

shall be subject to the applicable provisions of §123.9.

(d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Smoked and Smoke-Flavored Fishery Products

§ 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C—Raw Molluscan Shellfish

§ 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such 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

Sec.

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Subpart B—Buildings and Facilities

- 129.20 Plant construction and design.
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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, 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.