

§ 120.7

21 CFR Ch. I (4–1–07 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