AUDIT STANDARDS COMPARISON TO THE FDA HAZARD ANALYSIS AND CRITICAL POINT (JUICE HACCP) SYSTEMS REGULATION

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart A—General Provisions				
§120.5 Current good manufacturing practice. Except as provided by 21 CFR §117.5(c), 21 CFR parts 110 and 117 apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.				The exemption in 21 CFR 117.5(c) exempts the processing activities of juice processors from the requirements of subpart C, Hazard Analysis and Risk-Based Preventive Controls, and subpart G, Supply-Chain Program, if the juice processor is in compliance with the juice HACCP regulation with respect to the activities that are subject to part 120. Juice processors must meet the requirements of subparts A, B, and F (for the records required by subpart A) of part 117.
§120.6 Sanitation standard operating procedures.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(a) *Sanitation controls*. Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP 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;				

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(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 in 21 CFR part 110 and in subpart B of 21 CFR part 117 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 SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of 21 CFR 120.6. These records are subject to the recordkeeping requirements of §120.12.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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 21 CFR 120.6, 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;				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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 21 CFR 120.7;				
(4) Review of the current process to determine whether modifications are necessary; and				
(5) Identification of critical control points.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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. 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.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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 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 21 CFR 120.8 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:				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) List all food hazards that are reasonably likely to occur as identified in accordance with §120.7, and that thus must be controlled for each type of product;				
(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate: (i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and (ii) 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;				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(5) Include any corrective action plans that have been developed in accordance with §120.10(a), 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, that the processor will use in accordance with §120.11; and				
(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with §120.12. The records shall contain the actual values and observations obtained during monitoring.				
(c) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with 120.6, they are not required to be included in the HACCP plan.				
§120.10 Corrective actions.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of 21 CFR 120.10. (a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to 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.				
(b) 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 (b)(2) and (b)(3) of 21 CFR 120.10 are met;				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;				
(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; and				
(5) Perform or obtain timely verification in accordance with §120.11, by an individual or individuals who have been trained in accordance with §120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.				
(c) All corrective actions taken in accordance with 21 CFR 120.10 shall be fully documented in records that are subject to verification in accordance with §120.11(a)(1)(iv)(B) and the recordkeeping requirements of §120.12.				
§120.11 Verification and validation.				

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(a) Verification. Each processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.				
(1) Verification activities shall include:				
(i) 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;				
(ii) The calibration of process monitoring instruments;				
(iii) 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 §120.25.				
(iv) A review, including signing and dating, by an individual who has been trained in accordance with §120.13, of the records that document:				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, 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 1 week (7 days) of the day that the records are made;				
(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and				
(C) 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, at a minimum, 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; and				

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(v) The following of procedures in §120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and				
(vi) Additional process verification if required by §120.25.				
(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of 21 CFR 120.11, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of 21 CFR 120.11, are subject to the recordkeeping requirements of §120.12.				

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(b*) Validation of the HACCP plan*. Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 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. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed 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. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of 21 CFR part 120.				

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(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. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with §120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of §120.12.				
§120.12 Records.				
(a) Required records. Each processor shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:				

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(1) Records documenting the implementation of the sanitation standard operating procedures (SSOP's) (see §120.6);				
(2) The written hazard analysis required by §120.7;				
(3) The written HACCP plan required by §120.8;				
(4) Records documenting the ongoing application of the HACCP plan that include:				
(i) 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				
(ii) Corrective actions, including all actions taken in response to a deviation; and				
(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.				
(b) *General requirements.* All records required by 21 CFR part 120 shall include:				
(1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;				

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(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 21 CFR 120.12 need not include the time;				
(3) The signature or initials of the person performing the operation or creating the record; and				
(4) Where appropriate, 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 21 CFR 120.12 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 21 CFR 120.12 shall be signed and dated:				
(i) Upon initial acceptance;				
(ii) Upon any modification; and				

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(iii) Upon verification and validation in accordance with §120.11.				
(d) *Record retention*. (1) All records required by 21 CFR part 120 shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 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 21 CFR 120.12 is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of 21 CFR 120.12.				

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(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.				
(g) *Records maintained on computers*. The maintenance of computerized records, in accordance with part 11, is acceptable.				
(e) Official review. All records required by this part shall be available for review and copying at reasonable times.				
§120.13 Training.				
(a) Only an individual who has met the requirements of paragraph (b) of 21 CFR 120.13 shall be responsible for the following functions:				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 120 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Part 120, juice processors are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., the current good manufacturing process requirements in 21 CFR Part 117 Subpart B).

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) Developing the hazard analysis, including delineating control measures, as required by §120.7. (2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of §120.8; (3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in §120.10(b)(5) and the validation activities specified in §§120.11(b) and (c); and 120.7; (4) Performing the record review required by §120.11(a)(1)(iv).				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) The individual performing the functions listed in paragraph (a) of 21 CFR 120.13 shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.				
Subpart B—Pathogen Reduction				
§120.24 Process controls.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 120 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Part 120, juice processors are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., the current good manufacturing process requirements in 21 CFR Part 117 Subpart B).

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(a) In order to meet the requirements of subpart A of 21 CFR part 120, 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., 105) 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; 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.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(b) All juice processors shall meet the requirements of paragraph (a) of 21 CFR 120.24 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 21 CFR 120.24 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 21 CFR 120.24 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.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
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 21 CFR 120.25, processors shall take subsamples according to paragraph (a) of 21 CFR 120.25 for each of the covered juice products produced.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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.				

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PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 120 (e.g., definitions). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. In addition to meeting the applicable requirements of 21 CFR Part 120, juice processors are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., the current good manufacturing process requirements in 21 CFR Part 117 Subpart B).

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS [Juice HACCP]	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(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).				