



Ohio Administrative Code Rule 901:3-62-07 Processes and controls.

Effective: September 16, 2016

(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.