

Rules of Department of Health and Senior Services

Division 20—Division of Community and Public Health Chapter 1—Food Protection

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Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 20—Division of Community and Public Health

Chapter 1—Food Protection

19 CSR 20-1.010 Sanitation of Food Service Establishments

(Rescinded October 30, 1999)

AUTHORITY: sections 192.005.2, 192.020 and 196.045, RSMo 1986. This rule was previously filed as 13 CSR 50-61.010. Original rule filed Oct. 21, 1948, effective Oct. 31, 1948. Amended: Filed March 22, 1954, effective April 1, 1954. Amended: Filed March 24, 1958, effective April 3, 1958. Amended: Filed Jan. 23, 1963, effective Feb. 2, 1963. Rescinded and readopted: Filed Sept. 1, 1981, effective Dec. 11, 1981. Amended: Filed July 18, 1989, effective Sept. 28, 1989. Rescinded: Filed April 7, 1999, effective Oct. 30, 1999.

19 CSR 20-1.020 Sanitation of Retail Food Stores

(Rescinded October 30, 1999)

AUTHORITY: sections 192.005.2, 192.020 and 196.045, RSMo 1986. Original rule filed Feb. 4, 1986, effective April 25, 1986. Amended: Filed July 18, 1989, effective Sept. 28, 1989. Rescinded: Filed April 7, 1999, effective Oct. 30, 1999.

19 CSR 20-1.025 Missouri Food Code

PURPOSE: This rule establishes up-to-date sanitation standards for food establishments designated in Chapter 196, RSMo.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Food establishments shall comply with the sanitation standards and processes contained in the Department of Health and Senior Services *Missouri Food Code* manual. The manual is incorporated by reference in this rule as published June 3, 2013, by the

Department of Health and Senior Services and is available on the web at www.health.mo.gov or by contacting the department at PO Box 570, Jefferson City, MO 65102-0570, (573) 751-6095. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006 and 196.045, RSMo 2000, and section 192.020, RSMo Supp. 2012.* Original rule filed April 26, 1999, effective Oct. 30, 1999. Amended: Filed March 1, 2005, effective Sept. 30, 2005. Rescinded and readopted: Filed March 11, 2013, effective Sept. 30, 2013.

*Original authority 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004; 196.190, RSMo 1939; 196.195, RSMo 1939; 196.210, RSMo 1939; 196.220, RSMo 1939; 196.225, RSMo 1939; 196.235, RSMo 1939; 196.240, RSMo 1939; 196.245, RSMo 1939; 196.250, RSMo 1939; 196.250, RSMo 1939; 196.250, RSMo 1939; 196.250, RSMo 1939; and 196.250, RSMo 1939.

19 CSR 20-1.030 Sanitation and Production Standards for Frozen Desserts

PURPOSE: This rule defines and establishes sanitation and production standards for frozen desserts as they relate to public health.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

- (1) 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

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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) 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) 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) No ingredients shall be used in processing frozen desserts which are adulterated within the meaning of section 196.070, RSMo (1986).
- (5) 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) 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 to be drained and tight wood-floor construction is optional.
- (7) 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.



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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.

*Original authority: 196.872, RSMo 1980.

19 CSR 20-1.040 Good Manufacturing Practices

PURPOSE: This rule establishes sanitation standards of public health significance for manufactured foods.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Applicability. The requirements of this rule apply to buildings or facilities, or parts thereof, used for, or in connection with, the manufacturing, packaging, processing, or holding of human food.
- (2) Standards. Manufacturers, distributors, and warehouses shall operate in accordance with 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, revised as of September 17, 2015, hereby incorporated by reference and made a part of this rule as published by the U.S. Government Publishing Office, 732 North Capitol Street NW, Washington, DC 20401-0001, (202) 512-1800, http://bookstore.gpo.gov. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006, 192.020, and 196.045, RSMo 2016.* This rule was previously filed as 13 CSR 50-70.010. Original rule entitled Missouri Division of Health E 1.20 was filed Nov. 17, 1949, effective Nov. 27, 1949. Rescinded and readopted: Filed March II, 2013, effective Sept. 30, 2013. Emergency amendment filed Oct. 13, 2017, effective Oct. 23, 2017, expired April 20, 2018. Amended: Filed Oct. 13, 2017, effective April 30, 2018.

*Original authority: 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004, 2016; and 196.045, RSMo 1943, amended 1993, 1995.

19 CSR 20-1.042 Acidified Foods

PURPOSE: This rule establishes standards to assure the facilities, methods, practices, and controls used to manufacture, process, and package acidified foods are safe and conducted under sanitary conditions.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Applicability. The requirements of this rule apply to any person engaged in or connected with manufacturing, processing, and/or packaging of acidified foods.
- (2) Standards. Any person engaged in the manufacturing, processing, and/or packaging of acidified foods shall operate in accordance with 21 CFR Part 114 Acidified Foods, revised as of April 1, 2012, hereby incorporated by reference and made a part of this rule as published by the U.S. Government Printing Office, 732 North Capitol Street NW, Washington, DC 20401-0001, (202) 512-1800, http://bookstore.gpo.gov. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006 and 196.045, RSMo 2000, and section 192.020, RSMo Supp. 2012.* Original rule filed March 11, 2013, effective Sept. 30, 2013.

*Original authority: 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004; and 196.045, RSMo 1943, amended 1993, 1995.

19 CSR 20-1.045 Food Labeling

PURPOSE: This rule establishes food labeling standards for manufactured foods.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Applicability. The requirements of this rule apply to buildings or facilities or parts thereof, used for or in connection with the labeling of human food.
- (2) Standards. Manufacturers, distributors, and warehouses shall label human food in accordance with 21 CFR Part 101 Food Labeling, revised as of April 1, 2012, hereby incorporated by reference and made a part of this rule as published by the U.S. Government Printing Office, 732 North Capitol Street NW, Washington, DC 20401-0001, (202) 512-1800, http://bookstore.gpo.gov. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006 and 196.045, RSMo 2000, and section 192.020, RSMo Supp. 2012.* Original rule filed March 11, 2013, effective Sept. 30, 2013.

*Original authority: 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004; and 196.045, RSMo 1943, amended 1993, 1995.

19 CSR 20-1.050 Sanitation Standards for the Manufacture of Soft Drinks and Beverages

PURPOSE: This rule defines and establishes sanitation standards for nonintoxicating beverage and soft drink manufacturers.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

- (1) The following definitions shall apply in the interpretation and the enforcement of this rule:
- (A) Bottling means filling, capping, packaging and enclosing in bottles or other containers, including metal cans and premixed tanks:
- (B) Flavor manufacturing plant means a building in which soft drink flavors are prepared, manufactured and packaged, including any separate room used for the accommodation of workers;

- (C) Franchisee means a person authorized or given contractual permission to bottle, offer for sale or distribute a soft drink in a specified territory for a company or franchiser who owns the trademark or name and formula for the soft drink;
- (D) Governing jurisdiction means standards, codes or ordinances as administered by local, state or federal agencies;
- (E) Nonintoxicating beverage plant means a building in which soft drinks are produced including any separate room used in the preparation or storage of soft drink flavors and including any separate room used for the accommodation of production employees;
- (F) Nonnutritive sweeteners means saccharin salt, aspartame and other such nonsugar sweetening ingredients as may be approved by the federal Food and Drug Administration (FDA) and recognized by of the Department of Health;
- (G) Person means any individual, firm, corporation or other legal entity;
- (H) Sodium means the amount of this element expressed in terms of milligrams (mg) per eight (8) fluid ounces.
- Sodium-free means less than five milligrams (5 mg) of sodium per eight (8) fluid ounces.
- 2. Very low sodium means thirty-five milligrams (35 mg) or less of sodium per eight (8) fluid ounces.
- 3. Low sodium means one hundred forty milligrams (140 mg) or less of sodium per eight (8) fluid ounces;
- (I) Soft drink shall be held to mean and include all beverages of every kind manufactured or sold in the state which shall be understood to include those containing less than one-half (1/2) of one percent (1%) of or no alcohol, including carbonated beverages, still drinks, seltzer water, artificial or natural mineral waters and all other waters used and sold for beverage purposes. Among other products, this rule shall be interpreted to include carbonated beverages, soda, soda water, fruitade, any nonalcoholic flavored still beverages, artificial or natural mineral waters, bottled table waters, artificial waters whether carbonated or not, seltzer and club soda, and beverages that are manufactured or created by the use of parts of or natural fruit juices and the use of artificial flavoring and water such as orange juice, lemon drink, reconstituted orange juice or other similar names. These rules do not apply to whole or concentrated beverages such as concentrated grape juice, unfermented grape juice, orange juice, lemon juice, grapefruit juice, pineapple juice and apple juice or cider, provided that the same is the juice extracted from the natural fruit and that it is in its natural state and

- properly labeled. This rule does, however, cover all reconstituted products which are bottled from the concentrates referred to in this subsection;
- (J) Soft drink flavors mean any type of soda water flavor or beverage base, syrup extracts, concentrate, powder or other compound prepared for use as a flavoring for soft drinks; and
- (K) Sweetening ingredient means cane sugar or beet sugar, in liquid or crystal form, dextrose, corn sugar syrup in liquid or direct form, honey or any syrup from any sugar or any combination of these sugars;
- (2) Beverage Labeling. Beverages shall be labeled in compliance with sections 196.010, 196.015, 196.075, 196.120 and 196.415, RSMo (1986).
- (A) Labels or advertising pertaining to sodium content shall have the serving size and sodium content declared on the label and shall be in conformance with section (1) of this rule.
- (B) Supplemental printed information and graphics may appear on the label but shall not imply properties of the product or preparation methods which are not factual.
- (C) In addition, the following shall also be required when labeling bottled water:
- 1. If a public water system is used as the source of water for the bottled water, the container shall be labeled to clearly inform the consumer of the source of the water. If the bottler further processes, conditions or treats the water from the public water system, the additional treatments may also be included on the label;
- 2. A bottled water with or without natural or added carbonation may be prepared with added flavors, extracts, essences or fruit juice concentrates derived from a spice or fruit and comprising less than one percent (1%) by weight of the final product. The final product shall contain no sweeteners or additives—including nonnutritive sweeteners—other than any of the following flavors, extracts, essences or fruit juice concentrates and carbon dioxide and shall be designated on labels and in advertising as follows:
- A. The common or usual name of the characterizing flavor shall accompany the designation of the bottled water-product type;
- B. The product may be designated as natural only if it meets the requirements of the designation as defined in subparagraph (2)(C)3.E. of this rule and naturally derived flavors, extracts or essences are used;
- C. Products labeled as one (1) type or one (1) source of bottled water shall not be blended with water that is not bottled water or that is of another bottled water type; and

- D. Water which meets the definition of more than one (1) type of water as defined in paragraph (2)(C)3. of this rule may be labeled with either the applicable description or a combination of applicable descriptions; and
- 3. If a manufacturer or distributor provides information on the label or in advertising stating or implying it is the product of a specific water type—for example, spring water—or treated in a specific manner—for example, purified water—the type or treatment shall be on the label in an easily readable format. A label or advertising implying a specific water type or specific treatment shall conform to the following criteria:
- A. Artesian well water means water from a well tapping an aquifer in which the water level will stand above the bottom of the confining bed of the aquifer, and in which the hydraulic pressure of the water in the aquifer is greater than the force of gravity. Artesian well water shall not be altered by the addition or deletion of minerals or by blending it with water from a nonartesian well water source, except that artesian well water shall be treated with a disinfection process and may be filtered to reduce the concentration of any naturally occurring substance which exceeds the bottled water standards set forth in sections (6)–(8) of this rule;
- B. Fluoridated water means water containing naturally occurring or added fluoride. The label shall specify whether fluoride is naturally occurring or is added. Any water which meets the designation of fluoridated water shall contain at least eight-tenths of a milligram per liter (0.8 mg/l) fluoride and shall otherwise comply with standards established by the United States FDA in 21 CFR 103.35(d)(2)(1991);
- C. Mineral water means water containing more than five hundred milligrams per liter (500 mg/l) of total dissolved solids and originating entirely from an underground source, which may be a well, artesian well or spring. Mineral water may be derived from a natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Mineral water may not be altered by the addition or deletion of minerals or by blending it with water from a nonmineral water source, except that mineral water may be filtered and shall be treated with a disinfection process approved by the Department of Health and shall be treated to reduce the concentration of any naturally occurring substance which exceeds the bottled

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water standards set forth in sections (6)–(8) of this rule. Exemption from the requirement for a disinfection process of the mineral water may be granted on an individual basis and only if the bottler can demonstrate continuing compliance with the standards of the European Economic Community Directive 80/777/EEC for Natural Mineral Water, July 15, 1980. Mineral water may be collected and transported by pipes, tunnels, trucks or similar devices. Any water which meets the criteria of this paragraph may also be labeled natural mineral water.

- (I) Mineral water which contains carbon dioxide as it emerges from the source and is bottled directly with its entrapped gas, or from which the gas is mechanically separated and later reintroduced into the water at the time of bottling shall be labeled naturally carbonated or naturally sparkling.
- (II) Mineral water which contains carbon dioxide other than that naturally occurring in the source product shall be labeled with the words carbonation added or carbon dioxide added, whether the carbonation is obtained from a natural or manufactured source:
- D. Mineralized water means water which meets the requirements of mineral water in subparagraph (2)(C)3.C. of this rule, except that the water also contains added minerals;
- E. Natural water means spring, artesian well or well water which is unmodified by mineral addition or deletion, except natural water may be filtered and shall be treated with a disinfection process and treated to reduce the concentration of any substance which exceeds standards set forth in sections (6)–(8) of this rule;
- F. Purified water means water produced by distillation, deionization, ion exchange treatment or reverse osmosis and that meets the definition of purified water in the *United States Pharmacopeia*: Purified water is water obtained by distillation, exchange, reverse osmosis or other suitable exchange. It is prepared from water complying with the regulations of the United States Environmental Protection Agency (U.S. EPA) with respect to drinking water. It contains no added substance. Purified water which is vaporized and then condensed may be labeled distilled water;
- G. Sparkling, carbonated or carbonation added means water which contains carbon dioxide. Naturally sparkling water means water with a carbon dioxide content from the same source as the water:
- H. Spring water means water which issues by natural forces out of the earth at a particular place. Spring water may be derived

from the natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from the natural orifice by external force or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Spring water may not be altered by the addition or deletion of minerals or by blending it with water from a nonspring source. Spring water shall be treated with a disinfection process and may be filtered. Spring water may be collected and transported by pipes, tunnels, trucks or similar devices; and

- I. Well water means water from a hole bored or drilled into the ground which taps the water of an aquifer. Well water shall be treated with a disinfection process and may be filtered. Well water may not be altered by the addition or deletion of minerals or by blending it with water from a nonwell water source.
- (3) License Application and Expiration. Any person desiring to manufacture or distribute soft drinks or beverages as defined by the statute shall apply to the Department of Health for a license for each production facility and each warehouse operated by the applicant. The application shall be made on a form prescribed by the department for that purpose. Each license shall expire on the last day of June following the day of issuance. A license is not transferable and no refunds will be made. If the business is sold, the new owner shall obtain a new license.
- (4) Sanitary Requirements. Every building, room, basement or cellar occupied or used for the preparation for sale, holding for sale, manufacturing, packing, storage, sale or distribution of soft drinks or beverages shall be properly lighted, drained, plumbed and ventilated and conducted with due regard for the purity and wholesomeness of the products produced there and the strict regard to the influence of the conditions upon the health of the operatives, employees, clerks or other persons employed there.
- (A) The following rules regarding the building and premises used within Missouri for the manufacture and distribution of soft drinks and beverages shall be observed:
- 1. Location and use of building. The building or portion of the building shall be used for no other purpose and shall be so located as to be protected from objectionable surroundings;
- 2. Plant layout. Bottling plants shall be located in buildings so constructed that the bottling operation and syrup preparation are

located in a separate room. This relates specifically to operations such as bottle washing and filling, compounding and mixing of syrups, warehousing and loading. This requirement, except for the syrup room, does not apply to existing bottling plants which have been located continuously in the same building prior to the promulgation of this rule. In all cases of major structural changes to existing production facility or construction of a new production facility all separation requirements are to be achieved. The Department of Health will assist and recommend suggestions prior to the start of construction:

- 3. Floors. The floors of all rooms used for manufacturing operations shall be of a construction as to be impervious, easily cleaned, smooth and shall be kept sanitary and in good repair;
- 4. Walls and ceilings. Walls and ceilings in the syrup and bottling room shall be of hard, sound materials with smooth, easily cleaned surfaces and maintained clean. Surfaces that require painting shall be frequently painted with light colored paint;
- 5. Light. All processing areas shall have shielded fixtures with adequate footcandle lighting. All other areas shall be adequately lighted:
- 6. Ventilation. All room areas utilized for manufacture, bottling and container cleaning shall be provided with the necessary air movement to prevent excessive condensation on the ceiling and on filling equipment, which could contaminate the beverage or its ingredients. When overhead drip due to condensation is exposing cleaned containers on conveyor lines to possible contamination, shields shall be provided over the conveyor lines:
- 7. Screening and vermin control. Screens or other suitable equipment must be provided and used for the purpose of excluding insects from the processing area. All necessary vermin and rodent control measures must be taken;
- 8. Syrup room. All nonintoxicating beverage plants shall be equipped with a room known as a syrup room in which syrup, flavors, extracts and other liquid beverage ingredients or concentrates are measured, mixed or prepared. This room shall be separately enclosed and substantially constructed of easily cleanable material. It shall be well-ventilated and lighted, shall be provided with adequate facilities for washing and sanitizing equipment and shall have hot and cold running water easily accessible to all parts. It shall be protected against rodents, vermin, insects and dust and so constructed as to be easily cleaned;

- 9. Water and sewer connections. Water supply (if private) must meet construction requirements as found in 19 CSR 20-3.010 of the rules of the Department of Health and be of a sanitary quality. Running water under pressure from an approved source shall be easily accessible to all parts of the plant and adequate provisions for quickly carrying off and disposing of waste water shall be provided. If more than one (1) source of water is available in a plant, no cross connections shall be permitted between the two (2) sources. Sewage and other wastes must be disposed of in a manner approved by the Department of Natural Resources;
- 10. Toilet and washrooms. Every nonintoxicating beverage plant shall be provided with toilet facilities complying with plumbing codes of the governing jurisdiction. Toilet rooms should not open directly into any room used as a processing area. The doors of all toilet rooms shall be self-closing. Toilet rooms shall be kept in a clean condition, in good repair and well-ventilated. A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms used by employees;
- 11. Lavatory facilities. Adequate and convenient handwashing facilities shall be provided, including hot and cold running water, soap and approved sanitary towels. The use of a common towel is prohibited. No employee shall resume work after using the toilet room without first washing his/her hands; and
- 12. Clothing storage. Suitable places for changes of garments and proper care of same are required.
- (B) The following rules regarding the machinery and equipment used within Missouri for the manufacture and distribution of soft drinks and beverages shall be observed:
- 1. Equipment. Every plant manufacturing soft drinks, soft drink flavors and beverages shall be equipped with easily cleaned, suitable mechanical-washing apparatus and with approved machines for carbonating, filling and closing so that they may be readily accessible for cleaning and sanitizing;
- 2. Conveyors, palletizers and cases. These items shall be maintained free from accumulating dust, dirt, mud and other foreign materials;
- 3. Syrup making equipment. All vats, covers, jars, mixing and storage tanks, pipe lines, filters and other apparatus employed in the preparation of syrups shall be of sanitary construction and lined when necessary with materials resistant to the action of syrup ingredients;

- 4. Water clarification equipment. Electrical or chemical coagulation devices and filters employed for clarification of water shall be of types acceptable to the Department of Health, shall not be operated beyond their rated capacity and shall be maintained in a clean, wholesome and sanitary condition at all times; and
- 5. Miscellaneous equipment. Every plant shall be adequately provided with thermometers and methods for ascertaining the strength of the washer solution employed in bottle washing. All piping, vats, covers, tanks and other equipment or utensils shall be of easily cleanable construction and shall be kept in good repair. No containers shall be used for mixing or storing syrup or soft drink flavors unless they are of glass, stainless steel, good grade plastic, porcelain lined or block-tin lined; or made of or lined with, or both, some other suitable impervious, noncorrosive material. Utensils or equipment which are cadmium plated or zinc plated or in which cadmium, zinc or lead is a part of the metal are prohibited for the delivery of finished syrup or beverage. Only solder of a low lead content should be used for jointing.
- (C) The following rules regarding the manufacturing methods and operations of soft drink and beverage plants which manufacture beverage products in Missouri shall be observed:
- 1. Cleaning facilities. Adequate facilities must be provided for the proper cleaning of all containers, utensils and equipment used in the manufacturing and processing of soft drinks:
- 2. Cleaning. All pipe lines, apparatus and containers employed in the manufacturing process shall be cleaned and washed after each day's use. Sanitization shall be done as necessary to maintain at all times a sanitary system. Steam, hot water, chlorine or other equally efficient agents approved by the Department of Health are permissible for sanitization;
- 3. Sanitation of bottles. All closable containers in which soft drink flavors and beverages are sold or dispensed shall be washed or rinsed immediately before filling and shall be free of pathogenic bacteria. No containers intended by the manufacturer to be nonreturnable shall be refilled with beverages. Hand bottle washing, except as a preliminary before mechanical washing, shall be prohibited.
- A. All reusable glass containers used in the manufacture or bottling of soft drinks and beverages, before being filled, shall be sanitized during the washing cycle in a hot caustic solution of a temperature of not less than one hundred forty degrees Fahrenheit

- $(140^{\circ}F)$ that shall contain not less than four percent (4%) caustic or alkali, sodium hydrate or other residual materials acquired from the sanitizing procedure. Noncaustic cleansers may be used for reusable glass containers as described in subparagraph (4)(C)3.C. of this rule if the bottler can demonstrate to the Department of Health that the process is sufficient to clean and sanitize the glass.
- B. All premix and postmix containers, before being filled, shall be sanitized in a hot caustic solution at a temperature of not less than one hundred eighty degrees Fahrenheit (180°F) that shall contain not less than three percent (3%) caustic or alkali expressed in terms of sodium hydrate for a washing cycle of not less than one (1) minute and then thoroughly rinsed in clean water until free of alkali, sodium hydrate or other residual materials acquired from the sanitizing procedure.
- C. Polycarbonate and other plastic containers designed and intended for reuse shall be sanitized with noncaustic cleansers in the following manner:
- (I) Only noncaustic cleansers labeled for use for polycarbonate or plastic returnable containers shall be used. Specific washing conditions directed by the manufacturer shall be followed;
- (II) Washing shall be performed for at least one (1) minute if using high-velocity jets or for three (3) minutes if using soakertype wash;
- (III) A sanitizing rinse shall follow the washing of the container. The sanitizing rinse shall use either water at an inside bottle temperature not less than one hundred seventy degrees Fahrenheit (170° F) for not less than fifteen (15) seconds; or shall use a sanitizing solution. The sanitizing solution shall contain not less than one hundred parts per million (100 ppm) nor more than two hundred parts per million (200 ppm) chlorine water solution at seventy-five degrees Fahrenheit (75°F) for not less than thirty (30) seconds. Other sanitizing agents may be allowed upon approval of the Department of Health;
- (IV) A final rinse with product water or operations water shall be used to remove all traces of sanitizer; and
- (V) Manufacturers currently using caustics for sanitizing plastic containers as of July 1, 1992, the effective date of this rule may continue to use this method of sanitizing bottles as described for glass containers in subparagraph (4)(C)3.A. New installations of bottle washing equipment shall use the non-caustic cleanser method as described in this section.

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- D. A record of key operating parameters of the container washer shall be maintained. The record shall include wash temperature, concentration of caustic or cleanser, concentration of sanitizer when using noncaustic cleansers, lack of carry-over of caustic or cleanser in containers, and maintenance on washers. Records shall be kept on file at least two (2) years for regulatory inspection.
- 4. Preparation of syrup. Syrups shall be prepared in a clean manner and every precaution shall be taken against contamination or absorption of deleterious substances during the process, preparation and subsequent storage. All vats, tanks and other equipment must be provided with suitable covers so as to protect the syrup and other ingredients used in the manufacturing of soft drinks from contamination. Covers shall be in place on all vats which contain ingredients:
- 5. Filling and closing. Manual filling crowning, closing or both shall be prohibited. Containers shall be filled and closed with automatic machinery and neither the operator nor his/her clothes shall come in contact with any portion of the bottle, can or machinery which might result in contamination of the product. This shall not apply to premix or postmix tanks for which mechanical closing equipment is not available. If and when mechanical closing apparatus becomes available, manual closing shall be prohibited after a period of five (5) years;
- 6. Storage of closures. Crowns, can covers or any other closures shall be stored in dustproof containers:
- 7. Storage of sweetening ingredient. Sweetening ingredients shall be stored in a clean sanitary manner and protected from insects, rodents, dust and other contamination:
- 8. Storage of finished goods. The finished product shall be stored in a manner as not to interfere with the sanitation of the processing area;
- 9. Refuse and rubbish. All waste, broken bottles and other such refuse shall be promptly and properly disposed of and all garbage and trash shall be kept in suitable clean, covered receptacles in a manner as not to become a nuisance;
- 10. Storage and handling of utensils and equipment. After bactericidal treatment, utensils shall be stored in a clean, dry place protected from insects, dust or other contamination and utensils shall be handled in a manner as to prevent contamination; and
- 11. Miscellaneous. The surroundings of all plants shall be kept clean and free from litter or rubbish. None of the operations shall be conducted in any room used for domestic purposes. Clothing and hands shall be kept

- clean. Soiled linens, aprons and coats shall be kept in covered containers for this purpose. Animals such as dogs, cats or birds, etc. are not permitted in the plant.
- (D) The following rules regarding personnel employed in the manufacture and distribution of soft drinks and beverages must be observed:
- 1. Appearance and sanitary habits. All employees engaged in the mixing of syrups, filling of containers or in any other capacity which brings them in contact with the ingredients or containers of soft drinks, soft drink flavors or beverages shall be clean, have a neat appearance and wear clean clothes as determined by the licensee. Spitting or the use of tobacco in any form in the syrup room or bottling rooms is prohibited; and
- 2. Health. It is the employer's responsibility to assure him/herself that no employee has a contagious or infectious disease while engaged in handling, production, preparation, manufacture, packing, storage, sale or distribution of soft drinks, soft drink flavors or beverages.
- (E) All bulk water sources and facilities shall be approved and maintained for sanitary quality at all times.
- 1. Bulk water shall be from approved sources.
- A. All sources of water within the state intended for bulk water that is obtained from community public water supplies, noncommunity public water supplies or both shall comply with the laws and rules administered by the Public Drinking Water Program, Department of Natural Resources, governing public water supplies.
- B. All sources of water within the state intended for bulk water that is obtained from springs or private wells shall be approved by the Department of Health. The Department of Health shall request a preliminary review by the Division of Geology and Land Survey, Department of Natural Resources of the geology and potential sources of contamination of springs and their recharge areas, such as sinkholes or chemical pipelines. The review, at the option of the Division of Geology and Land Survey, may include site evaluation, dye tracing, flow movement or other criteria to assist in determining characteristics of the spring. The spring orifice shall be protected from avoidable contamination, such as keeping livestock out. Because each spring and surrounding area may be unique, plans for protection from avoidable contamination shall be presented for review and approval by the Department of Health.
- C. All privately owned wells within the state intended for bulk water shall be in

- compliance with the laws and rules administered by the Division of Geology and Land Survey, Department of Natural Resources, governing wells.
- D. Sources of water which may be classified as surface or ground water under the influence of surface water shall be provided with filtration or disinfection methods capable of controlling pathogenic organisms or both.
- E. All sources of water outside the state intended for bulk water, after treatment if needed, shall be in compliance with the appropriate regulatory authority for that jurisdiction and shall meet the requirements for microbiological, chemical and radiological standards set forth in sections (6)–(8) of this rule. Documentation of compliance with the appropriate regulatory authority shall be provided to the Department of Health.
- 2. Bulk water sources shall meet requirements for microbiological, chemical and radiological standards set forth in sections (6)–(8) of this rule.
- 3. All water storage facilities shall be maintained clean and sanitary at all times and shall meet the requirements set forth in section (4) of this rule.
- 4. Tank trucks, loading and unloading facilities, and other equipment used to transport bulk water shall be constructed of materials that do not import toxic substances, tastes, odor or color to the water, and shall be maintained clean and sanitary at all times. Tanks previously used to transport toxic materials, petroleum products or other deleterious substance shall not be used to haul drinking water.
- 5. Bulk transport and transfer procedures, at a minimum, shall meet the following requirements:
- A. The tank shall be sanitized monthly and at any time contamination is suspected or any substance other than water has been introduced or transported in the tank. The tank interior shall be cleaned, flushed with potable water, sanitized with a chemical sanitizer equivalent in bactericidal action of either a two (2)-minute exposure of fifty parts per million (50 ppm) of available chlorine at fifty-seven degrees Fahrenheit (57° F) when used as a circulating solution or an exposure of one hundred parts per million (100 ppm) available chlorine at fifty-seven degrees Fahrenheit (57° F) when used as a spray or fog. The tank cover shall not be opened after sanitizing:
- B. Tanks also used for the transport of dairy products must have the interior of the tank inspected with an ultraviolet lamp by the hauler each time water is to be transported. Tanks shall be rejected for use when odors or

contaminants are found. The dome cover shall be closed immediately after inspection;

- C. All hoses, connections and fittings shall be sanitized with a chemical solution equivalent in bactericidal action of a one (1) minute exposure of fifty parts per million (50 ppm) chlorine water solution by brushing solution on all exposed parts;
- D. A minimum chlorine residual of one-half parts per million (0.5 ppm) shall be maintained in the water being hauled;
- E. Tank trucks or tank trailers may be filled through the fitting on the inner-dome cover when the tailpipe cannot be used;
- F. Water quality in the tank, after twenty to thirty (20–30) gallons have been delivered into the tank, shall be checked as follows:
 - (I) Stop filling;
 - (II) Have discharge valve opened;
- (III) Inspect water as it discharges. If water has unpleasant odor or looks dirty, it shall be rejected for use; and
- (IV) When these checks indicate satisfactory water quality, proceed to fill the tank; and
- G. The dome cover and tank discharge valve cover shall be closed and sealed after filling to volume desired;
- H. When a fill connection is used, it shall be constructed in a manner to prevent contamination and shall be capped at all times when not in use; and
- I. Records, at a minimum, shall meet the following requirements:
- (I) Records shall be maintained and include the number of gallons delivered daily and cleansing and sanitizing methods used for tank truck and tank trailer interiors, riser, connections and hoses;
- (II) Records shall include date, time and location of delivery, concentration of chlorine residual and time of contact when applicable; and
- (III) The records shall be maintained for two (2) years and be available upon written or oral request by the Department of Health.
- (5) Approval of License. When the analysis of samples shows the beverages to be unadulterated and free from ingredients injurious to health and sanitation conditions are satisfied as described in subsections (5)(A) and (B) of this rule, the manufacturer, upon payment of license fee, will be issued a license authorizing the applicant to manufacture a nonintoxicating beverage or a soft drink. A license will be renewed annually upon the same terms and conditions as required for the original license. Licenses are not transferable and no refunds shall be made. If the business is sold,

the new owner shall obtain a new license to operate.

- (A) The buildings and equipment to be used by beverage manufacturers located in Missouri are found by the Department of Health to be in a sanitary condition as described in section (4) of this rule.
- (B) Out-of-state manufacturers shall provide a copy of a current license or permit from the regulatory authority of the state or country of origin to manufacture the beverage; a copy of a current inspection report indicating the manufacturer is approved for a license or permit by the regulatory authority of the state or country of origin and that application for a license or permit has been made and issuance of a license or permit is pending; or other documentation acceptable by the Department of Health may be provided when a license or permit is not yet available. If a license or permit is not required by the regulatory authority of the state or country of origin, the manufacturer shall provide the Department of Health a copy of a current inspection report indicating the manufacturer is in compliance with the standards of the regulatory authority. If no regulatory authority exists for the inspection of the manufacturer, the manufacturer shall provide either a copy of the most current inspection report from an independent third party acceptable to the Department of Health which indicates the manufacturer complies with the standards of the state or country of origin or a signed affidavit that the beverages were manufactured under sanitary conditions, are unadulterated and do not contain ingredients injurious to health.
- (6) Bacteria, Yeast and Mold Standards. All product-contact surfaces of nonreturnable containers shall be exposed to an adequate clean water rinse. Each size and flavor of beverage shall be sampled at least annually. The following bacteria, yeast and mold standards shall be used to determine the sanitary status of all containers and their contents:
- (A) No carbonated beverages, including carbonated natural and mineral waters, shall be sold, offered for sale or held in possession for sale in the state which contains a total bacterial count above one hundred (100) bacteria per milliliter as determined by the pour plate method using plate count agar, incubated at thirty-two degrees Centigrade (32° C) for seventy-two (72) hours; or a most probable number of coliforms which exceeds a count of two (2) per one hundred (100) milliliters as determined by the multiple-tube ferrmentation test method or which indicates the presence of coliforms as determined by the membrane filter method; or the yeast or

- mold count or a combination of yeast and mold count which exceeds ten (10) per milliliter;
- (B) No still beverage including nondairy fluid products used as a beverage, excluding bottled water, shall be sold, offered for sale or held in possession for sale in the state which contains a bacterial count in excess of one thousand (1,000) bacteria per milliliter; or a most probable number of coliforms which exceeds a count of two (2) per one hundred (100) milliliters as determined by the multiple-tube fermentation test method or which indicates the presence of coliforms as determined by the membrane filter method; or the yeast or mold count or a combination of yeast or mold count which exceeds ten (10) per milliliter;
- (C) No still, flat or uncarbonated bottled water shall be sold, offered for sale or held in possession for sale in the state: which contains a total bacterial count above twenty thousand (20,000) bacteria per milliliter as determined by the pour plate method using R2A agar, incubated at twenty-eight degrees Centigrade (28° C) for five (5) days or which contains a most probable number of coliforms which exceeds a count of two (2) per one hundred (100) milliliters as determined by the multiple-tube fermentation test method or which indicates the presence of coliforms as determined by the membrane filter method, presence-absence coliform method, minimal medium ONPG-MUG (MMO-MUG) method or any other analytical method approved by the U.S. EPA for the determination of coliform in drinking water; or which indicates the presence of Pseudomonas aeruginosa; or which contains a yeast or mold count or a combination of yeast or mold count which exceeds ten (10) per milliliter: and
- (D) Total bacteria counts by the rinse method shall not exceed two hundred fifty (250) bacteria per bottle for sanitized empty bottles. Sanitized equipment or premix containers should not exceed an estimated count of one hundred (100) bacteria per swabbed area of eight (8) square inches.
- (7) Chemical Quality Standards for Source Water for Bottled Water. Source water for bottled water shall meet standards of chemical quality as established by the United States FDA in 21 CFR 103.35 (1991) Standards of Quality for Bottled Water, except—
- (A) Samples for all chemical parameters shall be analyzed at least every three (3) years;
- (B) The total dissolved solids limitation and other standards for which the U.S. EPA

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has not established a primary drinking water standard shall not apply to mineral water; and

- (C) The level of lead shall not exceed fifteen thousandths milligrams per liter (0.015 mg/l).
- (8) Radiological Quality Standards for Source Water for Bottled Water. Source water for bottled water shall meet the standards of radiological quality as established by the United States FDA in 21 CFR 103.35 (1991) Standards of Quality for Bottled Water. Samples shall be analyzed at least every four (4) years. Instate sources of water may be exempted from these standards if they are located in areas unlikely to yield water excessive of the United States FDA standards. Sources will be exempted on an individual basis by the Department of Health after consultation with the Department of Natural Resources.
- (9) Routine Sampling of Beverages Including Bottled Waters. Manufacturers or their distributors shall send samples for microbiological quality standards either to the Department of Health laboratory or to an approved laboratory, as described in paragraph (9)(C)3. of this rule, with results of required analyses recorded and routinely forwarded to the Department of Health. Samples of source water or finished water for bottled water for chemical and radiological quality standards shall be sent to an approved laboratory, as described in paragraph (9)(C)3. of this rule, with results of required analyses recorded and routinely forwarded to the Department of Health.
- (A) Beverages shall be sampled at the minimum frequency and analyzed for the parameters described in sections (6)–(8) of this rule.
- (B) Samples for any parameter not specified in sections (6)–(8) of this rule shall be collected and analyzed as may be required by the Department of Health.
- (C) Sampling methods and analyses, at a minimum, shall meet the following requirements:
- 1. Source water samples for bulk water, bottled water or both shall be taken from each approved source;
- 2. Product samples shall be taken from a batch or segment of a continuous production run for each type of beverage produced in a day's production. The representative sample shall consist of a primary container of the beverage;
- 3. All beverage manufacturers and source water suppliers for bulk water, water bottled or both within Missouri shall submit microbiological samples either to the De-

partment of Health laboratory or to a laboratory meeting one (1) of the following criteria; and all chemical and radiological samples shall be sent to a laboratory meeting one (1) of the following criteria:

- A. A laboratory certified by the Department of Health for analyses required for beverages, bulk water or source water;
- B. A laboratory operated or approved the governmental regulatory agency having authority for beverage regulation or drinking water regulation or both in that state, province or country, provided their laboratory tests and procedures are acceptable to the Department of Health; or
- C. A laboratory operated by or approved by the United States FDA, the U.S. EPA or other appropriate federal agency, provided the laboratory tests and procedures are acceptable to the Department of Health; and
- 4. If a laboratory other than a Department of Health laboratory is used, each manufacturer or distributor must submit proof of certification approval or acceptance by an appropriate governmental agency concerning the ability to perform the designated analyses.

AUTHORITY: sections 192.005.2, 192.020 and 196.440, RSMo 1986.* This rule was previously filed as 13 CSR 50-74.010. Original rule entitled Missouri Department of Health E 7.19 filed on Sept. 28, 1967, effective Nov. 27, 1967. Amended: Filed April 11, 1975, effective June 12, 1975. Amended: Filed Nov. 26, 1980, effective April 11, 1981. Amended: Filed Nov. 26, 1991, effective July 1, 1992.

*Original authority: 192.005, RSMo 1985, amended 1993, 2011; 192.020, RSMo 1939, amended 1945, 1951, 2004; and 196.440, RSMo 1943.

19 CSR 20-1.060 Licensing of Beverage Manufacturers and Distributors and the Collection of Inspection Fees

(Rescinded October 30, 2005)

AUTHORITY: section 196.440, RSMo 1986. This rule was previously filed as 13 CSR 50-75.010. Original rule filed Nov. 1, 1961, effective Jan. 1, 1962. Amended: Filed June 2, 1982, effective Sept. 11, 1982. Rescinded: Filed April 15, 2005, effective Oct. 30, 2005.

19 CSR 20-1.070 Monitoring Animals for Presence of Diseases and Toxic Substances

Emergency rule filed March 19, 1986, effective March 29, 1986, expired July 12, 1986.

19 CSR 20-1.100 Seafood Hazard Analysis and Critical Control Points (HACCP)

PURPOSE: This rule establishes standards to determine whether the facilities, methods, practices, and controls used to process fish and fishery products are safe and that those products have been processed under sanitary conditions.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Applicability. The requirements of this rule apply to buildings or facilities, or parts thereof, used for or in connection with the processing of fish and fishery products.
- (2) Standards. Any person engaged in commercial, custom, or institutional processing of fish or fishery products shall operate in accordance with 21 CFR Part 123 Fish and Fishery Products, revised as of April 1, 2012, hereby incorporated by reference and made a part of this rule as published by the U.S. Government Printing Office, 732 North Capitol Street NW, Washington, DC 20401-0001, (202) 512-1800, http://bookstore.gpo.gov. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006 and 196.045, RSMo 2000, and section 192.020, RSMo Supp. 2012.* Original rule filed March 11, 2013, effective Sept. 30, 2013.

*Original authority: 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004; and 196.045, RSMo 1943, amended 1993, 1995.

19 CSR 20-1.200 Juice Hazard Analysis and Critical Control Points (HACCP)

PURPOSE: This rule establishes sanitation and Hazard Analysis and Critical Control Points (HACCP) standards for the processing of fruit and vegetable juices.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This



material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Applicability. The requirements of this rule apply to buildings or facilities, or parts thereof, used for or in connection with the processing of fruit and vegetable juices.
- (2) Standards. Manufacturers of any juice sold as such or used as an ingredient in beverages shall operate in accordance with 21 CFR Part 120 Hazard Analysis and Critical Control Point (HACCP) Systems, revised as of April 1, 2012, hereby incorporated by reference and made a part of this rule as published by the U.S. Government Printing Office, 732 North Capitol Street NW, Washington, DC 20401-0001, (202) 512-1800, http://bookstore.gpo.gov. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 192.006, 196.045, and 196.050, RSMo 2000, and section 192.020, RSMo Supp. 2012.* Original rule filed March 11, 2013, effective Sept. 30, 2013.

*Original authority: 192.006, RSMo 1993, amended 1995; 192.020, RSMo 1939, amended 1945, 1951, 2004; 196.045, RSMo 1943, amended 1993, 1995; and 196.050, RSMo 1943.