

## § 120.25

## 21 CFR Ch. I (4-1-06 Edition)

§ 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

### § 120.25 Process verification for certain processors.

Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of § 120.24 shall analyze the finished product for biotype I *Escherichia coli* as follows:

(a) One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced shall be sampled each production day. If less than 1,000 gallons of juice is produced per day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.

(b) If the facility is producing more than one type of juice covered by this section, processors shall take subsamples according to paragraph (a) of this section for each of the covered juice products produced.

(c) Processors shall analyze each subsample for the presence of *E. coli* by the method entitled "Analysis for *Escherichia coli* in Citrus Juices—Modification of AOAC Official Method 992.30" or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *E. coli*. This method is designed to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples). The method is as follows:

(1) *Sample size.* Total-20 mL of juice; perform analysis using two 10 mL aliquots.

(2) *Media.* Universal Preenrichment Broth (Difco, Detroit, MI), EC Broth (various manufacturers).

(3) *Method.* ColiComplete (AOAC Official Method 992.30—modified).

(4) *Procedure.* Perform the following procedure two times:

(i) Aseptically inoculate 10 mL of juice into 90 mL of Universal Preenrichment Broth (Difco) and incubate at 35 °C for 18 to 24 hours.

(ii) Next day, transfer 1 mL of preenriched sample into 10 mL of EC Broth, without durham gas vials. After inoculation, aseptically add a ColiComplete SSD disc into each tube.

(iii) Incubate at 44.5 °C for 18 to 24 hours.

(iv) Examine the tubes under longwave ultra violet light (366 nm). Fluorescent tubes indicate presence of *E. coli*.

(v) MUG positive and negative controls should be used as reference in interpreting fluorescence reactions. Use an *E. coli* for positive control and 2 negative controls—a MUG negative strain and an uninoculated tube media.

(d) If either 10 mL subsample is positive for *E. coli*, the 20 mL sample is recorded as positive and the processor shall:

(1) Review monitoring records for the control measures to attain the 5-log reduction standard and correct those conditions and practices that are not met. In addition, the processor may choose to test the sample for the presence of pathogens of concern.

(2) If the review of monitoring records or the additional testing indicates that the 5-log reduction standard was not achieved (*e.g.*, a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is identified), the processor shall take corrective action as set forth in § 120.10.

(e) If two samples in a series of seven tests are positive for *E. coli*, the control measures to attain the 5-log reduction standard shall be deemed to be inadequate and the processor shall immediately:

(1) Until corrective actions are completed, use an alternative process or

processes that achieve the 5-log reduction after the juice has been expressed;

(2) Perform a review of the monitoring records for control measures to attain the 5-log reduction standard. The review shall be sufficiently extensive to determine that there are no trends towards loss of control;

(i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or

(ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the 5-log reduction standard; and

(3) Take corrective action as set forth in §120.10. Corrective actions shall include ensuring no product enters commerce that is injurious to health as set forth in §120.10(a)(1).

## PART 123—FISH AND FISHERY PRODUCTS

### Subpart A—General Provisions

Sec.

123.3 Definitions.

123.5 Current good manufacturing practice.

123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan.

123.7 Corrective actions.

123.8 Verification.

123.9 Records.

123.10 Training.

123.11 Sanitation control procedures.

123.12 Special requirements for imported products.

### Subpart B—Smoked and Smoke-Flavored Fishery Products

123.15 General.

123.16 Process controls.

### Subpart C—Raw Molluscan Shellfish

123.20 General.

123.28 Source controls.

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### Subpart A—General Provisions

#### § 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are ap-

plicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c) *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 safety hazard.

(d) *Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) *Fishery product* means any human food product in which fish is a characterizing ingredient.

(f) *Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

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

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.