Rules of
Department of Health and Senior Services
Division 20—Division of Environmental Health and Communicable Disease Prevention
Chapter 1—Food Protection

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 20—Division of Environmental Health and Communicable Disease Prevention

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(Rescinded October 30, 1999)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 Rescinded and readopted: Filed Sept. 1, 1981, effective Dec. 11, 1981.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 Rescinded: Filed April 7, 1999, effective Oct. 30, 1999.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(Rescinded October 30, 1999)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 Rescinded: Filed April 7, 1999, effective Oct. 30, 1999.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 Sanitation of Food Establishments

PURPOSE: This rule establishes up-to-date sanitation standards for food-service establishments designated in Chapter 196, RSMo using the federal Food and Drug Administration 1999 Food Code.

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) General.

(A) The provisions of the *U.S. Department of Health and Human Services Public Health Service Food and Drug Administration 1999 Food Code*, U.S. Department of Commerce Technology Administration National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, shall apply and are incorporated by reference subject to the following additions, modifications, substitutions or deletions.

(B) Exceptions to the incorporation by reference are as follows:

1. Chapter 1-103.10 Statement. Delete: "This Code establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities, and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension." Substitute: "This Code establishes definitions, sets standards for management and personnel, food operations, equipment and facilities";

2. Chapter 1-201.10(B)(31)(a)(i) Delete: "Such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and" Substitute: "Such as a restaurant; central preparation facility; catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending (location) operation, if the operation provides potentially hazardous foods; conveyance used to transport people; institution; or food bank; and";

3. Chapter 1-201.10(B)(31)(b)(i) Delete: "An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and" Substitute: "An element of the operation such as a transportation vehicle or a satellite catered feeding location, a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and";

4. Chapter 1-201.10(B)(31)(c)(vi) Delete: "A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers food to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is not regulated and inspected by the regulatory authority; or" Substitute: "A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers food to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 4, breakfast is the only meal offered, the number of guests served does not exceed 12, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is not regulated and inspected by the regulatory authority; or";

5. Chapter 1-201.10(B)(31)(c)(viii) Add: "Where local codes allow, individual stands in which only foods meeting the following conditions are sold, sampled or served: (AA) Non-potentially hazardous processed foods, except low acid canned and acidified foods as specified in 21 CFR 113 and 114 respectively, including, but not limited to breads, cookies, fruit pies, jams, jellies, preserves, fruit butters, honey, sorghum, cracked nuts, packaged spices and spice mixes, dry cookie, cake, bread, and soup mixes; (BB) The seller is the individual actually producing the food or an immediate family member residing in the producer's household with extensive knowledge about the food; (CC) The seller only sells, samples or serves the food directly to the end consumer; (DD) All processed packaged foods bear a label stating the name and address of the manufacturer/processor preparing the food, common name of the food, name of all the ingredients in the food and a statement that the product is prepared in a kitchen that is not subject to inspection by the Department of Health and Senior Services. It is recommended that honey manufacturers/processors include this additional statement to its label, "Honey is not recommended for infants less than twelve (12) months of age"; and (EE) The consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to inspection by the Department of Health and Senior Services if the foods specified in Subparagraph 1-201.10(B)(31)(c)(viii)(AA) are sold, sampled or served in unpackaged individual portions. The Department of Health and Senior Services shall have the final authority in determining whether a food is non-potentially hazardous and may enjoin individuals who violate the provisions of this section from selling, sampling or serving these foods.";

6. Delete Chapter 1-201.10(B)(51) in its entirety;

7. Chapter 1-201.10(B)(52) Delete: "'Permit holder' means the entity that:

A. Is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person; and

B. Possesses a valid permit to operate a food establishment." Substitute: "'Operator' means the entity that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person";

8. Chapter 1-201.10(B)(63)(a) Delete the term "permit holder" and substitute "operator";

9. Chapter 1-201.10(B)(63)(b) Delete the term "permit holder" and substitute "operator";

10. Chapter 1-201.10(B)(93) Add: "'Vending operation' means a commercial operation that stores, prepares, packages, serves, vends or otherwise preserves food products for and in vending machines and may consist of one or more vending locations";

11. Chapter 1-201.10(B)(93) Modify "Warewashing" to "(94)";

12. Chapter 1-201.10(B)(94) Modify "Whole-muscle, intact beef" to "(95)";

13. Chapter 2-101.11 Delete the term "permit holder." Substitute: "operator";

14. Chapter 2-201.11 Delete the term "permit holder." Substitute "operator";

15. Delete Chapter 2-301.13 in its entirety;

16. Chapter 2-301.14 Add: "(I) Prior to use of gloves";

17. Chapter 2-302.11(B) Delete: "Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food." Substitute: "While preparing food, employees shall not wear artificial nails or fingernail polish";

18. Chapter 3-201.17 Add: "(C) Any political subdivision, elementary or secondary school or any charitable, religious, fraternal or other not-for-profit organization may prepare or serve wild game provided there is no charge for the wild game served as according to RSMo 252.244.";

19. Chapter 3-202.11(C) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

20. Chapter 3-304.12(F) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

21. Chapter 3-401.11(D)(3) Delete: "The regulatory authority grants a variance from ¶ (A) or (B) of this Chapter as specified in § 8-103.10 based on a HACCP plan that:" Substitute: "The regulatory authority grants a variance from ¶ (A) or (B) of this Chapter as based on a HACCP plan that:";

22. Chapter 3-401.11(D)(3)(a) Delete: "Is submitted by the permit holder and approved as specified under § 8-301.11," Substitute: "The regulatory authority grants a variance from ¶ (A) or (B) of this chapter as based on a HACCP plan that is submitted by the operator and approved by the regulatory authority."

23. Chapter 3-401.13 Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

24. Chapter 3-403.11(C) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

25. Chapter 3-501.14(A)(1) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

26. Chapter 3-501.16(A) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

27. Chapter 3-501.16(C)(2) Delete: "Within 5 years of the regulatory authority's adoption of this code, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less." Substitute: "Within 90 days of the adoption of this rule, all refrigeration equipment that is upgraded, replaced, or purchased must be able to maintain food temperatures of 41°F or below. If a refrigeration unit is found to be exceeding 45°F for 3 consecutive inspections, it shall be brought into compliance with 41°F or be replaced with a unit that is capable of maintaining product temperatures of 41°F or below";

28. Chapter 3-502.11 Variance Requirement. Delete: "A food establishment shall obtain a variance from the regulatory authority as specified in § 8-103.10 and under § 8-103.11 before smoking food as a method of food preservation rather than as a method of flavor enhancement; curing food; brewing alcoholic beverages; using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement or to render a food so that it is not potentially hazardous; packaging food using a reduced oxygen packaging method except as specified under § 3-502.12 where a barrier to Clostridium botulinum in addition to refrigeration exists; custom processing animals that are for personal use as food and not for sale or service in a food establishment; or preparing food by another method that is determined by the regulatory authority to require a variance." Substitute: "A food establishment shall obtain a variance from the regulatory authority before smoking food as a method of food preservation rather than as a method of flavor enhancement; curing food; brewing alcoholic beverages; using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement or to render a food so that it is not potentially hazardous; packaging food using a reduced oxygen packaging method except as specified under § 3-502.12 where a barrier to *Clostridium botulinum* in addition to refrigeration exists; custom processing animals that are for personal use as food and not for sale or service in a food establishment; or preparing food by another method that is determined by the regulatory authority to require a variance.";

29. Delete inserted page titled: "Current Status of Consumer Advisory Language" in its entirety;

30. Chapter 3-603.11 Delete: "Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(D), if animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended, or other item; or as a raw ingredient in another ready-to-eat food, the permit holder shall inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased risk associated with certain especially vulnerable consumers eating such foods in raw or undercooked form." Substitute: "If an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish that is raw, undercooked or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended, or other item; or as a raw ingredient in another ready-to-eat food, the operator shall inform or disclose to consumers that the product is raw, undercooked, or not otherwise processed to eliminate pathogens.";

31. Chapter 4-204.111(B)(2) Delete: "60°C (140°F):" Substitute: "57°C (135°F):":

32. Delete Chapter 4-204.19 in its entirety;

33. Chapter 4-204.110(B) Delete: "Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in § 8-103.10 and a HACCP plan that:" Substitute: "Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority and a HACCP plan that:";

34. Chapter 4-204.110(B)(1) Delete: "Is submitted by the permit holder and approved as specified under § 8-103.11; and" Substitute: "Is submitted by the operator and approved by the regulatory authority; and";

35. Delete Chapter 4-301.12(C)(5) in its entirety;

36. Delete "Chapter 4-301.12(C)(6)" Substitute: "Chapter 4-301.12(C)(5)";

37. Delete Chapter 4-301.12(D) and (E) in their entirety;

38. Chapter 4-602.11(D)(7) Delete: "60°C (140°F):" Substitute: "57°C (135°F):";

39. Delete Chapter 4-603.16(C) in its entirety;

40. Chapter 4-603.16(D)(2) Delete: "Wasted" Substitute: "Drained";

41. Chapter 5-103.12 Delete: "Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure." Substitute: "Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure if approved.";

42. Chapter 5-203.11(C) Delete: "If approved, when food exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing." Substitute: "If approved, when food exposure is limited to packaged food and handwashing lavatories are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes and/or approved hand sanitizers for handwashing.";

43. Delete Chapter 5-203.15 in its entirety;

44. Delete Chapter 5-205.13 in its entirety;

45. Chapter 6-202.13(B) Delete: "Insect control devices shall be installed so that:" Substitute: "All other insect control devices shall be installed so that:";

46. Chapter 6-202.17 Delete: "If located outside, a machine used to vend food shall be provided with overhead protection except that machines vending canned beverages need not meet this requirement." Substitute: "If located outside, a machine used to vend food shall be provided with overhead protection except that machines designed for outdoor use need not meet this requirement.";

47. Chapter 6-404.11 Delete the term "permit holder" and Substitute "operator";

48. Delete Chapter 8 in its entirety;

49. Delete Annexes 1–7 in their entirety; and

50. Chapter 3-502.12(B) Delete: "A food establishment that packages food using a reduced oxygen packaging method and Clostridium Botulinum is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under ¶ 8-201.14(D) and that:" Substitute: "A food establishment that packages food using a reduced oxygen packaging method and *Clostridium Botulinum* is identified as a microbiological hazard in the final packaged form shall have a HACCP plan submitted by the operator and approved by the regulatory authority and that:".

AUTHORITY: sections 192.006, 196.190, 196.195, 196.210, 196.220, 196.225, 196.230, 196.235, 196.240, 196.245, 196.250 and 196.265, RSMo 2000 and 192.020, RSMo Supp. 2004. Original rule filed April 26, 1999, effective Oct. 30, 1999. Amended: Filed March 1, 2005, effective Sept. 30, 2005.*

**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, amended 1977; 196.230, RSMo 1939; 196.235, RSMo 1939; 196.240, RSMo 1939; 196.245, RSMo 1939; 196.250, RSMo 1939; and 196.265, 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 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.

AUTHORITY: section 196.872, RSMo 1986. This rule was previously filed as 13 CSR 50-63.0l0. Original rule filed June 27, 1980, effective Oct. l1, 1980. Amended: Filed June 27, 1983, effective Nov. l1, 1983. Amended: Filed May 2, 1986, effective July 26, 1986.*

**Original authority: 196.872, RSMo 1980.*

19 CSR 20-1.040 Inspection of the Manuacture and Sale of Foods

PURPOSE: This rule establishes food labeling and sanitation standards of public health significance which are conducive to good manufacturing practices and techniques.

(1) Labeling is to include all written, printed or graphic matter accompanying a food at any time while it is in interstate or intrastate shipment or while it is held for sale after shipment.

(2) When there is a difference of opinion among experts qualified by scientific training and experience as to the truth of anything stated or implied on the labels of a food product, the label will be considered misleading unless it reveals all pertinent information except where there is material weight of opinion contrary to it.

(3) In the case of the giving of a guaranty or undertaking referred to in section 196.015(7), RSMo (1986), each person signing a guaranty, or undertaking shall be considered to have given it.

(A) A guaranty or undertaking referred to in section 196.015(7), RSMo (1986) may be—

1. Limited to a specific shipment or other delivery of an article which may be a part of or attached to the invoice or bill of sale covering the shipment or delivery; or

2. General and continuing, applying to any shipment or other delivery or an article and shall be considered to have been given at the date the article was shipped or delivered by the person who gives the guaranty or undertaking.

(B) The following are suggested forms of guaranty or undertaking under section 196.015(7), RSMo (1986):

1. Limited form for use on invoice or bill of sale (name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of this rule or is an article which may not be introduced into commerce under the provisions of section 196.080 or 196.105, RSMo (1986) (signature and post-office address of person giving the guaranty or undertaking); and

2. General and continuing form. The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to or on the order (name and post office address of person to whom the guaranty or undertaking is given) is guaranteed as of the date of the shipment or delivery not to be adulterated or misbranded within the meaning of this rule and not an article, which under the provisions of section 196.080 or 196.105, RSMo (1986), may not be introduced into commerce (signature and post office address of person giving the guaranty or undertaking).

(C) The application of a guaranty or undertaking referred to in section 196.015, RSMo (1986) to any shipment or other delivery of an article shall expire when the article after shipment or delivery by the person who gave the guaranty or undertaking, becomes adulterated or misbranded within the meaning of this rule or becomes an article which may not be introduced into commerce under the provisions of section 196.080 or 196.105, RSMo (1986).

(D) A guaranty or undertaking, if signed by two (2) or more persons, shall state that each of the persons separately guarantees the article to which it applies.

(E) No statement or suggestion that an article is guaranteed under this rule shall be used on labels.

(4) In collection of samples for examination—

(A) The term examination as applied to samples collected includes analyses, tests or other examinations;

(B) When a sample of a food is collected, the owner is the person who owns the shipment or other lot of the article from which the sample is collected;

(C) When an officer or employee of the department collects a sample of a food for examination under this rule, s/he shall collect at least twice the quantity estimated by him/her to be sufficient for examination, unless—

1. The amount of the food available and reasonably accessible for sampling is less than twice the quantity so estimated;

2. The cost of twice the quantity so estimated exceeds ten dollars ($10);

3. The article is perishable;

4. The sample is collected from a person named on the label of the article or his/her agent and the person is also owner of the article;

5. The sample is collected from the owner of the article or his/her agent and the article bears no label or if it bears a label, no person is named on the label; or

6. The examination consists principally of rapid analytical procedures, taste examination or other field examinations or tests made at the place where the sample is collected or in a mobile or temporary laboratory;

(D) In addition to the quantity of sample needed in subsection (4)(C) of this rule, the officer or employee, if practicable, shall collect an additional amount of the article needed for use as exhibits in the trial of any case that may arise under this rule;

(E) After the Department of Health has completed an adequate examination of a sample of food and finds the article is adulterated or misbranded within the meaning of this rule or is otherwise subject to the prohibitions of this rule; and after reserving an amount of the article the department estimates to be adequate for use as exhibits in the trial of any case that may arise under this rule based on the sample, a part of the sample—if any remains available—shall be provided for analysis upon written request by any person on the label of the article, its owner, or the attorney or agent of the person or owner, except when—

1. After collection, the sample or remaining part has become decomposed or otherwise unfit for examination; or

2. The request is not made within a reasonable time before the trial of any case under the rule, based on the sample, to which the person or owner is a party; and

(F) The Department of Health is authorized to destroy—

1. Any sample when it determines that no examination of the sample will be made;

2. Any sample or part of it when the department determines that no notice under section 196.040, RSMo (1986) is or will be based on the sample;

3. Any sample or part of it when the sample was the basis of a notice under section 196.040, RSMo (1986) and when, after opportunity for presentation of views following the notice, the department determines that no other notice and no case under the RSMo (1986) is or will be based on the samples;

4. Any sample or part of it, when the sample was the basis of a case under section 196.070 or 196.075, RSMo (1986) which has gone to final judgment and when the department determines that no other case is or will be based on the sample;

5. Any sample or part of it if the article is perishable; or

6. Any sample or part of it when, after collection, the sample or part of it has become decomposed or otherwise unfit for examination.

(5) A food is considered misbranded when—

(A) A statement is false or misleading with respect to another food; or

(B) The label of the food states a name which includes or suggests the name of one (1) or more but not all of the ingredients, even though the names of all the ingredients are stated elsewhere on the label.

(6) Packaged Food Label Requirements.

(A) If a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection the person has with the food, such as "Manufactured for and packed by. . .", "Distributed by. . ." or a similar phrase which expresses the facts.

(B) The statement of the place of business shall include the street address, if any, unless the street address is shown in a current city directory or telephone directory.

(C) When a person manufactures, packs or distributes a food at a place other than his/her principal place of business, the label may state the principal place of business instead of the actual place where each package of the food was manufactured or packed or is to be distributed, if the statement is not misleading in any particular.

(D) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(E) The statement of the quantity of the content on a label shall—

1. Reveal the quantity of the food in the package, exclusive of wrappers and other material packed with the food; and

2. Be expressed in terms of weight, measure, numerical count or a combination of numerical count and weight or measure generally used by consumers to express quantity of the food and which give accurate information as to the quantity. If no general consumer usage exists to express accurate information as to the quantity of the food, the statement shall be in terms of liquid measure if the food is liquid or in terms of weight if the food is solid, semisolid, viscous or a mixture of solid and liquid.

(F) Statements of weights and measures on labels shall—

1. Be in terms of the avoirdupois pound and ounce for solids. Liquid measure shall be stated in terms of the United States gallon of two hundred thirty-one (231) cubic inches and quart, pint and fluid ounce subdivisions and except in case of frozen food which is so consumed shall state the volume at sixty-eight degrees Fahrenheit (68° F) or twenty degrees Celsius (20° C). A statement of dry measure shall be in terms of the United States bushel of two thousand one hundred fifty and forty-two hundredths (2150.42) cubic inches and peck, dry quart and dry pint subdivisions; or in terms of the United States standard barrel and its subdivisions of one-third (1/3), one-half (1/2) and three-fourths (3/4) barrel. In an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which the shipment is exported;

2. Be in terms specified in paragraph (6)(F)1. of this rule and may be supplemented by a statement in terms of the metric system;

3. Be supplemented by a statement of weight, measure or size of the individual units of the food unless an unqualified statement of numerical count gives accurate information on the quantity of food in the package;

4. Use only fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two (2) places; and

5. Express the number of the largest unit contained in the package except as provided in paragraph (6)(F)1. of this rule. (For example, the statement on the label of a package which contains one (1) quart of food shall be "1 quart" and not "2 pints" or "32 fluid ounces".) When the statement is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller unit is specified in paragraphs (6)(F)1.–4. of this rule. (For example, 1 3/4 quarts may be expressed as "1 quart 1 1/2 pints" or "1 quart 1 pint 8 fluid ounces".) The stated number of any unit which is smaller than the largest unit contained in the package shall not equal or exceed the number of the smaller units in the next larger unit. (For example, instead of "1 quart 16 fluid ounces" the statement shall be "1 1/2 quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1 1/2 pounds" or "1 pound 8 ounces".)

A. When there exists an established custom of stating the quantity of the contents of a food as a fraction of a unit which is larger than the quantity contained in the package or as units smaller than the largest unit in it, the statement may be made in accordance with the custom if it is informative to the consumer.

B. The statement shall express the minimum quantity or the average quantity of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to mean the average quantity.

(G) In a statement that expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure after the food is received from commerce or introduced into commerce to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(H) When the statement does not express minimum quantity—

1. Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure after the food is introduced into commerce to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

2. Variations from the stated weight, measure or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring or counting individual packages which occur in good packing practice; or

3. Under paragraph (6)(H)2. of this rule, variations shall not be permitted to the extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated and no unreasonable shortage in any package shall be permitted even though overages in other packages in the same shipment or delivery compensate for the shortage.

(I) The extent of variations from the stated quantity of the contents permissible under subsections (6)(G) and (H) of this rule shall be determined by the facts in the case of each shipment or other delivery.

(J) A food shall be exempt from compliance with the requirements of section 196.075(5)(b), RSMo (1986) if—

1. The quantity of the contents as expressed in terms applicable to the food under the provisions of paragraph (6)(E)2. of this rule, is less than one-half (1/2) ounce avoirdupois; or less than one-half (1/2) fluid ounce; or in packages where the units of the food can be easily counted without opening the package, less than six (6) units; or

2. The statement on the label of the quantity of the contents of the package, together with all other words, statements and information required by or under authority of this rule, because of insufficient label space, cannot be so placed on the label as to comply with the requirements of section 196.075(6), RSMo (1986) and the corresponding rules.

(7) Prominence and Conspicuousness of Labels.

(A) A word, statement or other information to appear on the label may lack that prominence and conspicuousness required by section 196.075(6), RSMo (1986) because of—

1. The failure of a word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

2. The failure of a word, statement or information to appear on two (2) or more parts or panels of the label, each of which has sufficient space and is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

3. The failure of the label to extend over the area of the container of package available for the extension, so as to provide sufficient label space for the prominent placing of the word, statement or information;

4. Insufficient label space for the prominent placing of the word, statement or information resulting from the use of label space for any word, statement, design or device which is not required to appear on the label;

5. Insufficient label space for the prominent placing of a word, statement or information resulting from the use of label space to give greater conspicuousness to any other word, statement or information or to any design or device; or

6. Smallness or style of type in which a word, statement or information appears; insufficient background contrast; obscuring designs or vignettes; or crowding with other written, printed or graphic matter.

(B) No exemption depending on insufficiency of label space as prescribed in rules promulgated under section 196.075(5) or (9), RSMo (1986) shall apply if the insufficiency is caused by the use of label space—

1. For any word, statement, design or device which is not required to appear on the label;

2. To give greater conspicuousness to any word, statement or other information that is required by section 196.075(6), RSMo (1986); or

3. For any representation in a foreign language.

(C) All words, statements and other information required to appear on the label shall appear in the English language. If the label(ing) contains any information in a foreign language, all words, statements and other information required to appear on the label shall appear in the foreign language.

(8) Possible Misleading Ingredient Designations on Labels.

(A) No ingredient shall be designated on the label as a spice, flavoring or coloring unless it is a spice, flavoring or coloring within the meaning of the term as commonly understood by consumers. The term coloring shall not include any bleaching substance.

(B) An ingredient which is both a spice and a coloring or both a flavoring and a coloring shall be designated as spice and coloring or flavoring and coloring, unless the ingredient is designated by its specific name.

(C) A label may be misleading for the following reasons:

1. The order in which the names of ingredients appear on the label or the relative prominence otherwise given those names; or

2. It fails to reveal the proportion of an ingredient or another fact about it when the proportion or other fact about the ingredient was used in fabricating the food.

(9) Label Exemptions.

(A) A food shall be exempt from the requirements of section 196.075(9)(b), RSMo (1986) if all words, statements and other information required to appear on the label of the food cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 196.075(6), RSMo (1986). The exemption shall be on the condition that, if omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly all the information required, the statement of the quantity of the contents shall be omitted as authorized under section 196.075(5)(b), RSMo (1986) and the information required by it shall be stated as prominently as practicable even though the statement is not of the conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(B) In an assortment of different items of food packaged together with variations in the ingredients in different packages, these foods shall be exempt from compliance with the requirements of section 196.075(9)(b), RSMo (1986) with respect to any ingredient which is not common to all packages. The exemption shall be on the condition that the label shall bear, in conjunction with the names of the ingredients common to all packages, a statement in terms as informative as practicable and which is not misleading and which indicates that other ingredients may be present.

(C) An open container of a fresh fruit or fresh vegetable of a quantity not more than one (1) dry quart shall be exempt from the labeling requirements of sections 196.075(5) and (7), RSMo (1986) with respect to the name of the food specified in the definition and standard and section 196.075(9)(a), RSMo (1986); but the exemption shall be on the condition that if two (2) or more containers are enclosed in a crate or other shipping package, the crate or package shall bear labeling showing the number of containers enclosed and the quantity of the contents of each. An open container is a container of rigid or semirigid construction not closed by lid, wrapper or otherwise.

(D) Except as provided by subsections (9)(E) and (G) of this rule, a shipment or other delivery of a food which is to be processed, labeled or repacked in substantial quantity at an establishment other than that where originally processed or packed, during the time of introduction into and movement in commerce and the time of holding in an establishment shall exempt from compliance with the labeling requirements of section 196.075(3), (5), (7), (8)(a) and (b), (10) and (11) RSMo (1986), if—

1. The person who introduced the shipment or delivery into commerce is the operator of the establishment where the food is to be processed, labeled or repacked; or

2. The person is not the operator, the shipment or delivery is made to the establishment under a written agreement, signed by and containing the post office addresses of the person and the operator, and containing the specifications for the processing, labeling or repacking as the case may be of a food in the establishment as will insure, if the specifications are followed that a food will not be adulterated or misbranded within the meaning of the rule, upon completion of the processing, labeling or repacking. The person and the operator shall keep a copy of each agreement until all the shipment or delivery

has been removed from the establishment and shall make the copies available for inspection at any reasonable hour to any officer or employee of the department who requests them.

(E) An exemption of a shipment or other delivery of a food under subsection (9)(D) of this rule shall become void *ab initio* at the beginning of the act of removing from the establishment the shipment or delivery or any part of it if the food comprising the shipment, delivery or part is adulterated or misbranded when removed.

(F) An exemption of a shipment or other delivery of a food under paragraph (9)(D)2. of this rule shall become void *ab initio* with respect to the person who introduced the shipment or delivery into commerce upon refusal by the person to make available for inspection a copy of the agreement.

(G) An exemption of a shipment or other delivery of a food under paragraph (9)(D)2. of this rule shall expire—

1. At the beginning of the act of removing the shipment or delivery or any part of it from the establishment if the food comprising a shipment, delivery or part is adulterated or misbranded when so removed; or

2. Upon refusal by the operator of the establishment where the food is to be processed, labeled or repacked to make available for inspection a copy of the agreement.

AUTHORITY: section 196.045, RSMo 1986. 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.*

**Original authority: 196.045, RSMo 1943.*

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.

1. 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 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°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 soaker-type 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 noncaustic cleanser method as described in this section.

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 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 Department 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; 192.020, RSMo 1939, amended 1945, 1951; and 196.440, RSMo 1943.*

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

PURPOSE: This rule defines requirements for licensing of manufacturers and collecting nonintoxicating beverage inspection fees.

(1) The following definitions shall apply in the interpretation and the enforcement of this rule:

(A) A nonintoxicating beverage is any soft drink or beverage, excepting malt beverages, as used in section 196.365, RSMo (1986);

(B) Manufacturer is any person who formulates, mixes or packages a nonintoxicating beverage for sale;

(C) A distributor is any person who purchases nonintoxicating beverages from a manufacturer for further distribution through wholesale accounts or any person who contracts with one (1) or more manufacturers to bottle or can private-label beverages for distribution. A distributor of products of a licensed manufacturer of franchised brands is a person who delivers nonintoxicating beverages in a designated territory and shall be exempt from licensure requirements; and

(D) Inspection fees are moneys for sanitation inspection of the manufacturing or warehouse facilities, label review and laboratory analysis of nonintoxicating beverage products, paid by either the manufacturer or distributor as determined by contractual agreement.

(2) Every wholesale manufacturer or distributor of nonintoxicating beverages shall pay inspection fees based on the gallonage of beverage produced, shipped or sold or on a rated capacity of filling machines. Fees shall be paid to the Department of Health as provided by section 196.375, RSMo (1986).

(3) Every dealer in nonintoxicating beverages when listed as a manufacturer or distributor with the county assessor of the county in which the place of business, warehouse, factory or other establishment is located as required in section 150.050, RSMo (1986) shall apply for and obtain a beverage manufacturer's or distributor's license from the Department of Health. Failure to hold a valid license shall not excuse any manufacturer or distributor of nonintoxicating beverages from payment of inspection fees on nonintoxicating beverages shipped or sold during the period of nonconformance with state licensing requirements.

(4) Every manufacturer or distributor of nonintoxicating beverages shall report monthly to the Department of Health—unless the Department of Health agrees to a quarterly report—those quantities of nonintoxicating beverages shipped or sold in Missouri. Reports shall be considered delinquent if not received by the tenth day of the month following the reporting period.

(5) When billed by the Department of Health every manufacturer or distributor of nonintoxicating beverages shall pay the beverage inspection fees established by law to the Department of Health as agent for the Department of Revenue. The Department of Health or the state auditor may audit records of sales for the purpose of determining complete reporting of all sales subject to the nonintoxicating beverage inspection fees.

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.*

**Original authority: 196.440, RSMo 1943.*

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.