Food and Drug Administration, HHS

§ 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their
Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (i.e., 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the “pertinent microorganism” is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by §120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in §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.

Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section for each of the covered juice products produced.

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).


(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 ultraviolet light (366 nm). Fluorescent tubes indicate presence of E. coli.