

processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

**§ 123.28 Source controls.**

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in §1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in §1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

- (1) The date of harvest;
- (2) The location of harvest by State and site;
- (3) The quantity and type of shellfish;
- (4) The date of receipt by the processor; and
- (5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification

number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with §1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

- (1) The date of receipt;
- (2) The quantity and type of shellfish; and
- (3) The name and certification number of the packer or repacker of the product.

**PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER**

**Subpart A—General Provisions**

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**Subpart B—Buildings and Facilities**

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**Subpart D [Reserved]**

**Subpart E—Production and Process Controls**

- 129.80 Processes and controls.

AUTHORITY: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

SOURCE: 42 FR 14355, Mar. 15, 1977, unless otherwise noted.

**Subpart A—General Provisions**

**§ 129.1 Current good manufacturing practice.**

The applicable criteria in part 110 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling,

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holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

#### § 129.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Approved source* when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.

(b) *Bottled drinking water* means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) *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.

(d) *Multiservice containers* means containers intended for use more than one time.

(e) *Nontoxic materials* means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking 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.

(f) *Operations water* means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) *Primary container* means the immediate container in which the product water is packaged.

(h) *Product water* means processed water used by a plant for bottled drinking water.

(i) *Shall and should*. "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) *Shipping case* means a container in which one or more primary containers of the product are held.

(k) *Single-service container* means a container intended for one time usage only.

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

[42 FR 14355, Mar. 6, 1977, as amended at 44 FR 12175, Mar. 6, 1979]

## Subpart B—Buildings and Facilities

### § 129.20 Plant construction and design.

(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 drinking 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.