

Title 19: HEALTH AND SENIOR SERVICES
Division 20: Community and Public Health
Chapter 1: Food Protection

PROPOSED AMENDMENT

19 CSR 20-1.030 *[Sanitation and Production Standards for]* **Frozen Dessert[s] License.** The Department of Health and Senior Services is amending the rule title, amending sections (1) through (7), and deleting sections (8) through (36).

PURPOSE: This amendment describes the application process and requirements for acquiring a frozen dessert license.

(1) Applicability. This rule applies to food establishments, food processing plants, and brokers manufacturing and/or distributing frozen dessert products. *[The following definitions shall apply in the interpretation and enforcement of this rule:*

- (A) A frozen dessert shall mean a frozen product made from any of the following: milk solids or other milk products, water, organic acids, natural or artificial flavoring, sweetening agents, and harmless coloring together with any safe or suitable functional ingredient. Frozen desserts shall include ice cream, frozen custard, ice milk, sherbet, water ice, mellorine or any other frozen product intended to be eaten in its frozen state, but which in its unfrozen, but otherwise edible state, is recognized by a common or usual name for a nonstandardized food. Any of these frozen products which are prepared for special dietary use are also included as a frozen dessert;*
- (B) The term mix shall mean the unfrozen combination of all ingredients of a frozen dessert with or without fruits, fruit juices, candy, nut meats, flavor or harmless color;*
- (C) The terms pasteurization and pasteurized shall refer to the process of heating in approved and properly operated equipment every particle of mix to one (1) of the following minimum temperatures and holding at this temperature continuously for the specified time: one hundred fifty-five degrees Fahrenheit (155 F) and holding at that temperature for at least thirty (30) minutes; or one hundred seventy-five degrees Fahrenheit (175 F) and holding at that temperature for at least twenty-five (25) seconds; or any other method or process demonstrated to be equally efficient and approved by the Missouri Department of Health;*
- (D) A frozen dessert processor is any person who freezes any pasteurized mix into semi-solid or solid form for retail distribution or sale as a frozen dessert;*
- (E) A frozen dessert distributor is any person who offers for sale or sells to another any frozen dessert or mix for human consumption;*
- (F) A frozen dessert plant is any place or premises where frozen desserts or mixes are processed, pasteurized, frozen or packaged for distribution or sale;*
- (G) An official laboratory is a biological, chemical or physical laboratory which is under the direct supervision of the state or local health authority and which has been approved by the appropriate state laboratory agency;*
- (H) Health authority shall mean the director of the Department of Health or his/her designated representative;*

- (I) *The word person shall mean an individual, partnership, corporation, company, firm, trustee, cooperative or association;*
- (J) *Adulterated shall mean the condition of a frozen dessert when it contains any poisonous or harmful substance in a quantity which may render it injurious to health; when it contains any added poisonous or harmful substance for which no safe tolerance has been established by regulation or in excess of that tolerance if one has been established; when it consists in whole or in part of any substance unfit for human consumption; when it has been processed, prepared, packaged or held under unsanitary conditions whereby it may have been rendered injurious to health; when its container is composed in whole or in part of any toxic or harmful substance which may render the contents injurious to health or when it contains any substance that does not conform with section 196.856, RSMo (1986) or this rule;*
- (K) *Misbranded shall mean the presence of any false or misleading written, printed or graphic matter upon a container of frozen dessert or accompanying a frozen dessert or any label which violates any applicable federal, state or local labeling laws or regulations; and*
- (L) *Confectionary shall mean candy, cakes, cookies and glazed fruits.]*

(2) Definitions. The following definitions shall apply in the interpretation and application of this rule and shall have the meaning stated below:

- (A) “Administrative authority” shall mean the department, local public health agency (LPHA), and/or U.S. Food and Drug Administration that has authority to govern food establishments and/or food processing plants.**
- (B) “Broker” shall mean any person operating a food processing plant located outside of Missouri that manufactures and/or distributes frozen dessert products into Missouri.**
- (C) “Department” shall mean the Missouri Department of Health and Senior Services.**
- (D) “Food establishment” shall be defined as specified in 19 CSR 20-1.025.**
- (E) “Food processing plant” shall be defined as specified in 19 CSR 20-1.025.**
- (F) “Frozen dessert” shall mean ice cream, ice cream mix, ice milk, sherbet, frozen malt, ice milk mix, mellorine, edible fat frozen dessert or ices that meet the definition of a potentially hazardous food as defined in 19 CSR 20-1.025.**
- (G) “Person” shall mean an individual, partnership, corporation, organization, and association. [All frozen dessert processors and frozen dessert plants shall be inspected at least annually to determine eligibility for license. The inspection procedure for renewal of license shall be the same as that for initial licensing.]**

(3) Responsibilities. The person shall:

- (A) Allow the administrative authority access to the premises during normal hours of operation for the purposes of conducting health and sanitation inspections.**
- (B) Allow the administrative authority to collect water, food and environmental samples as needed.**
- (C) In the event of a suspected communicable disease outbreak, implement health and sanitation control measures as required by the department and/or Local Public Health Agency (LPHA).**
- (D) In the event food products are deemed adulterated or misbranded, implement health and sanitation control measures as required by the department. [Raw milk and raw milk products used in the manufacture of frozen desserts shall meet at least the**

minimum requirements as defined in the Missouri Department of Agriculture Farm Certification Regulations.]

(4) General Criteria.

(A) Food establishments shall:

- 1. Be in compliance with sanitation requirements specified in 19 CSR 20-1.025 or local food ordinance; and**
- 2. Clean and maintain frozen dessert equipment in accordance with manufacturer's specifications.**

(B) Food processing plants shall:

- 1. Be in compliance with sanitation requirements specified in 19 CSR 20-1.040; and**
- 2. Be in compliance with labeling requirements specified in 19 CSR 20-1.045.**

(C) Brokers shall:

- 1. Be in compliance with equivalent local sanitation requirements; and/or**
- 2. Be in compliance with sanitation requirements specified in 21 CFR Part 117; and**
- 3. Be in compliance with labeling requirements specified in 21 CFR Part 101. *[No ingredients shall be used in processing frozen desserts which are adulterated within the meaning of section 196.070, RSMo (1986).]***

(5) Application Requirements for Initial Frozen Dessert License.

(A) Prior to the issuance of a license, an applicant shall complete and submit an application packet to the department. The department may require additional information when deemed necessary to assure compliance with the requirements of this rule. The application packet shall include:

- 1. A completed Application for Frozen Dessert License form (which can be requested by contacting the department);**
- 2. A nonrefundable licensing fee of ten dollars (\$10);**
- 3. Certificate of No Tax Due as required in 144.083 RSMo; and**
- 4. A copy of the most current sanitation inspection report from the administrative authority.**

(B) Private homes, hospitals, churches, or fraternal organization manufacturing frozen dessert products for their own use or food establishments serving and/or selling ice cream or frozen dessert products received in its final frozen form from a licensed manufacturer shall not be required to obtain a frozen dessert license. *[At irregular intervals during any six (6)-month period at least four (4) samples of frozen desserts or pasteurized mix shall be taken and examined by an official laboratory designated by the Missouri Department of Health or its authorized representative. Pasteurized mix and frozen desserts shall not exceed fifty thousand (50,000) standard plate count or ten (10) coliform per gram in three (3) out of the last five (5) consecutive samples taken by the health authority.]*

(6) Procedure for Issuance or Denial of Frozen Dessert License.

(A) The applicant shall be notified in writing or electronic mail (email), by the department, when the application is approved, incomplete, or denied.

- 1. If the application is approved, the notice shall specify the application is approved and a frozen dessert license shall be issued.**
- 2. If the application is incomplete, the notice shall specify the necessary information or documentation required to complete the application.**

- A. The applicant shall submit the requested information and/or documentation to the department within thirty (30) calendar days from the issuance date of the notice.
 - B. Failure to submit the requested information within the thirty (30) calendar days may result in the department denying the application.
 3. If the application is denied, the notice shall specify the reason(s) for the denial.
- (B) The applicant shall be denied a frozen dessert license for any one (1) or any combination of the following:
1. Failure to submit a complete application;
 2. False or misleading statement(s) on the application; or
 3. Failure to comply with the applicable requirements specified in sections (3) and (4) of this rule.
- (C) If the applicant is aggrieved by a determination to deny licensure, the applicant may appeal the department's decision to the Administrative Hearing Commission as provided by section 621.045 RSMo. *[The floors of all rooms in which frozen desserts or frozen dessert mix or the ingredients for them are processed or frozen or in which containers and utensils are washed shall be constructed of concrete or other equally impervious and easily cleaned material; and shall be smooth, properly drained, provided with trap drains and kept clean and in good repair. Cold storage rooms used for storing frozen desserts, milk, cream, milk products, frozen fruits, frozen eggs and comparable ingredients need not be provided with floor drains, but the floors shall be sloped to drain to one (1) or more exits and shall be kept clean. Dry storage rooms need not be drained and tight wood-floor construction is optional.]*
- (7) **License Renewal.**
- (A) A frozen dessert license shall be valid for one (1) year.
 - (B) Prior to the issuance of a renewal license, within sixty (60) calendar days but no later than thirty (30) calendar days prior to the expiration of the current license, a licensee shall complete and submit an application packet to the department. The department may require additional information when deemed necessary to assure compliance with the requirements of this rule. The application packet shall include:
 1. A completed Application for Frozen Dessert License form (which can be requested by contacting the department);
 2. A nonrefundable licensing fee as specified in 196.866 RSMo;
 3. Certificate of No Tax Due as required in 144.083 RSMo; and
 4. A copy of the most current sanitation inspection report from the administrative authority. *[Walls and ceilings of rooms in which frozen dessert mix, frozen desserts or ingredients for them are processed or frozen or in which containers or utensils are washed shall have a smooth, washable, light-colored surface and shall be kept clean and in good repair.]*
- (8) *Effective means shall be provided to prevent flies and rodents from entering a frozen dessert plant. All doors shall be self-closing.*
- (9) *All rooms shall be well lighted and ventilated. All exposed working surfaces shall have at least twenty (20) footcandles of light as measured by a light meter. Dry storage and cold storage rooms shall have at least ten (10) footcandles of light at a distance of thirty inches (30") from the floor.*

- (10) *The pasteurization, processing, cooling, freezing and packaging operations must be separated by solid partitions from other plant operations. Unless prohibited by existing construction, plants receiving milk products or frozen dessert mix in bulk transport tanks shall provide a room for receiving, cleaning and sanitizing transport tanks. Unless all milk products and mix are received in bulk transport tanks, a receiving room that is separate from rooms already listed in this section of this rule shall be required. Rooms in which milk products, frozen dessert ingredients or frozen desserts are handled, processed, sorted or packaged or in which product-contact containers, utensils and equipment are washed or stored shall not open directly into any room used for domestic purposes. All milk, milk products, mix or frozen desserts that have overflowed, leaked or been spilled shall be discarded.*
- (11) *Every frozen dessert plant shall have conveniently located toilet facilities. Toilet rooms shall not open directly into any room in which milk products, frozen desserts or frozen dessert ingredients are processed or packaged. Toilet rooms shall be completely enclosed and shall have tight-fitting self-closing doors. Dressing rooms and toilet rooms shall be kept clean, in good repair and well ventilated.*
- (12) *The water supply shall be easily accessible, adequate and of a safe and sanitary quality.*
- (13) *Convenient handwashing facilities shall be provided, including hot and cold or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Handwashing facilities shall be kept in a clean condition and in good repair.*
- (14) *All piping and fittings used to conduct milk, cream, milk products, mix or frozen desserts shall be of sanitary design and construction. Mix, frozen desserts, fluid milk products and ingredients shall be conducted from one (1) piece of equipment to another only by sanitary piping and fittings.*
- (15) *All multiuse containers, utensils and equipment which come in contact with mix, frozen desserts, milk, cream and milk products and other ingredients shall be smooth, impervious, noncorrodible, nontoxic, relatively low-absorbent material. Equipment shall be designed and installed so it is easily cleaned and shall be kept in good repair. All single-service containers, closures, gaskets and other articles shall be manufactured, packaged, transported and handled in a sanitary manner.*
- (16) *All waste shall be disposed of in a sanitary manner. All plumbing and appurtenances to plumbing shall be so designed and installed in a manner that prevents the contamination of mix or frozen desserts or any ingredient, utensil, container or equipment by drip, condensation or backflow.*
- (17) *All multiflow utensils, containers and equipment shall be thoroughly cleaned before each use. All product-contact surfaces of utensils, containers and equipment shall be subjected effectively to an approved bactericidal process immediately prior to use. Multiuse containers used for the transportation of mix shall be thoroughly rinsed immediately after emptying. Cleaning in place shall be used only on equipment and pipeline systems that are designed and engineered for that purpose. Installation and cleaning procedures shall be in accordance with Standard 605-04 of the 3-A Accepted Practices formulated by the International Association of Milk, Food and Environmental Sanitations, United States Public Health Service and the Daily Industry Committee.*
- (18) *After cleaning, all multiuse utensils, containers and equipment shall be stored to drain dry in a manner so they will not be contaminated before usage.*

- (19) *Caps; parchment paper; wrappers; liners; gaskets and single-service sticks, spoons, covers and containers for frozen dessert mix or frozen desserts or their ingredients shall be purchased and stored in sanitary tubes, wrappings or cartons. All of these shall be kept in a clean, dry place until used and shall be handled in a sanitary manner.*
- (20) *Between bactericidal treatment and usage and during usage, containers and equipment shall be handled or operated in a manner that prevents contamination of mix, frozen desserts or their ingredients. Pasteurized milk and frozen desserts shall not be permitted to come into contact with equipment with which unpasteurized mix, milk, cream or milk products have been in contact unless the equipment has been thoroughly cleaned and effectively subjected to an approved bactericidal process.*
- (21) *All frozen desserts which are made from liquid dairy and egg products must be pasteurized after formulation; flavoring ingredients and the reconstituted liquid mixes prepared from dry powder mixes are exempt from the pasteurization requirement. All milk and egg products used in dry mixes shall have been subjected to a pasteurization process. The design and operation of all pasteurization equipment and all appurtenances of that equipment shall comply with applicable specifications and operational procedures as outlined by the most recent recommendations of the federal Food and Drug Administration (FDA).*
- (22) *All milk, cream and milk products in fluid form received at a frozen dessert plant for use in frozen dessert mix shall immediately be cooled to a temperature of forty-five degrees Fahrenheit (45 F) or less and maintained at that temperature until pasteurized and all pasteurized mix shall be cooled immediately in approved equipment to a temperature of forty-five degrees Fahrenheit (45 F) or less and shall be maintained at that temperature until frozen.*
- (23) *A manufacturer of frozen desserts must comply with the following manufacturing practices:*
- (A) *Powder or dry frozen dessert mixes intended for reconstitution with water and which contain no milk or other fluid dairy product ingredients but contain egg ingredients, dry whey, reduced mineral whey, whey protein concentrate or whey reduced in lactose or caseinates are exempt from the pasteurization requirement of section (21) of this rule. Any of these ingredients used in the formulation of powder or dry frozen dessert mixes shall have been pasteurized;*
 - (B) *Powder or dry frozen dessert mixes shall contain no ingredients except those which are generally recognized as safe by the federal FDA;*
 - (C) *Water ices are exempt from the pasteurization requirements of section (21) of this rule; and*
 - (D) *All frozen dessert manufacturers shall apply for a license from the Department of Health prior to the manufacture or sale and distribution of their products in the state. Volume of powder or dry frozen dessert mixes required on the application shall be reported as gallons of mix after reconstitution. The application shall also include the name under which the frozen dessert is to be advertised or offered for sale; a list of the ingredients, including optional ingredients, with percentages in the product; method of preparation; and any other relevant information.*
- (24) *Packaging, cutting, molding and other preparations of mix or frozen desserts or their ingredients shall be done in a sanitary manner.*
- (25) *After delivery, mix or frozen desserts in broken or open containers may be returned to the plant for inspection but shall not be sold or used for making mix or frozen desserts.*

- (26) *Product drip or overflow or spilled mix or frozen desserts or their ingredients shall not be sold for human consumption.*
- (27) *No person, while affected with any disease in communicable form or while a carrier of that disease, or while affected with boils, infected wounds, sores or an acute respiratory infection, shall engage in pasteurization handling of ingredients, filling, packaging or freezing operation or in any capacity in which there is a likelihood that this person will contaminate mix, frozen desserts or mix and frozen dessert-contact surfaces with pathogenic organisms or transmit disease to other individuals. No person known or suspected of being affected with any disease or condition shall be employed in such a capacity.*
- (28) *All persons who come in contact with milk, cream, milk products, mix, frozen desserts, containers or equipment shall wear clean outer garments and head coverings and shall keep their hands clean at all times while engaged in that work.*
- (29) *All vehicles used for the transportation of mix, frozen desserts, cream, milk and milk products shall be constructed and operated so as to protect their contents from sun and contamination. These vehicles shall be kept clean and no substance capable of contaminating mix, frozen desserts, cream, milk and milk products shall be transported in the vehicles. Any such vehicle shall have the name of the distributor prominently displayed on it. Transport tanks used for transporting mix, cream, milk and milk products shall comply with the construction, cleaning, bactericidal treatment storage and handling requirements of this rule. Each shipment shall be sealed and labeled in an approved manner.*
- (30) *Surroundings of frozen dessert processors and plants shall be kept clean, neat and free from conditions which might attract or harbor flies or other insects and rodents or which might otherwise constitute a nuisance.*
- (31) *Lubricants, such as orange oil or petroleum jelly, which are applied to filling machine pistons and cylinders, pumps and valves, shall be sterile and shall be applied in a sanitary manner.*
- (32) *No person shall transfer frozen desserts from one container to another on the street, in any vehicle or store, or in any other place except under sanitary conditions as permitted by the health authority.*
- (33) *Frozen desserts from points beyond the limits of routine inspection of the health authority may be sold in the state if they are processed and pasteurized under provisions which are substantially equivalent to the requirements of this rule as determined by the health authority.*
- (34) *All frozen dessert plants which are constructed, reconstructed or extensively altered after the effective date of this rule shall conform to construction requirements of this rule. Properly prepared plans for all frozen dessert plants which are constructed, reconstructed or extensively altered after October 11, 1980 shall be submitted to the health authority for approval before work is begun. Signed approval shall be obtained from the health authority.*
- (35) *Notice shall be sent to the health authority immediately by any frozen dessert processor or distributor when any employee has any infectious, contagious or communicable disease.*
- (36) *Whenever reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk, milk products, frozen desserts, frozen dessert ingredients or frozen dessert mix, the health authority is authorized to require the immediate exclusion of that person from product handling. In addition, the health authority can require the immediate exclusion of the products concerned from distribution and require*

adequate medical and bacteriological examination of the person and of his/her associates and of his/her and their body discharges.]

AUTHORITY: section 196.872, RSMo 1986. This rule was previously filed as 13 CSR 50-63.010. Original rule filed June 27, 1980, effective Oct. 11, 1980. Amended: Filed June 27, 1983, effective Nov. 11, 1983. Amended: Filed May 2, 1986, effective July 26, 1986. Amended: Filed June 2, 2021

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Community and Public Health, Adam Crumbliss, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received with thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*