

§ 129.37

21 CFR Ch. I (4-1-01 Edition)

(ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).

(iii) The finished bottled water must comply with bottled water quality standards (21 CFR 165.110(b)) and section 402(a)(1) of the act 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; 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 lunchrooms.* 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 and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

[42 FR 14355, Mar. 15, 1977, as amended at 44 FR 12175, Mar. 6, 1979; 60 FR 57123, Nov. 13, 1995]

EFFECTIVE DATE NOTE: At 66 FR 16865, Mar. 28, 2001, §129.35 was amended by redesignating paragraph (a)(4)(iii) as paragraph (a)(4)(iv) and by adding new paragraph (a)(4)(iii), effective Jan. 1, 2002. For the convenience of the user, the added text is set forth as follows:

§ 129.35 Sanitary facilities.

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(iii) Firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in §165.110(b)(4)(iii)(H) of this chapter. Firms that do not use a public water system as the source of their water but whose source water

has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in §165.110(b)(4)(iii)(H) that are likely to result from such treatment.

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§ 129.37 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.

Subpart C—Equipment

§ 129.40 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.

(2) All product water contact surfaces shall be constructed of nontoxic and

nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

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

Subpart D [Reserved]

Subpart E—Production and Process Controls

§ 129.80 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 409 of the Federal Food, Drug, and Cosmetic Act. 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 government agency or agencies having jurisdiction.

(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 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 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F 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 °F 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 °F 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) When containers are sanitized using a substance other than one provided for in §178.1010 of this chapter, 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