901:3-23-02 **Sanitation standard operating procedures.**

(A) Sanitation controls.

Each processor shall have and implement a sanitation standard operating procedure that addresses sanitation conditions and practices before, during, and after processing. The sanitation standard operating procedure shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

(B) Monitoring.

The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified Chapter 901:3-17 of the Administrative Code that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(C) Records.

Each processor shall maintain sanitation standard operating procedure records that, at a minimum, document the monitoring and corrections prescribed by paragraph (B) of this rule. These records are subject to the recordkeeping requirements of rule 901:3-23-07 of the Administrative Code.

901:3-23-03 **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 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 rule;

(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 safety hazards that can occur before, during, and after harvest. The hazard analysis shall be conducted by an individual or individuals who have been trained in accordance with rule 901:3-23-08 of the Administrative Code and shall be subject to the record keeping requirements of rule 901:3-23-07 of the Administrative Code.

(C) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of Chapters 901:3-3 and 901:3-5 of the Administrative Code. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

901:3-23-04 **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 rule 901:3-23-03 of the Administrative Code. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with rule 901:3-23-08 of the Administrative Code and shall be subject to the record keeping requirements of rule 901:3-23-07 of the Administrative Code. 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 rule 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 rule 901:3-23-03 of the Administrative Code;

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

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

(b) 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 rule 901:3-23-05 (A) of the Administrative Code, 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 by the processor in accordance with rule 901:3-23-06 of the Administrative Code; and

(7) Provide for a record keeping system that documents the monitoring of the critical control points in accordance with rule 901:3-23-07 of the Administrative Code. The records shall contain the actual values and observations obtained during monitoring.

(C) Sanitation.

Sanitation controls that are monitored in accordance with rule 901:3-23-02(B) of the Administrative Code need not be included in the HACCP plan.

901:3-23-05 **Corrective actions.**

(A) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (C) of this rule.

(B) If a written corrective action plan is developed, it shall become part of the HACCP plans in accordance with rule 901:3-23-04(B)(5) of the Adminstrative Code, by which they predetermine the corrective actions that they will take whenever there is a deviation form a critical limit. A corrective action plan shall 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.

(C) 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 (C)(2) and (C)(3) of this rule are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with rule 901:3-23-08 of the Administrative Code, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan an necessary.

(D) All corrective actions taken in accordance with this rule shall be fully documented in records that are subject to verification in accordance with rule 901:3-23-06 of the

Administrative Code and the record keeping requirements of rule 901:3-23-07 of the Administrative Code.

901:3-23-06 **Verification and validation.**

(A) Verification.

Each processor shall verify that the hazard analysis and critical control point plan is being implemented according to design.

(1) Verification activities shall include:

(a) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(b) The calibration of process monitoring instruments;

(c) At the option of the processor, the performance of periodic end-product or in-process testing; except that processors of citrus juice that rely in whole or in part on surface treatment of fruit shall perform end-product testing in accordance with rule 901:3-23-09 of the Administrative Code.

(d) A review, including signing and dating, by an individual who has been trained in accordance with rule 901:3-23-08 of the Administrative Code, of the records that document:

(i) The monitoring of critical control points to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within seven days of the day that the records are made;

(ii) The taking of corrective actions to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with rule 901:3-23-05 of the Administrative Code. This review shall occur within seven days of the day that the records are made; and

(iii) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(e) The following of procedures in rule 901:3-23-05 of the Administrative Code whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(f) Additional process verification if required by rule 901:3-23-09 of the Administrative Code.

(2) Records that document the calibration of process monitoring instruments, and the performance of any periodic end-product and in-process testing, in accordance with this rule, are subject to the record keeping requirements of rule 901:3-23-07 of the Administrative Code.

(B) Validation of the HACCP plan.

Each processor shall validate that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur; this validation shall occur at least once within twelve months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. The validation shall be performed by an individual or individuals who have been trained in accordance with rule 901:3-23-08 of the Administrative Code and, shall be subject to record keeping requirements of rule 901:3-23-07 of the Administrative Code. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this chapter.

(C) Validation of the hazard analysis.

Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with rule 901:3-23-08 of the Administrative Code, and, records documenting the validation shall be subject to the record keeping requirements of rule 901:3-23-07 of the Administrative Code.

901:3-23-07 **Records.**

(A) Required records.

Each processor shall maintain the following records documenting the processor's hazard analysis and critical control point plan:

(1) Records documenting the implementation of the sanitation standard operating procedures;

(2) The hazard analysis required by rule 901:3-23-03 of the Administrative Code;

(3) The HACCP plan required by rule 901:3-23-04 of the Administrative Code;

(4) Records documenting the ongoing application of the HACCP plan that include:

(a) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and

(b) Corrective actions, including all actions taken in response to a deviation.

(5) Records documenting verification and validation of the HACCP plan or hazard analysis, as appropriate.

(B) General requirements.

All records required by this chapter shall include:

(1) The name of the processor and the location of the processor, if the processor has more than one location;

(2) The date and time of the activity that the record reflects, except that records required by paragraphs (A)(2), (A)(3), and (A)(5) of this rule need not include the time;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) The identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during

monitoring.

(C) Documentation.

(1) The records in paragraphs (A)(2) and (A)(3) of this rule shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (A)(2) and (A)(3) of this rule shall be signed and dated:

(a) Upon initial acceptance;

(b) Upon any modification; and

(c) Upon verification and validation in accordance with rule 901:3-23-06 of the Administrative Code.

(D) Record retention

(1) All records required by this chapter shall be retained at the processing facility as follows:

(a) Perishable or refrigerated juices, at least one year after the date that such products were prepared,

(b) Frozen, preserved, or shelf stable products, two years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (A)(1) and (A)(4) of this rule is permitted after six months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within twenty-four hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with this rule.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible

location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(E) Official review.

All records required by this chapter shall be available for review and copying at reasonable times.

(F) Records maintained on computers.

The maintenance of computerized records is acceptable.

901:3-23-08 **Training.**

(A) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to juice processing:

(1) Conducting the hazard analysis, including delineating control measures, as required by rule 901:3-23-03 of the Administrative Code;

(2) Developing a hazard analysis and critical control point plan that is appropriate for a specific processor, in order to meet the requirements of rule 901:3-23-04 of the Administrative Code;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in rule 901:3-23-05 (C)(5) of the Administrative Code and the validation activities specified in rule 901:3-23-06(B) and (C) of the Administrative Code; and rule 901-3-23-03 of the Administrative Code;

(4) Performing the record review required by rule 901:3-23-06(A)(1)(d) of the Administrative Code.

(B) An individual described in paragraph (A) of this rule shall provide the director, upon request, a copy of their certificate of completion for the application of HACCP principles to juice processing.

(C) Job experience may qualify an individual to perform the functions specified in paragraph (A) of this rule. The trained individual need not be an employee of the processor.

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

(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 901:3-3 of the Administrative Code and Chapter 901:3-5 of the Administrative Code; 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 rule 901:3-23-01 (C)(1) and (C)(7) 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 approved 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.

901:3-23-10 **Adulteration.**

Failure of a processor to have and to implement a hazard analysis and critical control point plan that complies with rules 901:3-23-02, 901:3-23-03 and 901:3-23-04 of the Administrative Code, or otherwise to operate in accordance with the requirements of this chapter, shall render the juice products of that processor adulterated under section 3715.59 of the Revised Code. 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 plan.