

PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

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SECTION I. AUTHORITY

The following Rules and Regulations Pertaining to the Processing and Bottling of Bottled Drinking Water are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the Laws of the State of Arkansas including, without limitation, Act 96 of 1913 (Ark. Code Ann. § 20-7-109).

SECTION II. PURPOSE

To protect the health of the citizens of Arkansas by establishing acceptable criteria for the processing and bottling of bottled drinking water.

SECTION III. DEFINITIONS

For the purposes of these Regulations, the following terms are defined:

- A. "Approved Laboratory" means a laboratory approved by the Arkansas Department of Health.
- B. "Approved source" means any source of water, whether it be a spring, artesian well, drilled well, municipal water system, or other source, and any water treatment devices or systems, that have been inspected and found to be in compliance with the applicable portions of the "Rules and Regulations Pertaining to Public Water Systems", and any other relevant regulations and laws of the State of Arkansas. The presence in the plant of current certificates or notifications of approval from the Arkansas Department of Health constitutes evidence that the source has been approved.
- C. "Artesian Water" means bottled water from a well tapping a confined aquifer in which the water level stands above the water table. "Artesian Water" shall meet the requirements of "Natural Water".

D. "Bottled drinking water" means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

E. "Bottled Water Plant" or "Plant" means any place or establishment in which bottled water is prepared for sale.

F. "Carbonated Water" or "Sparkling Water" means bottled water containing carbon dioxide.

G. "Distilled Water" means bottled water which has been produced by a process of distillation and meets the definition of purified water in the most recent edition of the United States Pharmacopeia.

H. "Drinking Water" means bottled water obtained from an approved source that has at minimum undergone treatment consisting of filtration (activated carbon or particulate) and ozonation or an equivalent disinfection process.

I. "Fluoridated Water" means bottled water containing fluoride. The label shall specify whether the fluoride is naturally occurring or added. Any water which meets the definition of this paragraph shall contain not less than 0.8 milligrams per liter fluoride ion and otherwise comply with the Food and Drug Administration (FDA) quality standards in Section 103.35 (d)(2) of Title 21 of the Code of Federal Regulations (CFR).

J. "Lot" means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

K. "Mineral Water" means bottled water coming from an approved source tapped at one or more boreholes or natural springs, originating from a geologically and physically protected underground water source. Mineral water shall be clearly distinguishable from other types of water by its specific content of minerals and trace elements which in the original state at the point of emergence remain constant. The total dissolved solids (TDS) of natural mineral water shall appear on a label of the bottle and be stated in milligrams per liter.

L. "Multiservice containers" means containers intended for use more than one time.

M. "Natural Water" means bottled spring, mineral, artesian or well water which is derived from an underground formation and is not derived from a municipal system or public water supply.

N. "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

O. "Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

P. "Plant Operator" means any person who owns or operates a bottled water plant.

Q. "Primary container" means the immediate container in which the product water is packaged.

R. "Product water" means processed water used by a plant for bottled drinking water.

S. "Purified Water" means bottled water produced by distillation, deionization, reverse osmosis or other suitable process and that meets the definition of purified water in the most recent edition of the United States Pharmacopoeia. Water which meets the definition of this paragraph and is vaporized, then condensed, may be labeled "distilled water".

T. "Shipping case" means a container in which one or more primary containers of the product are held.

U. "Single-service container" means a container intended for one-time use only.

V. "Spring Water" means water derived from an underground formation from which water flows naturally to the surface of the earth. "Spring Water" shall meet the requirements of "Natural Water".

W. "Unit Package" means a standard commercial package of bottled drinking water, which may consist of one or more containers.

X. "Water Dealer" means any person who imports bottled water or causes bulk water to be transported for bottling for human consumption or other consumer uses.

Y. "Well Water" means water from a hole bored, drilled or otherwise constructed in the ground which taps the water of an aquifer. Well water shall meet the requirements of natural water.

SECTION IV. LABELING

All bottled water produced or offered for sale within the State of Arkansas shall be labeled in accordance with the Arkansas Food, Drug and Cosmetic Act (Ark. Code Ann. § 20-56-201, et seq.), the Federal Fair Packaging and Labeling Act, as amended, and the U.S. Food, Drug and Cosmetic Act, as amended.

SECTION V. BUILDING AND FACILITIES.

A. Plan Review

Prior to beginning construction or extensive remodeling, plans for proposed water bottling plants must first be submitted to the Plan Review Section of the Division of Sanitarian Services for review and approval. A pre-opening inspection must be conducted by the County Sanitarian to assure that construction has been accomplished in accordance with approved plans.

B. Plant Construction and Design

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas. Light fixtures in these rooms shall be shielded or shatterproof.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room. Washing and sanitizing facilities shall include hot and cold water under pressure and, where necessary, a two-compartment sink.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

(f) Walls and ceilings in bottling rooms, utensil washing rooms, toilet rooms and storage rooms shall be smooth, easily cleanable, non-absorbent and light-colored. Floors in these areas must be smooth and non-absorbent.

(g) On-site toilet facilities must be provided for employees. Toilet room doors must be self-closing, and toilet rooms must be provided with mechanical ventilation to the outside. Toilet facilities must be kept clean and in good repair.

(h) Handwashing facilities, including hot and cold water under pressure, soap, and approved sanitary towels, must be provided in all production rooms and toilet rooms.

(i) All plumbing shall be installed in accordance with the Arkansas State Plumbing Code.

C. Sewage

(a) All water-carried sewage shall be disposed of by means of:

(1) A public sewerage system; or,

(2) An approved sewage disposal system which is constructed and operated in conformance with the standards established for such systems by the Arkansas Department of Health.

(b) Non-water carried sewage disposal facilities shall not be used except where water-carried disposal methods have been determined by the Health Authority to be impractical. Under such conditions, only facilities which have been approved by the Health Authority shall be used, and operation of these facilities shall be in conformance with the Rules and Regulations of the Arkansas State Board of Health Pertaining to General Sanitation.

D. Sanitary Facilities

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) Product water and operations water

(1) The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in compliance at all times with the "Rules and Regulations Pertaining to Public Water Systems" and the applicable portions of the National Primary Drinking Water Standards.

(2) Operations water. If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in compliance at all times with the "Rules and Regulations Pertaining to Public Water Systems" and the applicable portions of the National Primary Drinking Water Standards.

(3) Product water and operations water from approved sources. Samples of water are to be taken and analyzed in accordance with the monitoring and analytical requirements for Non-Transient Non-Community Public Water Systems, as prescribed in the National Primary Drinking Water Standards. Records of approval of the source water by the Arkansas Department of Health and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.

(b) Air under pressure. Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

(c) Locker and breakrooms. When employee locker and breakrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

E. Sanitary Operations.

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water. Bottles must be automatically filled and capped without the caps of bottles coming in contact with the hands of the operator, or the above operations performed in a manner that meets the approval of the Arkansas Department of Health.

SECTION VI. PERSONNEL

A. Employee Health

No person while infected with a disease in a communicable form that can be transmitted by water or who is a carrier of organisms that cause such disease or while afflicted with a boil, an infected wound, or an acute respiratory infection, shall work in a water bottling plant in any capacity in which there is any likelihood of such person contaminating water or water-contact surfaces with pathogenic organisms or transmitting diseases to other persons.

B. Personal Cleanliness

Employees shall thoroughly wash their hands and the exposed portions of their arms with soap and warm water before starting work, during work as often as is necessary to keep them clean and after smoking, eating, drinking, or using the toilet. Employees shall keep their fingernails clean and trimmed.

C. Clothing

(a) The outer clothing of all employees shall be clean.

(b) Employees shall use effective hair restraints to prevent the contamination of water or water-contact surfaces.

D. Employee Practices.

(a) Employees shall not use tobacco in any form while engaged in water processing or bottling, nor while in areas used for equipment or container washing. Employees shall use tobacco only in designated areas. An employee tobacco use area shall not be designated for that purpose if the use of tobacco there may result in contamination of water, equipment, containers, or other items needing protection.

(b) Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during all working periods in the water bottling plant.

SECTION VII. EQUIPMENT

A. Equipment and Procedures.

(a) Suitability.

(1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water. In order to minimize the potential for microbiological contamination of the finished product, noncarbonated bottled water shall not be transported, stored, processed or bottled in or through lines or equipment through which has passed milk, fruit juice or other food products likely to contribute nutrients for microbial growth.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbent material which can be adequately cleaned and sanitized.

(b) Design. Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

SECTION VIII. PRODUCTION AND PROCESS CONTROLS

A. Processes and Controls.

(a) Treatment of product water. All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the Arkansas Department of Health. All water treatment devices and chemicals shall be certified as meeting ANSI/NSF Standards 60 and 61, as appropriate, in accordance with the "Rules and Regulations Pertaining to Public Water Systems".

(b) Containers.

(1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results.

Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the bottled water plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) Cleaning and sanitizing solutions. Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) Sanitizing operations. Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170 degrees Fahrenheit for at least 15 minutes or at least 200 degrees Fahrenheit for at least 5 minutes.

(2) Hot water in enclosed system: At least 170 degrees Fahrenheit for at least 15 minutes or at least 200 degrees Fahrenheit for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57 degrees Fahrenheit when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57 degrees Fahrenheit or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) Sanitizers shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.

(e) Unit package production code. Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

(f) Filling, capping, or sealing.

(1) During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used.

(2) Sampling: All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab or rinse count or both should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the Arkansas Department of Health. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

(g) Compliance procedures. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws and regulations of the Arkansas Department of Health, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.

(2) Analyze such samples by methods approved by the Arkansas Department of Health. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) Record retention. All records required shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the Arkansas Department of Health approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times. All records relating to water quality shall be retained in accordance with the requirements of the National Primary Drinking Water Standards.

(i) Recall procedure. Each bottled water plant operator shall develop and maintain procedures for the notification of the Department, consumer notification and product recall and shall implement any said procedure as necessary with respect to any product for which the operator or Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. In order to facilitate product identification or recall, each bottled water product shall contain a code that is designed to remain affixed to the container during use and which contains the date of manufacture and the batch or segment number.

SECTION IX. PERMITS

A. In-State Bottled Water Plants.

No bottled water plant shall be allowed to operate unless it has procured a food establishment permit from the Division of Environmental Health Protection of the Department of Health. Any bottled water plant may obtain a permit by paying an annual permit fee as prescribed by law to the Department of Health and by meeting the requirements established by these regulations.

B. Out-of-State Bottled Water Plants.

Any bottler of water that is not a resident of Arkansas shall obtain a permit from the Division of Environmental Health Protection of the Department of Health in order to sell its bottled water in Arkansas. The bottler shall submit to the department annually a bacteriological analysis conducted by a laboratory approved by the Department, a certificate of operation from the bottler's resident

state and the appropriate permit fee as prescribed by law. The certificate of operation from the bottler's country or state of origin shall include evidence of compliance with the Non-Transient Non-Community portions of the National Drinking Water Standards.

SECTION X. PENALTIES

Penalties for violations of these Rules and Regulations may be imposed as provided in (Ark. Code Ann. § 20-7-101).

SECTION XI. REPEAL

All regulations in conflict herewith are hereby repealed.

SECTION XII. CERTIFICATION

This will certify that the foregoing Rules and Regulations Pertaining to the Processing and Bottling of Bottled Drinking Water were adopted by the Arkansas Board of Health at a regular executive session of said held in Little Rock, Arkansas, on the 23rd day of January, 1992.

M. Joycelyn Elders, M.D.

Secretary, State Board of Health

Director, Arkansas Department of Health

Dated at Little Rock, Arkansas, on the 23rd day of January, 1992.

The foregoing Rules and Regulations, copy having been filed in my office, are hereby approved this day 8th day of February, 1992.

Bill Clinton

Governor