

## § 120.1

- 120.13 Training.  
120.14 Application of requirements to imported products.

### Subpart B—Pathogen Reduction

- 120.20 General.  
120.24 Process controls.  
120.25 Process verification for certain processors.

AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

SOURCE: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

### Subpart A—General Provisions

#### § 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than \$500,000, or if their total annual sales are greater than \$500,000 but their total food sales are less than \$50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were

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sold in the United States, the regulations are binding on January 20, 2004.

### § 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, §101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or