

**§ 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 measurements to assess whether a process, point, or procedure is under

control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

**§ 120.5 Current good manufacturing practice.**

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the

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food has been processed under sanitary conditions.

### § 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

- (1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;
- (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
- (3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
- (4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
- (6) Proper labeling, storage, and use of toxic compounds;
- (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
- (8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are sub-

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ject to the recordkeeping requirements of § 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Sanitation standard operating procedure controls may be included in the HACCP plan required under § 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

### § 120.7 Hazard analysis.

(a) Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control those hazards. The written hazard analysis shall consist of at least the following:

- (1) Identification of food hazards;
- (2) An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. This evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs;
- (3) Identification of the control measures that the processor can apply to control the food hazards identified as reasonably likely to occur in paragraph (a)(2) of this section;
- (4) Review of the current process to determine whether modifications are necessary; and
- (5) Identification of critical control points.

(b) The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. The hazard analysis shall