

CHAPTER 11

BOTTLED WATER REQUIREMENTS

Section 1. Water Quality and Source.

(a) All bottled water except mineral water shall meet quality standards prescribed in 21 CFR 165.110 Bottled Water. Mineral water shall not contain any contaminant in quantities injurious to health taking into account the natural constituents and the rate of consumption of mineral water, as compared to drinking water.

Section 2. Good Manufacturing Practices and Operational Requirements.

(a) All bottled water, including mineral water, shall be processed and packaged in accordance with 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and 21 CFR 129 Processing and Bottling of Bottled Drinking Water.

(b) Bottled water shall not be processed or bottled through a line or other equipment that is used for any other food.

(c) Artesian water may be collected with the assistance of external force to enhance the natural underground pressure so long as such measures do not alter the composition and quality of the water.

(d) Natural water may be treated to reduce the concentration of any substance which exceeds standards set under 21 CFR. 165.110 Bottled Water. It may be collected and transported by pipes, tunnels, trucks and similar devices.

(e) Spring water shall be collected only at the natural orifice of the spring or through a bore hole that is adjacent to the natural orifice. Spring water collected with the assistance of external force to protect the water source shall retain all the physical properties of and be of the same composition and quality as the water that flows naturally to the surface of the earth.

Section 3. Source Water Sampling.

(a) Water samples shall be:

(i) Taken from approved sources by the plant as often as necessary but at least annually to assure compliance with 21 CFR 129.35 (a) (3) Sanitary Facilities;

- (ii) Analysis for microbiological contaminants shall be weekly if the source is other than a public water system;
- (iii) The sampling and analyses shall be by qualified personnel and shall be in addition to any sampling performed by government agencies or laboratory;
- (iv) Records of the sampling and analyses shall be maintained on file at the plant for two years;
- (v) Analysis of the samples shall be performed by an accredited Laboratory;
- (vi) Analysis for chemical contaminants shall be at a minimum frequency of once each year; and
- (vii) Analysis for radiological contaminants shall be at a minimum frequency of once every four (4) years.

Section 4. Finished Product Sampling.

(a) To assure the plant's production of bottled water is in compliance with 21 CFR 129.80 Processes and Controls, the following product analyses shall be performed by an accredited laboratory:

- (i) According to 21 CFR 129.80 Processes and Controls, analyze a representative sample from a batch or segment of a continuous production for each type of bottled water produced by the plant at least weekly for microbiological purposes; and
- (ii) According to 21 CFR 129.80 Processes and Controls, analyze a representative sample from a batch or segment of continuous product run for each type of bottled drinking water produced by the plant at least annually for chemical, physical, and radiological purposes.

(b) The representative sample shall be derived from the bottled product.

(c) All records pertaining to sampling and analysis shall be maintained at the plant for two years. All required documents shall be available for official review upon request.

Section 5. Exemptions.

(a) A bottled water plant operator may request an exemption from sampling source water and finished product if bottling is conducted less than on a weekly basis.

(i) An operator exempted under this section shall sample source water and finished products each production day.

(b) Bottled soda or seltzer or other food complying with 21 CFR 165.110 Bottled Water, is exempt from the requirements of this Rule.