

§ 120.7

21 CFR Ch. I (4–1–06 Edition)

of this section. These records are subject 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

be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

(c) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:

- (1) Microbiological contamination;
- (2) Parasites;
- (3) Chemical contamination;
- (4) Unlawful pesticides residues;
- (5) Decomposition in food where a food hazard has been associated with decomposition;
- (6) Natural toxins;
- (7) Unapproved use of food or color additives;
- (8) Presence of undeclared ingredients that may be allergens; and
- (9) Physical hazards.

(d) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer.

(e) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or part 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

§ 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. A HACCP plan shall be specific to:

- (1) Each location where juice is processed by that processor; and
- (2) Each type of juice processed by the processor. The plan may group

types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List all food hazards that are reasonably likely to occur as identified in accordance with §120.7, and that thus must be controlled for each type of product;

(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate:

(i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and

(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;

(3) List the critical limits that shall be met at each of the critical control points;

(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with §120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with §120.11; and

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with §120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §120.6, they are not required to be included in the HACCP plan.

§ 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with §§120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

§ 120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;