, address &amp; phone number of plant or plant permit number.</td>
<td></td>
<td>the box or wrap</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR each individual package.</td>
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<tr>
<td></td>
<td></td>
<td>each individual package.</td>
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</tbody>
</table>

**Notes:**

- **Principal display panel** - Must contain the pertinent product information.
- **Re-usable containers** – Must have a letter from the manufacturer stating that the container materials are in compliance with the Federal Food, Drug & Cosmetic Act as amended (that the materials are food grade).

### COLORS & COLORING

Ingredient labeling of color additives subject to certification under the FD&C Act and those not subject to certification are discussed below. Although in the past (with the exception of FD&C Yellow No.5), **certified** colors were only required to be declared as “colorings”, they are now required (due to the NLEA) to be declared by their specific certification number. Ingredient labeling of **non-certified** colors did not change because of the NLEA provisions. Like other ingredients, certified and non-certified colors must be listed in the ingredient statement in order of predominance by weight or if they are present in a weight of 2% or less, an appropriate qualifying statement may be used. **NOTE:** There is no standard of equivalency for foreign colors.

#### Certified Colors

Color additives subject to certification must be declared by the name of the certified color in the ingredient statement (21 CFR Part 101.22 *Foods; labeling of spices, flavorings, colorings and chemical preservatives*). While ice cream (21 CFR Part 135.110 *Ice Cream*) is exempt from color labeling under the FD&C Act, the voluntary declaration of all colorings in the ingredient statement is recommended and encouraged by FDA. All foods, however, including ice cream, are **required** to declare the presence of the certified color FD&C yellow No.5 in the ingredient statement.
The following is a list of certified colors (21 CFR, Part 74, Subpart A):

FD&C Blue No. 1          Citrus Red No. 2
FD&C Blue No. 2          FD & C Red No. 3
FD&C Green No. 3          FD & C Red No. 40
Orange B                  FD&C Yellow No. 5
FD & C Yellow No. 6

The “FD&C” prefix is not required to accompany the name of the certified color in the ingredient statement. Similarly, the abbreviation “No.” is not required in the declaration. The term “lake” is required when appropriate. Examples of acceptable certified color labeling for FD&C Red No. 40 include “FD&C Red No. 40”, “Red No. 40”, and “Red 40”. Additionally, manufacturers may parenthetically list an appropriate alternative name following its common or usual “certified” name (e.g., Yellow No 5 (tartrazine)).

**APPENDIX H – THERMOMETER SPECIFICATIONS**

**RECORDING THERMOMETERS ON MECHANICAL CLEANING SYSTEMS**

**Location** - Temperature sensor is in the return solution line downstream from the process.

**Case** - Moisture proof under operation conditions.

**Scale** - Shall have a range from 16°C (60°F) to 83°C (180°F), with extensions of scale on either side permissible and graduated in time-scale divisions of not more than fifteen (15) minutes. The chart is to be graduated in temperature divisions of not more than 1°C (2°F), spaced not less than 1.6 millimeters (0.0625 inch) apart, above 44°C (110°F). Provided, that temperature-scale divisions of 1°C (2°F), spaced not less than 1 millimeter (0.040 inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line.

**Temperature Accuracy** - Within ± 1°C (± 2°F), above 44°C (110°F).

**Pen-Arm Setting Device** - Easily accessible and simple to adjust.

**Pen and Chart Paper** - Designed to make a line not over .635 millimeters (0.025 inch) wide and easy to maintain.

**Temperature Sensor** - Protected against damage at 100°C (212°F).

**Stem Fitting** - A pressure-tight seat against the inside wall of the pipe with no threads exposed to solution.

**Chart Speed** - Circular charts shall make one (1) revolution in not more than twenty-four (24) hours. Strip charts shall not move less than 25 millimeters (1 inch) per hour. More than one (1) record of the cleaning operation shall not overlap on the same section of the chart for either circular- or strip-type charts.
INDICATING THERMOMETERS USED IN STORAGE TANKS

Scale Range - Shall have a span not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees), including normal storage temperatures, ± 3°C (± 5°F), with an extension of scale on either side permitted, and graduated in not more than 1°C (2°F) divisions. Temperature Scale Division: Spaced not less than 1.6 millimeters (0.0625 inch) apart between 2°C (35°F) and 13°C (55°F).

Temperature Accuracy - Within ± 1°C (± 2°F) throughout the specified scale range.

Stem Fitting - A pressure-tight seat or other suitable sanitary fittings with no threads exposed.

RECORDING THERMOMETERS USED ON STORAGE TANKS

Case - Moisture proof under operating conditions in milk plants.

Scale - Shall have a scale span of not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees) including normal storage temperature, ± 3°C (± 5°F), graduated in not more than 1°C (2°F) divisions. Lines spaced not less than 1 millimeter (0.040 inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line. They shall be graduated in time scale divisions of not more than one (1) hour, having a chord of straight-line length of not less than 3.2 millimeters (0.125 inch) at 5°C (40°F). These charts must be capable of recording temperatures up to 83°C (180°F). Span specifications do not apply to extensions beyond 38°C (100°F).

Temperature Accuracy - Within ± 1°C (± 2°F), between the specified range limits.

Pen-Arm Setting Device - Easily accessible and simple to adjust.

Pen and Chart Paper - Designed to make a line not over .635 millimeters (0.025 inch) wide when in proper adjustment and easy to maintain.

Temperature Sensor - Protected against damage at 100°C (212°F).

Stem Fittings - A pressure-tight seat or other suitable sanitary fitting with no threads exposed.

Chart Speed - The circular chart shall make one (1) revolution in not more than seven (7) days and shall be graduated for a maximum record of seven (7) days. Strip chart shall move not less than 2.54 centimeters (1 inch) per hour and may be used continuously for one (1) calendar month.