

CHAPTER 225. BOTTLED DRINKING WATER REGULATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

310:225-1-1. Purpose

The rules in this Chapter implement the Bottled Drinking Water Regulations, 63 O.S. 1981, Section 1-1915 et seq. and 1-1101 et seq.

310:225-1-2. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Approved laboratory" means a laboratory approved by the Commissioner of Health or certified by the U.S. Environmental Protection Agency ("EPA"), or certified (accredited) by a third-party organization acceptable to the Commissioner of Health.

"Approved source" when used in reference to a bottled water plant's product water or water used in the plant's operations, means the source of the water whether it be from a spring, artesian well, drilled well, public water system or any other source that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality. Bottled water covered by these rules and regulations must be from a source which is permitted in accordance with the design standards for public water supply facilities.

"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".

"Bottled water" means water that is placed in a sealed container or package and is offered for sale for human consumption or other consumer uses.

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

"Carbonated water" or "sparkling water" means bottled water containing carbon dioxide.

"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.

"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.

"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 no 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 ("C.F.R.").

"Mineral water" means bottled water that contains not less than 500 parts per million total dissolved solids. "Natural Mineral Water" shall meet the requirements of "Natural Water".

"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.

"Plant operator" means any person who owns or operates bottled water plant.

"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 Pharmacopeia. Water which meets the definition of this paragraph and is vaporized, then condensed, may be labeled "distilled water".

"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".

"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.

"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 requirement of "Natural Water".

310:225-1-3. Soda water/soft drink exemptions

Bottled, soft drinks, soda or seltzer or other products commonly recognized as soft drinks and labeled with a common or usual name other than one of those specified in Section 310:225-1-2 are exempt from the requirements of these regulations. Water that is not in compliance with the requirements of these regulations may not be labeled as "Artesian Water", "Natural Water", "Bottled Water", "Distilled Water", "Drinking Water", "Fluoridated Water", "Mineral Water", "Purified Water", "Spring Water", or "Well Water".

310:225-1-4. Severability

If any provision or application of any provision of the rules of this Chapter is held invalid, that invalidity shall not affect other provisions or applications of these rules.

SUBCHAPTER 3. PRODUCT QUALITY

310:225-3-1. Source approval

All bottled water shall be from an approved source and shall not contain any constituent in quantities that may be injurious to health, as established through rulemaking by the Oklahoma State

Department of Health. All bottled water shall meet the standards prescribed by the FDA in 21 C.F.R. Section 103.35, except that the total dissolved solids limitation of Section 103.35(d) shall not apply to mineral water.

310:225-3-2. Maximum contaminant level

Except as provided in Section 310:225-3-1, bottled water, including mineral water, shall not exceed any Maximum Contaminant Level ("MCL") established by EPA under the Safe Drinking Water Act if adopted by FDA or by the State Board of Health for any organic or inorganic chemicals.

**SUBCHAPTER 5. GOOD MANUFACTURING PRACTICES
AND OPERATIONAL REQUIREMENTS**

310:225-5-1. Process standards

All bottled water, including mineral water, shall be filtered or processed and packaged in accordance with, and in facilities which comply with, the FDA Good Manufacturing Practice Regulations ("GMPs") 21 C.F.R. Parts 110 and 129.

310:225-5-2. Microbiological control standards

Bottled water production, including transporting, processing, packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination of the finished product. These conditions shall include the following:

(1) Bottled water shall be subject to effective germicidal treatment by ozonation or carbonation at a minimum of three volumes of carbon dioxide or other equivalent disinfection;

(2) Bottled water shall not be transported or stored in bulk tanks or

310:225-5-3. Multi-food equipment

(a) For optimum consumer protection, in order to minimize the potential for microbiological contamination of the finished product, it is recommended that non-carbonated bottled water not be transported, stored, processed or bottled in or through lines or equipment through which any food product other than water is passed.

(b) Bottled water shall not be transported, stored, processed or bottled through lines or equipment through which any food product other than water is passed except under procedures that prevent the potential for microbiological contamination in bottled water.

310:225-5-4. Cleaning and sanitizing procedures

(a) Non-dairy foods.

(1) Where foods other than milk or dairy products have been transported, stored, processed or bottled, each time before water

is transported, stored, processed or bottled through the same lines or equipment all product contact surfaces shall be thoroughly cleansed and sanitized using appropriate procedures as specified in 21 C.F.R. Section 129.80. Where noncarbonated bottled water is processed or bottled, cleansing and sanitizing of the filler shall be manually, after disassembly, and all product contact surfaces of the filler shall be sanitized with 50 ppm chlorine for one minute at 75 degrees F. or equivalent.

(2) Subject to Department review and approval, for equipment, lines and surfaces may be cleaned in place and sterilized with saturated steam at 252 degrees F. for ten minutes.

(b) Dairy foods.

(1) Where milk or other dairy products are processed or bottled through the same lines or equipment as bottled water, the feed line used to convey water to the filler shall be dedicated to water only.

(2) Each time before water is processed or bottled all other product contact surfaces shall be disassembled and manually cleaned in accordance with procedures specified in 21 C.F.R. 129.80 and shall then be sanitized with 50 ppm chlorine for one minute at 75 degrees F., or equivalent.

(3) Subject to Department review and approval, for equipment, lines and surface may be cleaned in place and sterilized with saturated steam at 252 degrees F. for ten minutes.

(4) All product contact surfaces of tanks used for storage or transport for ten minutes.

(c) Ozone resistant material. Where ozone is used as a germicidal agent for bottled water, all gaskets, o-rings and similar flexible material shall be made of silicone rubber, teflon or other ozone resistant material. These flexible parts shall be replaced whenever they show evidence of surface deterioration.

310:225-5-5. Product recall procedures

Each bottled water plant operator and water dealer shall develop and maintain a procedure for product recall and shall implement said procedure for any product for which the operator or dealer knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer.

SUBCHAPTER 7. WATER MONITORING

310:225-7-1. Approved source sampling and analysis

(a) The bottled water plant operator shall be responsible for sampling and analysis of all approved sources for the contaminants specified in Section 310:225-3-1 to assure that product water derived from approved sources continues to comply with Section 310:225-3-1. Such monitoring shall be at least annually, except that analysis for microbiological contaminants shall be weekly if

the source is other than a public water system.

(b) Approved sources shall be monitored every five years for the contaminants for which U.S. EPA under the Safe Drinking Water Act or the Department requires source water monitoring.

(c) Source monitoring shall not be required of a plant using an approved public drinking water supply.

(d) The required source water sampling shall be performed by qualified personnel and required analysis shall be performed by an approved laboratory. Records of the required sampling and analyses shall be maintained on file at the plant for not less than two years and shall be available for official review upon request of the Department.

310:325-7-2. Possible source contamination

(a) Where a bottled water plant operator, water dealer or regulatory agency knows or has reason to believe that a contaminant not otherwise monitored is present in the source water because of a spill, release of a hazardous substance or otherwise, and its presence would create a potential health hazard to consumers, the plant operator or water dealer upon receipt of such information shall monitor the source water for said contamination.

(b) Detection of contaminant(s) in source monitoring required pursuant to this Subchapter shall be followed immediately by a program of periodic monitoring to confirm the presence in the source water of said contaminant(s). If such listed unregulated contaminant(s) is confirmed to be present in the source water at a concentration that exceeds a published U.S. EPA Health Advisory, or a U.S. EPA or Department Action Level for drinking water, the plant operator or water dealer shall employ appropriate treatment techniques to remove or to reduce said contaminant in the product water below said concentration and shall employ a program of periodic monitoring for said contaminant in the source water until such time as said contaminant is not detectable in the source water.

310:225-7-3. Finished product monitoring

To assure that bottled water complies with Section 310:225-3-2, the following product monitoring using representative samples derived from the bottled product shall be performed:

(1) For microbiological contaminants specified in Section 310:225-3-2 analyze weekly a representative sample from a batch or segment of a continuous production run for each type of bottled water produced by the plant.

(2) For chemical, physical and radiological contaminants specified in Section 310:225-3-2 analyze annually a representative sample from a batch or segment of continuous product run for each type of bottled drinking water produced by the plant.

310:225-7-4. Finished product sampling and analysis

(a) The required product water sampling shall be performed by qualified personnel and required analysis shall be performed by approved laboratory.

(b) Records of required sampling and analysis shall be maintained at the plant not less than two years and shall be available for official review upon request of the Department.

SUBCHAPTER 9. LABELING REQUIREMENTS

310:225-9-1. Labeling requirements

All bottled water shall conform to applicable federal and state labeling laws and be labeled in compliance with the following standards:

(1) Mineral water may be labeled "Mineral Water". Bottled water to which minerals are added shall be labeled so as to disclose that minerals are added, and may not be labeled "Natural Mineral Water".

(2) Spring water may be labeled "Spring Water" or "Natural Spring Water".

(3) Water containing carbon dioxide that emerges from the source and is bottled directly with its entrapped gas or from which the gas is mechanically separated and later reintroduced at a level not higher than naturally occurring in the water may bear on its label the words "Naturally Carbonated" or "Naturally Sparkling".

(4) Bottled water which contains carbon dioxide other than that naturally occurring in the source of the product shall be labeled with the words "Carbonated", "Carbonated Added" or "Sparkling" when the carbonation is obtained from a natural or manufactured source.

(5) Well water may be labeled "Well Water" or "Natural Well Water".

(6) Artesian water may be labeled "Artesian Water", or "Natural Artesian Water".

(7) Purified water shall be labeled "Purified Water" and the method of preparation shall be stated on the label, except that purified water produced by distillation may be labeled as "Distilled Water".

(8) Drinking water may be labeled "Drinking Water".

(9) Any bottler, distributor or vendor of bottled water whose corporate name appears on each bottle with the type of bottled water as defined in Section 310:225-1-2 in typeface at least equal to the size of the typeface of the corporate name, brand name or trademark, if the type of the bottled water is different from the type stated or implied in the corporate name, brand name or trademark.

(10) The use of word "Spring", or any derivative thereof other than a trademark, shall be prohibited.

(11) A product meeting more than one definition as stated in Section 310:225-1-2 may be identified by any one of the applicable product types defined in Section 310:225-1-2, except where otherwise specified.

otherwise specifically prohibited.

(12) Supplemental printed information and graphics concerning recognized uses of the water may appear on the label but shall not imply properties of the product or preparation methods which are not factual.

SUBCHAPTER 11. LICENSES TO PROCESS, SELL OR DISTRIBUTE BOTTLED WATER

310:225-11-1. Licenses to process, sell, or distribute bottled water

Any person desiring to operate a bottled water plant, or to sell or distribute bottled water, in Oklahoma shall make application to the State Commissioner of Health for a permit, and obtain a valid license prior to the operation of the bottled water plant or the distribution and sale of bottled water. Application for such license shall be on a form supplied by the Commissioner and shall contain such information as the Commissioner deems necessary to determine that the operation of the bottled water plant or sale of bottled water will in no manner be injurious or hazardous to the health or safety of the people of the state. Each application for a license and license renewal shall be accompanied by the proper fee. The fee paid and license issued shall be for the particular bottled water plant to be operated and shall not be transferred to another person or location.

310:225-11-2. Out-of-state licenses

Out-of-State licenses to process, sell, or distribute bottled water shall be issued, upon receipt of the following:

- (1) Documentation from the State where the facility is located that the
- (2) Receipt of a signed application along with the appropriate fee.

310:225-11-3. Plan review

Before any bottled water plant is constructed, reconstructed, or extensively altered, properly prepared plans shall be approved by the State Commissioner of Health.

310:225-11-4. Access

Representatives of the Oklahoma State Department of Health, after proper identification, shall be permitted to enter any bottled water facility at any reasonable time for the purpose of making inspections to determine compliance with the rules of this Chapter. The representative shall be permitted to examine the records of the facility to obtain information pertaining to the operation of the facility.

310:225-11-5. License revocation and suspension

Procedures for revocation and suspension of licenses to process, sell, or distribute bottled water are stated in the Oklahoma

Administrative Procedures Act.

310:225-11-6. Inspection

As a condition of receiving a license, and annually thereafter, the water bottler shall receive a plant inspection demonstrating compliance with the Good Manufacturing Practices and Operational Requirements of these regulations. Said inspection shall be conducted by the State in which the bottling facility is located, by the FDA, or by a third party inspection organization (such as NSF) acceptable to the Department.

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