

901:3-62-01

Criteria and definitions for processing bottled water.

(A) Food processing establishments processing and bottling drinking water shall comply with Chapter 901:3-62 and the applicable provisions of Chapter 901:3-17 of the Administrative Code.

(B) Definitions.

As used in Chapter 901:3-62 of the Administrative Code:

(1) "Approved source" means:

(a) A public water system, as defined in division (A) of section 6109.01 of the Revised Code, with a current license issued by the director of the EPA under authority of section 6109.21 of the Revised Code;

(b) A private water system, as defined in division (A) of section 3701.344 of the Revised Code, for which a permit has been issued under authority of paragraph (C) of rule 3701-28-03 of the Administrative Code and which is operating in compliance with the requirements of Chapter 3701. of the Revised Code and the rules adopted thereunder;

(c) A source of water which is not required by law to be licensed either as a public water system; or to be operated as a private water system in compliance with the requirements of Chapter 3701. of the Revised Code, but for which:

(i) A written opinion from either a geologist or hydrologist has been obtained stating that the location and geological characteristics of the source do not expose water from the source to contamination by a chemical, biological and radiological pollutants injurious to human health, and

(ii) An analysis of the water from the source, done by a United States environmental protection agency certified laboratory, a state EPA laboratory or a state certified laboratory, has been obtained verifying that the water from the source meets the chemical, biological and radiological quality requirements for bottled water and bottled water packaged in the United States contained in 21 CFR 165.110(b) (2011).

(2) "Board of health" means a board of health of a city or general health district or the authority having the duties of a board of health under Chapter 3709. of the Revised Code.

- (3) "Bottled water" means all water, that is intended for human consumption, including artesian water, mineral water, purified water, sparkling bottled water, and spring water, and that is sealed in bottles, packages, or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Floride may be optionally added within the limitations established in 21 C.F.R. Part 165.110 (b)(4)(ii) (2011).
- (4) "C.F.R." means Code of Federal Regulations.
- (5) "Director" means the director of the Ohio department of agriculture.
- (6) "E.P.A." means the Ohio environmental protection agency.
- (7) "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.
- (8) "Multi-service containers" means containers intended for use more than one time.
- (9) "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled 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.
- (10) "Operations water" means water that is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.
- (11) "ppm" means parts per million.
- (12) "Primary container" means the immediate container in which the product water is packaged.
- (13) "Product water" means processed water used by a plant for bottled water.
- (14) "Shipping case" means a container in which one or more primary containers of the product are held.

(15) "Single-service container" means a container intended for one time usage only.

(16) "TDS" means total dissolved solids.

(17) "Unit package" means a standard commercial package of bottled water, which may consist of one or more containers.

901:3-62-02

License.

- (A) No person shall manufacture or bottle for sale within the state bottled water unless the person has a license as prescribed in section 913.23 of the Revised Code. Applicants shall apply for a license on a form provided by the director.

- (B) Prior to licensing, the director shall determine if the source and operations water originates from an approved source, inspect the bottled water plant to determine compliance with this chapter and the applicable good manufacturing practices of Chapter 901:3-1 of the Administrative Code, and that any label shall be in conformance with the provisions of this chapter and rule 901:3-1-11 of the Administrative Code.

901:3-62-03

Nomenclature and labeling.

(A) The name of the food is bottled water or alternatively one or more of the following terms as appropriate:

- (1) Artesian water or artesian well water is the name of the water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water or artesian well water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.
- (2) Ground water is the name of the water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water as defined in 40 C.F.R. Part 141.2 (1975).
- (3) Mineral water is the name of the water containing not less than two hundred fifty ppm total dissolved solids. Mineral water must come from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.
- (4) Purified water is the name of the water from an approved source, that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of "purified water" in the United States pharmacopeia, 23rd revision, January 1, 1995. Purified water may be called "deionized water" if the water has been processed by deionization, "distilled water" if it is produced by distillation, "reverse osmosis water" if the water has been processed by reverse osmosis, and "drinking water" with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., "purified drinking water" or "deionized drinking water").
- (5) Sparkling bottled water is the name of the water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source.
- (6) Spring water is the name of the water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water shall be collected only at the spring or through a bore hole tapping the

underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

- (7) Sterile water is the name of the water that meets sterility tests in the United States pharmacopeia, 23rd revision, January 1, 1995, which can be found at www.usp.org. Alternatively the water may be called sterilized water.
- (8) Well water is the name of the water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

(B) Labeling.

In addition to labeling standards set forth in paragraph (A) of this rule and rule 901:3-1-11 of the Administrative Code, the following standards shall also apply:

- (1) If the TDS content of mineral water is below five hundred ppm, or if it is greater than one thousand five hundred ppm, the statement "low mineral content" or the statement "high mineral content", respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between five hundred and one thousand five hundred ppm, no additional statement need appear.
- (2) When bottled water comes from a community water system, as defined in 40 C.F.R. Part 141.2 (1975), except when it has been treated to meet the definition of purified water in paragraph (A)(4) of this rule, or sterile water in paragraph (A)(7) of this rule, and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (B)(3) of this rule, in type size at least

one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

- (3) When the label or labeling of a bottled water product states or implies that the bottled water is for use in feeding infants, and the product is not commercially sterile under paragraph (B)(4) of rule 901:3-3-01 of the Administrative Code, the product's label shall bear conspicuously and on the principal display panel the statement "Not sterile. Use as directed by physician or by labeling directions for use of infant formula."
- (4) For the purposes of this rule, the standard of quality for bottled water, including water for use as an ingredient in beverages shall be specified in 21 C.F.R., Part 165.110 (2011). When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed in 21 C.F.R. Part 165.110 (2011), the label shall bear the statement of substandard quality as applicable:
 - (a) "Contains Excessive Bacteria."
 - (b) "Excessively Turbid", "Abnormal Color," or "Abnormal Odor."
 - (c) "Contains Excessive _____," with the blank filled in with the name of the chemical for which a maximum contaminant level is exceeded. Except that "Contains Excessive Chemical Substances" may be used if the bottled water is not mineral water.
 - (d) "Excessively Radioactive."

901:3-62-04

Plant construction, design, and equipment.

- (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.
- (D) The washing and sanitizing of containers for bottled 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.
- (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) When employee locker and lunchrooms 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. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.
- (G) 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.
 - (2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbent material which can be adequately cleaned or sanitized and is in compliance with section 3715.62 of the Revised Code.
- (H) Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

901:3-62-05

Sanitary facilities.

(A) Product water and operations water.

- (1) The product water supply for each bottled water plant shall be from an approved source properly located, protected, and operated; and shall be easily accessible, adequate, and of a safe, sanitary quality.
- (2) 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.
- (3) Product water and operations water from approved sources.
 - (a) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for total coliform at least once each week. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli* (E. Coli). This sampling is in addition to any monitoring performed to comply with the E.P.A. or the local board of health requirements, as applicable. Records of approval of the source water by the E.P.A. or the local board of health, as applicable, and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.
 - (i) Source water found to contain E. Coli is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (A)(1) of this rule.
 - (ii) Before a bottler can use source water from a source that has tested positive for E. Coli, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of E. Coli contamination of that source in manner sufficient to prevent its recurrence.
 - (iii) A source previously found to contain E. Coli will be considered negative for E. Coli after five samples collected over a twenty-four hour period from the same sampling site that originally tested positive for E. Coli are tested and found to be E. Coli negative.

- (b) Test and sample methods shall be those recognized and approved by the E.P.A. or the local board of health, or the director, as applicable, over the approval of the water source and shall be consistent with the minimum requirements set forth in 21 C.F.R. Part 165.110(b) (2011).
- (c) Samples of source water shall be tested by a United States environmental protection agency certified laboratory, a state EPA laboratory, or a state certified laboratory.
- (d) Finished product water must comply with the bottled water quality standards in 21 C.F.R. Part 165.110(b) (2011) and section 3715.59 of the Revised Code dealing with adulterated foods.

(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; and shall not affect the bacteriological quality of the water.

901:3-62-06

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 water.

901:3-62-07

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 and in accordance with section 3715.62 of the Revised Code. 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.

(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 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 following times and intensities shall be considered a minimum:

- (1) Steam in enclosed system: At least one-hundred-seventy degrees Fahrenheit for at least fifteen minutes or at least two-hundred degrees Fahrenheit for at least five minutes.
- (2) Hot water in enclosed system: At least one-hundred-seventy degrees Fahrenheit for at least fifteen minutes or at least two-hundred degrees Fahrenheit for at least five minutes.
- (3) Chemical sanitizers shall be equivalent in bactericidal action to a two-minute exposure of fifty ppm of available chlorine at fifty-seven degrees Fahrenheit when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum one-hundred ppm of available chlorine at fifty-seven degrees Fahrenheit or its equivalent in bactericidal action.
- (4) One-tenth ppm ozone water solution in an enclosed system for at least five minutes.
- (5) When containers are sanitized using a substance other than one provided for in 21 C.F.R. Part 178.1010 (1977), such substance 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 bacterial or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (D)(3) of this rule.

(E) Unit package production code.

Each unit package from a batch or segment of a continuous production run of bottled 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.

- (2) Containers which are not satisfactory shall be reprocessed or rejected.
- (3) Only nontoxic containers and closures shall be used.
- (4) All containers and closures shall be sampled and inspected to ascertain that they are free from contamination.
- (5) At least once each three months, a bacteriological swab or rinse count or both shall 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.

Tests shall be performed either by personnel at the plant or an approved laboratory.

(G) Compliance procedures.

To assure that the plant's production of bottled water complies with this chapter, the plant will analyze product samples as follows:

- (1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.
- (2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli*. If the finished product is positive for *E. coli* it is considered adulterated under section 3715.59 of the Revised Code.
- (3) Analyze such samples by methods prescribed in 21 C.F.R. Part 165.110(b) (2011). 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 by rules 901:3-62-05 and 901:3-62-07 of the Administrative Code shall be maintained at the plant for not less than two years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the E.P.A. or the local board of health, or an engineer or hydrologist, as applicable, 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.

(I) Quality.

Bottled water shall meet the standards of microbiological, physical, chemical, and radiological quality set forth in 21 C.F.R. Part 165.110 (2011).

(J) Bottled water containing a substance at a level considered injurious to health shall be considered adulterated under section 3715.59 of the Revised Code, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed in paragraph (I) of this rule.