



Ohio Administrative Code

Rule 901:3-23-09 Process controls and verification.

Effective: April 1, 2025

(A) In order to meet the requirements of rules 901:3-23-01 to 901:3-23-09 of the Administrative Code, processors of juice products shall include in their hazard analysis and critical control point plans control measures that will consistently produce, at a minimum, a five-log reduction of the pertinent microorganism, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. For the purposes of this rule, 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 Chapter 901:3-5 of the Administrative Code or 21 C.F.R. 113; 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 rule 901:3-23-03 of the Administrative Code.

(B) All juice processors shall meet the requirements of paragraph (A) of this rule 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 paragraphs (C)(1) and (C)(7) of rule 901:3-23-01 of the Administrative Code 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 rule and perform final product packaging within a single production facility operating under the applicable provisions found in Chapter 901:3-17 of the Administrative Code. Processors claiming an exemption under paragraph (A)(1) or (A)(2) of this rule shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under the applicable provisions found in Chapter 901:3-17 of the Administrative Code.



(D) 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 this rule shall analyze the finished product for biotype I *Escherichia coli* at an accredited laboratory at the following frequency and sample sizes:

(1) One twenty mL sample (consisting of two ten mL subsamples) for each one-thousand gallons of juice produced shall be sampled each production day. If less than one thousand gallons of juice is produced per day, the sample must be taken for each one-thousand gallons produced but not less than once every five 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.

(2) If the facility is producing more than one type of juice covered by this rule, processors shall take subsamples according to paragraph (D)(1) of this rule for each of the covered juice products produced.

(3) Processors shall analyze each subsample for the presence of *E. coli* by a method designed to detect the presence or absence of *E. coli* in a twenty mL sample of juice (consisting of two ten mL subsamples).

(4) If either ten mL subsample is positive for *E. coli*, the twenty mL sample is recorded as positive and the processor shall:

(a) Review monitoring records for the control measures to attain the five-log reduction standard and correct those conditions and practices that are not met.

(b) If the review of monitoring records or the additional testing indicates that the five-log reduction standard was not achieved, the processor shall take corrective action as set forth in rule 901:3-23-05 of the Administrative Code.

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

(a) Use an alternative process or processes that achieve the five-log reduction after the juice has been



expressed until corrective actions are completed;

(b) Perform a review of the monitoring records for control measures to attain the five-log reduction standard. The review shall be sufficiently extensive to determine if there are 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 five-log reduction standard.

(c) Take corrective action as set forth in rule 901:3-23-05 of the Administrative Code.