GUIDANCE DOCUMENT

Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition

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Center for Food Safety and Applied Nutrition

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Highlights of the Juice HACCP Regulation

- Both interstate and intrastate juice processors must evaluate their processing operations using HACCP principles.
- Effective dates for the regulation are January 20, 2002, January 21, 2003, or January 22, 2004, depending upon the size of your business.
- The regulation does not preempt the existing requirements to follow the current Good Manufacturing Practice (CGMP) regulations for your juice processing operations.
- The HACCP plan and other records of your sanitation standard operating procedures (SSOPs) and HACCP operations must be available for official inspection and copying.
- Employees involved in developing, or in certain aspects of implementing, a HACCP plan, must be trained in HACCP principles.
- The 5-log pathogen reduction must
    - be accomplished for the microbe you identify as the "pertinent microorganism," which is the most resistant microorganism of public health significance that is likely to occur in the juice, e.g., *E. coli* O157:H7,
    - take place in one facility just prior to or after packaging,[(2)] and
    - be applied directly to the juice, except for citrus juices.
- Fruit surface treatments may be used to accomplish the 5-log reduction for citrus fruits, but cleaned and undamaged tree-picked fruit must be used and the effectiveness of the treatment must be verified by regularly testing your product for generic *E. coli*.

- Shelf stable juices made using a single thermal processing step and juice concentrates made using a thermal concentration process that includes all of the ingredients are exempt from the requirement to include control measures in your HACCP plan to achieve the 5-log pathogen reduction, but a copy of the thermal process must be included in your hazard analysis.
- Low-acid canned juice and juice subject to the acidified foods regulation is exempt from the requirement to include control measures in your HACCP plan to achieve the 5-log pathogen reduction, but the juice is still subject to the low-acid canned food regulation, or the acidified foods regulation, as appropriate, and all of the other requirements of the juice HACCP regulation.
- Retail establishments or businesses that make and sell juice directly to consumers and do not sell or distribute juice to other businesses are exempt from the juice HACCP regulation, but must comply with FDA's food labeling regulation in 21 CFR 101.17(g) that requires a warning statement on packaged fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present, and with any applicable state regulations.

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I. Introduction

A. Status

This is the first edition of the Food and Drug Administration's (FDA) "Juice HACCP Hazards and Controls Guidance." FDA recommends that this guidance be used in conjunction with FDA's final regulation (21 CFR Part 120) that requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, to develop and implement HACCP systems (i.e., a system of preventive control measures based upon HACCP principles) for it's operations. The final regulations were published in the Federal Register on January 19, 2001, and become effective one, two, or three years from that date, depending upon the size of your business. We may revise and reissue this guidance from time to time as the state of knowledge advances relative to juice hazards and controls. We will accept public comment on this edition of the guidance at any time for consideration in drafting a future edition. Comments should be submitted to:

U.S. Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Comments should be identified with Docket Number 02D-0333.

B. Purpose

The purpose of this guidance is to assist you in the development of a HACCP plan, should your hazard analysis show that such a plan is necessary under 21 CFR 120.8(a). You will find information in this guidance that will help you identify hazards that may potentially occur in your products, and help you identify and use methods of controlling and preventing hazards. This guidance is also intended to serve as a tool for federal and state regulatory officials in the evaluation of HACCP plans for juice products.

To help you understand some key aspects of the juice HACCP regulation and plan how you will initiate your HACCP activities, we have included information on some other important aspects of the juice HACCP regulation such as effective dates, use of the label warning statement, and training. Additional information on juice HACCP is available at www.cfsan.fda.gov under "Program Areas" and "HACCP." The information available at this website includes the HACCP regulation, the publication, "The Juice HACCP Regulation Questions and Answers," and additional guidance FDA has issued related to the juice HACCP regulation. By periodically checking this website you will have access to the most up-to-date FDA information on juice HACCP. The documents at this website also are available by mail from the address given in section I. C below. In addition, all FDA Compliance Policy Guide (CPG) documents referred to in this guidance are available at Manual of Compliance Policy Guides.

On our website, you can also find background information on fruit and vegetable juice safety, and in particular, foodborne illness outbreaks involving juice that in part, led to the establishment of the juice HACCP regulation. This information can be viewed at: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp (https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp)

C. Scope and Limitations

The controls and practices provided in this guidance are recommendations and guidance from FDA primarily to the juice industry. This guidance is not a set of binding requirements. Importantly, this guidance may not identify all hazards that need to be controlled, and it is the ultimate responsibility of the juice processor to identify all hazards that are reasonably likely to occur and all appropriate controls for such hazards. You may choose to use other control measures, as long as they meet the requirements of the juice HACCP regulation and are consistent with relevant state and federal laws or regulations.

The information contained in section IV provides guidance for determining which hazards are "reasonably likely to occur" in specific types of juice products under ordinary circumstances. This section lists potential hazards for specific types of juice products. We recommend that this information be combined with other relevant information available to you and used in conducting the hazard analysis to determine the likelihood of occurrence of a hazard.

This guidance is not a substitute for a processor's performance of its own hazard analysis as required by FDA's regulations. Hazards not covered by this guidance may be relevant to certain products under certain circumstances. In particular, you should be alert to new or emerging problems.

This guidance does not cover the hazard associated with the formation of *Clostridium botulinum* toxin in juices that are low acid canned foods or shelf stable acidified foods. Mandatory controls for this hazard are contained in the Low Acid Canned Foods regulation (21 CFR Part 113) and the Acidified Foods regulation (21 CFR Part 114). As explained in section VI, such controls need not be included in HACCP plans for these juice products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

II. Terms and Definitions

This section lists definitions of several terms as they appear in FDA's juice HACCP regulation. Following many of the definitions below, you will find *Additional helpful information* about the defined term. Although not formally defined in the juice HACCP regulation, this section also describes the terms "fallen fruit," "hazard analysis," "HACCP," "HACCP plan," HACCP team," "juice concentrate," "pasteurization," "process authority," and "retail establishment."

Cleaned means washed with water of adequate sanitary quality.

Control means to prevent, eliminate, or reduce.

Control measure means any action or activity that is used to prevent, reduce to acceptable levels, or eliminate a hazard.

Additional helpful information: You are required to identify control measures in your hazard analysis for all hazards that were determined to be "reasonably likely to occur" in your hazard analysis. This is illustrated in Column 5 of the Hazard Analysis examples in section VII. A.

Critical control point (CCP) means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to prevent, reduce to an acceptable level, or eliminate an identified food hazard.
Additional helpful information: You are required to identify CCPs in your hazard analysis for all hazards that were determined to be "reasonably likely to occur" in your hazard analysis. This is illustrated in Column 6 of the Hazard Analysis examples in section VII. A.

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 levelthe occurrence of the identified food hazard.

Additional helpful information: You are required to specify critical limits in your HACCP plan for each hazard to be controlled at a critical control point. This is illustrated in Column 3 of the HACCP plan examples in section VII. B.

Culled means separation of damaged fruit from undamaged fruit. Under this guidance, for processors of citrus juices using treatments to fruit surfaces to comply with 21 CFR 120.24, FDA will consider tree-picked, undamaged citrus fruit to be "culled" for purposes of compliance with the juice HACCP regulation. *(Note: The definition of the term "culled" in 21 CFR 120.3(f) includes the requirement that the fruit is of U.S. Department of Agriculture (USDA) choice or higher quality, however, there is no current USDA standard for choice or higher quality.)*

Fallen fruit means fruit that has fallen naturally from the tree to the ground in an orchard. It does not include mechanically harvested fruit, which is obtained by shaking the tree and collecting the fruit from the ground with appropriate mechanical machinery; also called *grounders, windfall fruit, or drops.*

Food hazard means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis and Critical Control Points (HACCP) means a systematic approach to the identification, evaluation, and control of food safety hazards.

HACCP Plan means the written document that is based upon the principles of HACCP and delineates the procedures to be followed.

HACCP Team means the group of people who are responsible for developing, implementing, and maintaining the HACCP system.

Hazard Analysis means the process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Additional helpful information: All juice processors subject to the juice HACCP regulation are required to prepare a written hazard analysis. The hazard analysis process for juice products is covered in section IV. Example hazard analyses for refrigerated pasteurized apple juice, fresh orange juice, and not-from-concentrate pasteurized orange juice are covered in section VII. A.

Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

Additional helpful information: The juice HACCP regulation requires that processors apply HACCP principles if they make juice or juice concentrates for subsequent beverage use. Any processor making a product that could be labeled as 100 percent juice under 21 CFR 101.30, or a concentrate of that juice for subsequent beverage use must apply HACCP principles. For beverages containing less than 100 percent juice, only the juice ingredient must be made applying HACCP principles.

Juice concentrate means the aqueous liquid expressed or extracted from one or more fruits or vegetables and reduced in weight and volume through the removal of water from the juice.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for future use in verification.

Additional helpful information: You are required to specify monitoring procedures including what, how, how often, and who is performing the monitoring, in your HACCP plan for each hazard to be controlled at a critical control point. This is illustrated in the HACCP Plan examples in section VII. B.

Pasteurization means a heat treatment sufficient to destroy vegetative cells of pathogens.

Process Authority means an expert in the processes for controlling pathogenic microorganisms in food, and as such, is qualified by training and experience to evaluate all of the aspects of your pathogen control measures, e.g., process time, temperature, type of equipment, etc., and determine that your control measures, if properly implemented, will control pathogens effectively.

Retail Establishment means an operation that provides juice directly to consumers and does not sell or distribute juice to other businesses. The term "provides" includes storing, preparing, packaging, serving, and selling juice.

Shelf stable productmeans a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

Additional helpful information: If you process certain types of shelf stable juice products, you are exempt from the requirements in 21 CFR 120.24 to include control measures in your HACCP plans for those products for achieving a 5-log reduction in the pertinent microorganism. This exemption applies to the following types of products:

- products subject to the requirements of the Low Acid Canned Foods and Acidified Foods regulations in 21 CFR Parts 113 and 114, respectively
- acidic juices such as canned orange juice and "juice box" style grape juice, which are made shelf stable using a single thermal processing step
- juice concentrates like orange juice concentrate or apple juice concentrate in which all ingredients of the concentrate receive a thermal concentration process

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP system, when properly implemented, will control effectively the identified food hazards.

Additional helpful information: A person trained in accordance with the requirements of 21 CFR 120.13 must validate your HACCP plan initially and at least annually thereafter, or whenever changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way.

Even if your hazard analysis shows that there are no food hazards that are reasonably likely to occur during the processing of your juice, a person with appropriate training or experience must validate your hazard analysis. In addition, your hazard analysis must be reassessed (e.g., revalidated) by a person with appropriate training or experience whenever there is any change in the process that could reasonably affect whether a food hazard exists.

Section 120.25 of the juice HACCP regulation also describes circumstances in which it may be necessary to revalidate your HACCP plan due to process deviations, problems noted in the weekly review of monitoring records, or positive generic *E. coli* test results for certain citrus juices.

Verification means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan. It includes validation procedures.

Additional helpful information: Section 120.11 specifies certain actions, e.g., a review of consumer complaints and a review of records of the monitoring of CCPs, which you must carry out as part of your verification activities. You should review this section and take note that review of records for verification purposes must be carried out by an appropriately trained or qualified individual (as set forth in Section 120.13) within a specified period of time.

III. Overview of the Juice HACCP Regulation

Section III provides a brief discussion of the juice HACCP regulation. The section includes details on who must comply, the deadlines for compliance, the key requirements, the CGMPs requirements, and the exemptions to the regulation.

A. Compliance Required for All Juice Processors

All juice (as defined in 21 CFR 120.1(a)) sold as juice or for use as an ingredient in other beverages is subject to the requirements of the juice HACCP regulation, with the exception of juice produced at a retail establishment (i.e., for sale directly to consumers only; see definition of "Retail Establishment"), (However, see subpart D 1.0 of this section for information about labeling requirements for certain juices produced at a retail establishment).

1.0 Intrastate and Interstate Firms

The regulation's requirements apply equally to juices produced and sold within the same state as well as juices sold in interstate commerce.

2.0 Effective Dates--Very Small Businesses, Small Businesses, All Others

The requirements take effect on the following dates. However, FDA recommends that all firms implement HACCP as quickly as possible.

- January 20, 2004, for very small businesses (as defined in 21 CFR 120.1(b)(2)) which are those operations that have either total annual sales of less than $500,000, or have total annual sales greater than $500,000 but their total food sales are less than $50,000, or are operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the United States.
- January 21, 2003, for small businesses (as defined in 21 CFR 120.1(b)(1)) which are those operations employing fewer than 500 persons.
- January 22, 2002, for all businesses not defined as "small businesses" or "very small businesses."

3.0 Juice Importers

Section 120.14 of the juice HACCP regulation specifically describes requirements for imported juice. In brief, if you are an importer of juice you must either:

- ensure that all juice offered for import into the U.S. has been processed in compliance with the juice HACCP regulation, or
- import juice from a country that has an appropriate memorandum of understanding (MOU) with the U.S. that covers juice and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety (At this time, no such MOU has been established with any country concerning juice. Should an MOU be established with any country concerning juice, FDA will publish a notice to this effect in the Federal Register and make the MOU available on its website.)

In addition, if you import juice, you are required to maintain records that document the performance and the results of your affirmative steps as specified in 21 CFR 120.14 (a)(2)(ii).

4.0 If You Process a Non-Juice Beverage with a Juice Ingredient

The juice HACCP regulation applies to the processing of any product that may be labeled as 100 percent juice under 21 CFR 101.30 that is sold either as "juice" or for use as an ingredient in beverages. Non-juice beverages that contain juice as an ingredient, e.g., carbonated beverages that contain juice, or fruit flavored drinks that contain juice, are not required to be produced under a HACCP system. However, juice that is used as an ingredient in the non-juice beverage is required to be produced under a HACCP system.

B. Some Key Requirements of the Juice HACCP Regulation

1.0 Warning Label Statement Versus HACCP System

Since September 8, 1998, for apple juice (including apple cider) and November 5, 1998, for all other juices, 21 CFR 101.17(g) has required that any container of juice that has not been treated to achieve a 5-log reduction in the most resistant pathogen bear a warning label informing consumers of the risk associated with consuming untreated juice. Upon your applicable date of coverage under the HACCP regulation, you may no longer sell juice that has not been treated to achieve the 5-log pathogen reduction, even if you use the label warning statement. You may continue to use the label warning statement until your applicable effective date. For example, after January 22, 2003, very small businesses may still use label-warning statements for an additional year. After the respective effective date, the label warning statement is no longer an alternative to compliance with the HACCP regulation.

2.0 Specialized Training in HACCP Principles Required

Individuals who perform certain functions, such as developing the hazard analysis and HACCP plan and reviewing the HACCP records, must have successfully completed training in the application of HACCP principles to juice processing. The training must be at least equivalent to that received under the standardized curriculum described in section VI. B.

Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

The training requirements are in 21 CFR 120.13. Insection VI. B. we have listed several sources of information about HACCP resource materials and HACCP training.

3.0 Trained Employee or Consultant Acceptable

The trained individual who performs functions under the juice HACCP regulation, such as development of your HACCP plan, may be an employee of the processing firm, an outside consultant, or both. For example, you may retain a qualified consultant to carry out the hazard analysis and use a trained plant employee to carry out the periodic review of HACCP records.

4.0 Record Keeping and Electronic Records

You must maintain several types of records to document each HACCP system. These records include records pertaining to sanitation standard operating procedures (SSOPs), the hazard analysis, the HACCP plan, and operational records such as records of monitoring, corrective actions, and verification and validation activities. These requirements are listed in 21 CFR 120.12.

When the records required by the HACCP regulation are to be collected electronically, we recommend that the systems used to generate the electronic records comply with the electronic records and electronic signature provisions of 21 CFR Part 11. These regulations address procedures for system validation, system access, audit trails, authority and data checks, user education, documentation control, and if used in conjunction with electronic signatures, electronic signature control. Most of today's processing systems of today have incorporated an electronic record keeping system for all of the process control variables. For example, if pasteurization, which is a heat treatment sufficient to destroy the vegetative cells of pathogens, is used as a control step, and the system incorporates an electronic control/recording system, the electronic record data generated for temperature and time would be an electronic record and the data c ollection system should be in compliance with 21 CFR Part 11.

4.1 Official Review of Records

You must make certain records available for review and copying by the regulatory agency at reasonable times. 21 CFR 120.12 lists these records.

C. Part 110 (CGMPs) Applicable to Firms Subject to Juice HACCP Regulation

When your firm becomes subject to the juice HACCP regulation, you must still comply with the CGMPs requirements in 21 CFR Part 110. Compliance with the juice HACCP regulation does not substitute for compliance with 21 CFR Part 110. In fact, compliance with 21 CFR Part 110, e.g., maintaining appropriate sanitation, employee hygiene, and pest control practices in a facility, is an essential foundation for a successful HACCP system.

D. Exemptions and Items Not Subject to the Regulation

1.0 Retail Businesses

If you qualify as a retail establishment, you are not required to process juice under a HACCP system. However, packaged juice produced at a retail establishment is subject to FDA's food labeling regulation in 21 CFR 101.17(g), which requires a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms.

A retail establishment is an operation that provides juice directly to consumers and does not sell or distribute juice to other businesses. The term "provides" includes storing, preparing, packaging, serving, and selling juice.

If you hire someone to make juice from your fruit and sell the juice at your roadside stand, you, the retailer, are exempt from the juice HACCP regulation, but the processor who makes your juice is subject to the regulation. That processor is not a retail establishment because the processor is not selling the juice directly to consumers.

If you produce your own juice and sell it at your roadside stand, and also sell or distribute some of your juice to other businesses to sell or resell, your juice must be processed under a HACCP system because you are not providing all of the juice directly to consumers.

For more information on what types of businesses qualify as retail establishments, see the publication, "Juice HACCP Regulation Questions and Answers (see section I. C for availability information).

2.0 Non-Beverage Foods with Juice Ingredient (e.g., fruit flavored candy)

The juice HACCP regulation only applies to the processing of juice that is sold either as juice or for use as an ingredient in beverages. Thus, in the case of a non-beverage food, such as a fruit flavored candy that contains juice as an ingredient, neither the candy nor the juice ingredient is subject to the requirements of the juice HACCP regulation. Processors may find it beneficial to use HACCP systems voluntarily to produce such foods.

3.0 Processors of Ingredients from Fruit Other than Juice

Food ingredients other than juice that are derived from fruits and vegetables, e.g., citrus oil, are not subject to the juice HACCP regulation. The juice HACCP regulation applies only to juice that is sold either as juice or for use as an ingredient in beverages and not to any other fruit or vegetable product.

IV. Juice Hazard Analysis

Section IV begins with a definition of hazard analysis and outlines a process that will help prepare you to conduct the analysis, covers the basic steps of a hazard analysis, and identifies potential hazards for juice and juice products.

A. Overview of the Hazard Analysis

1.0. Description

The juice hazard analysis is a process of collecting and evaluating information on hazards associated with juice, to determine which hazards are reasonably likely to occur and, thus, pursuant to 21 CFR 120.8(a) must be addressed in a HACCP plan.

Under 21 CFR 120.7(a), you are required to produce, for each type of juice you process, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur and to identify measures that you can apply to control those hazards. This is illustrated in the hazard analysis examples in section VII.A. The regulation requires a written hazard analysis for each type of juice unless different types of juice have identical hazards and control measures and then they may be grouped in one hazard analysis.

2.0 Relevance to HACCP Plan and SSOPs

All juice processors subject to the juice HACCP regulation are required to prepare a written hazard analysis.

If you determine that any hazard is "reasonably likely to occur" in a particular juice product, pursuant to 21 CFR 120.8(a), you must control that hazard in the product by applying control measures as part of a properly designed and implemented HACCP plan, except that some hazards for which you could reach this conclusion may be controlled under your SSOPs as discussed in section IV.[3] C. 3.2. If you produce a shelf stable juice or a thermally concentrated juice as described in 21 CFR 120.24, and you determine that no hazards are "reasonably likely to occur" in your juice, you are not required to develop a HACCP plan, but you must establish and implement SSOPs as required under 21 CFR 120.6. Your SSOP monitoring and corrective action records and your hazard analysis are still subject to the record keeping and official record review requirements in 21 CFR 120.12.

3.0 Developed by HACCP-trained Employee or Consultant

Your hazard analysis must be developed by an appropriately trained individual (or individuals), as specified in 21 CFR 120.13. This person may be your employee or a hired outside expert.

B. Preparing for a Hazard Analysis - Five Preliminary Steps

Although not required by FDA, the 5 preliminary steps of HACCP as outlined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will help you in conducting your hazard analysis and developing your HACCP plan, and will prove valuable for other HACCP functions. The recommended steps are:

Step 1 Assemble a HACCP team.

Step 2 Describe the food and its distribution.

Step 3 Identify the intended use and consumers of the food.

Step 4 Develop a flow diagram that describes the process.

Step 5 Verify the flow diagram, *i.e., ensure that it is accurate*.

For more information, see the NACMCF publication *"Hazard Analysis and Critical Control Point Principles and Application Guidelines,"* Journal of Food Protection*, Vol. 61, No. 9, pp. 1246-1259 (1998)* (the "HACCP Principles and Guidelines" publication).

C. Basic Steps of the Hazard Analysis

In order to prepare the written hazard analysis, your HACCP team should carry out the basic steps of a hazard analysis as described in the following sections 1.0-4.0 of this guidance. In carrying out these steps, we recommend that your team refer to Appendix C, "Examples of Questions to be Considered When Conducting a Hazard Analysis" and Appendix D, "Examples of How the Stages of Hazard Analysis Are Used to Identify and Evaluate Hazards" in the HACCP Principles and Guidelines publication.

1.0 Identify All Potential Hazards

Step 1 -- We recommend that you shouldidentify all potential physical, chemical, and biological hazards associated with the juice. Section 120.7 (c) lists specific types of hazards, e.g., natural toxins, microbial contaminants, undeclared allergenic ingredients, that at a minimum, we recommend be considered in your hazard analysis.

In this section, we have included some specific biological, chemical, and physical hazards that we recommend you consider in your hazard analysis. However, depending on your product, process, equipment, and facility, you may need to consider additional hazards in your hazard analysis.

1.1 Biological Hazards

1.11 Pathogens that may Occur in Acidic Juices (pH 4.6 or less)

Acidic juices (pH 4.6 or less) containing enteric bacterial pathogens such as *E. coli* O157:H7, various Salmonella species, and the protozoan parasite *Cryptosporidium parvum* have caused serious foodborne illness outbreaks. Some of the illnesses associated with juices have been very severe (e.g., cases of long-term reactive arthritis and severe chronic illness). In one case, consumption of contaminated juice resulted in the death of a child and in another case, consumption of contaminated juice contributed to the death of an elderly man. These microorganisms inhabit the intestinal tracts of animals; when animals and their manure or feces share proximity in an environment, produce can become contaminated, either directly or indirectly through such means as contaminated irrigation water or runoff. The use of contaminated produce to produce the juice, and the ability of some of these pathogens to survive in acidic foods like juices, along with use of inadequate controls for these pathogens during juice processing, are believed to be among the causative factors for these outbreaks. Illness-causing organisms that are ubiquitous in nature, such as *Listeria monocytogenes*, have also been identified as possible contaminants in juice. Guidance on selecting the pertinent microorganism for acidic juices for purposes of meeting the 5-log pathogen reduction requirement is provided in Section V. C. 1.1.

1.12 Pathogens that may Occur in Low-acid Juices (pH greater than 4.6)

While enteric pathogens present in acidic fruit juices have been the cause of most food-borne illness outbreaks associated with juice, these are not the only types of harmful microorganisms that could occur in juice. We recommend that a processor of low acid juices, such as carrot juice, that are distributed under refrigeration and that are not subject to the Low Acid Canned Foods regulation (in 21 CFR Part 113) give consideration to toxins produced by non-proteolytic and proteolytic strains of *Clostridium botulinum* as potential hazards to be controlled under its HACCP plan. Guidance on control measures and on selecting the pertinent microorganism for low-acid juices for purposes of meeting the 5-log pathogen reduction requirement is provided in Section V. C. 1.1.

1.13 Pathogen Hazard Identification/Evaluation for Acidic Shelf Stable Juices

If you produce acidic shelf stable juice, under 21 CFR 120.24 (a)(2), you are exempt from the requirement to include control measures in your HACCP plan for the control of microbial pathogens. We recommend that you identify the relevant pertinent microorganism for your juice, e.g., salmonella, as a potential hazard in the hazard identification phase of your

hazard analysis, but in the hazard evaluation phase, you may conclude that such hazards are not reasonably likely to occur because the product is processed to achieve shelf stability. A partial hazard analysis summary table (illustrating only the receipt of raw fruit and pasteurization steps) for such an analysis could be as follows:

(1) Ingredient/Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for Column 3	(5) What preventative measure(s) can be applied to prevent/reduce/elimin-ate the hazard?	(6) Is this step a critical control point? (Yes//No)
Receipt of raw fruit	B - pathogens such as *Salmonella*	No	Product is shelf stable per attached process. 21 CFR 120.24 (a) (2) provides exemption for 5-log reduction requirement for juice processors producing shelf stable product		
Pasteurization	B - pathogens such as *Salmonella*	No	Product is shelf stable per attached process. 21 CFR 120.24 (a) (2) provides exemption for 5-log reduction requirement for juice processors producing shelf stable product		

1.14 Viruses

Juices contaminated with viruses have been implicated in foodborne illness outbreaks.
Contamination of food by viruses is most likely to be caused by an ill individual, such as a farm worker or food handler. Thus, contamination of juice by viruses is not likely to occur in a processing facility that controls, under its SSOPs, employee health and hygiene conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces.

We also encourage you to work with your suppliers to promote their use of FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," (FDA's GAPs guidance document). This guidance document (see Section V. B. 1.0 below for availability information) includes provisions that address worker health and hygiene for individuals that handle the fruits and vegetables you use to produce juice.

1.2 Chemical Hazards

1.21 Patulin

Patulin is a mycotoxin that is produced by fungi commonly found on apples. High levels of patulin can be produced in rotting or moldy apples. Fallen fruit, apples that have been damaged, e.g., by insects or birds, or bruised, e.g., during handling, are more susceptible to the growth of patulin-producing molds. Storage of apples under conditions that are not inhibitory to the growth of molds also can lead to high levels of patulin in the apples. If fallen fruit, moldy, rotten, bruised or damaged apples, or improperly stored apples, are used to make juice, high levels of patulin may occur in the juice, including pasteurized juice, because thermal processing does not destroy patulin.

Exposure over time to high levels of patulin may pose a health hazard. FDA has established an action level[4] for patulin in apple juice of 50 micrograms per kilogram (50 parts per billion) as determined on single strength apple juice or reconstituted single strength apple juice. (See FDA's Compliance Policy Guide (CPG Section 510.150) concerning patulin; section I. C provides availability information.) In fact, if one rotten apple (containing >10,000 parts per billion (ppb) patulin) is used along with 200 sound apples to make juice, the resulting patulin level in the juice could exceed FDA's action level for patulin.

1.22 Undeclared Food Allergens[5] in Juice due to Cross-Contact from Shared Processing Equipment

If you are a juice processor and handle other foods containing allergenic food ingredients in the same facility, you should consider the potential for hazards from cross-contact of your juice by other food substances that can cause allergic reactions.

A chemical hazard (specifically, an undeclared food allergen) can occur when juice is processed on equipment that has been used to process a potentially allergenic food without adequate cleaning prior to the juice run. FDA believes that there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies:

1. Peanuts
2. Soybeans
3. Milk
4. Eggs
5. Fish
6. Crustacea
7. Tree nuts
8. Wheat

For instance, inadvertent introduction of milk protein into juice can occur if juice is processed using inadequately cleaned equipment previously used to produce milk or a dairy-based beverage. An individual who is allergic to milk could face a potentially serious and unexpected health risk upon consuming the juice containing the milk protein.

Under 21 CFR 120.6 of the juice HACCP regulation, you may address these types of potential hazards by establishing effective equipment cleaning procedures at a CCP in your process, or as part of your SSOPs. (Section IV. C. 3.4, discusses this issue.)

FDA has issued a Compliance Policy Guide (CPG Section 555.250) entitled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (see Section I. C for availability) and an inspection guide entitled "Guide to Inspections of Firms Producing Products Susceptible to Contamination with Allergenic Ingredients" (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/manual-compliance-policy-guides (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/manual-compliance-policy-guides)). We encourage you to read these documents and consider the information in them as you establish your HACCP system.

1.23 Allergens and Food Intolerance Substances Added to Juice as Ingredients

The juice HACCP regulation applies to any juice, juice concentrate, or puree product that could be labeled as 100 percent juice in accord with the requirements of 21 CFR 101.30, "Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice." Some products that may be labeled as 100 percent juice under 21 CFR 101.30 also may contain added ingredients such as soy protein or a preservative such as sulfites, which can cause allergic or allergic-type (food intolerance) reactions in sensitive individuals. Because these types of products are juice with added ingredients, and not beverages that contain juice as an ingredient (e.g., a flavored bottled water or a dairy-based beverage with juice), these products are subject to the HACCP regulation. Should any ingredient of a 100 percent juice product have the potential to cause allergic or allergic-type (food intolerance) reactions in sensitive individuals, the presence of the ingredient must be declared on the label in accord with the food labeling regulations in 21 CFR Part 101. Controls to ensure that proper labels are used should be part of your HACCP plan. The following is a list of some ingredients for which we recommend that you implement such controls:

1. Any of the 8 foods listed in Section 1.22
2. Sulfites, in concentrations of 10 parts per million (ppm) or greater
3. FD&C Yellow No. 5

1.24 Pesticide Residues

Pesticides are used widely to treat (e.g., for insect control) fruits, vegetables, grains, and other foods, and may be present in small amounts as residues on these foods. Before a pesticide may be sold in the United States, the Environmental Protection Agency (EPA) evaluates the pesticide and determines whether or not to grant a registration that permits its sale and use. For pesticides used on foods, EPA also must establish a tolerance, which is the amount of residue legally permitted to remain in or on each treated food commodity, or an exemption from the requirement of a tolerance for the pesticide residue on the particular commodity.

Residues from unapproved pesticides, or residues in excess of pesticide tolerances, are illegal and could pose a potential hazard in juice warranting control in a HACCP plan if the residues occurred over a period of time at levels capable of causing health effects from repeated exposure, or if they occurred for only a brief period of time at levels capable of causing acute health effects. See additional information on pesticides in section IV. C. 2.0.

1.25 Lead

Juice can become contaminated with lead if lead-contaminated produce is used to make the juice. Lead contamination of produce can occur as a result of past use of lead in agricultural settings. For example, past use of lead arsenate as a pesticide in what were apple orchards is believed to have caused persistent lead contamination of the soil causing carrots presently grown on these sites to contain elevated lead levels. Produce could also become contaminated with airborne lead if it is handled at sites where vehicles or equipment are operated that use leaded fuel, if the equipment is operated in a manner that exposes the produce to excessive emissions from the equipment.

Lead is especially hazardous to young children. In 1993, FDA established an emergency action level of 80 ppb and above for lead in juice packed in lead soldered cans. (See the Federal Register notice of April 1, 1993 (58 FR 17233).) However, based upon a recent toxicological assessment for lead carried out by the Joint WHO/FAO Expert Committee on Food Additives, the Codex Alimentarius Commission, an international food standards organization that establishes safe levels for the protection of consumers, has recently established a maximum level of 50 ppb for lead in ready-to-drink fruit juices, including fruit nectars that are in international trade, to protect the public health. FDA concurs with this recent assessment that lead levels in juice above 50 ppb may constitute a health hazard, and FDA may in the future establish an action level for lead in juice at levels above 50 ppb. If you determine that lead is a hazard that is reasonably likely to occur in your juice, we recommend that you establish controls to ensure that lead levels do not exceed 50 ppb.

If produce used to make your juice is to be purchased from a source, e.g., a country, a geographic region, or a local region, that is known or suspected to have lead contamination problems with produce, you should consider in your hazard analysis whether lead is a hazard that is reasonably likely to occur. If you determine that lead is a hazard that is reasonably likely to occur, you could control this hazard by requiring a supplier guarantee specifying that the shipment of fruit supplied was harvested from sources known not to yield lead-contaminated fruit. (See section V. D on "Control strategies for patulin for apple juice processors" for examples of how control measures for incoming fruit based upon a supplier guarantee could be incorporated into your HACCP plan.) It also would be useful as a periodic verification activity to test your juice to affirm the efficacy of your controls for lead.

1.26 Tin

Tin is used frequently as a coating in unlacquered metal cans used to pack light colored juices, such as pineapple juice. Typically, some tin plating leaches into the juice in small amounts that help retain the light color of the juice due to the antioxidant activity of tin. These small amounts generally do not pose any potential harm.

However, some factors that may be encountered in juice processing can contribute to excessive amounts of tin leaching into juice. The manner in which these factors affect the leaching of tin into juice is complex. These factors include the amount of ions such as nitrate and sulfate in the juice (e.g., as affected by the level of nitrate in the soil in which a fruit or vegetable is grown and the level of nitrate in water used to reconstitute juice concentrate), the amount of residual oxygen in the metal can after the juice is packed, the thickness of the tin layer of the container, the presence of certain food components in the juice (such as organic acids and pigments), the length of time and the temperature of storage of the juice, and the pH of the juice, including the presence of any additive that can affect its pH.

Consumption of juice containing excessive levels of tin can lead to acute gastrointestinal illness. The Codex Alimentarius Commission is considering establishing a maximum level of 200 ppm for tin in canned liquid foods for the protection of consumers.

Although it is not common for levels of tin in canned juice to approach 200 ppm, if you pack juice in unlacquered metal cans, we recommend that you know what levels of tin are present in your juice after the longest anticipated storage time at the highest anticipated storage temperature for the juice. If the tin levels in your juice may approach 200 ppm, you should consider whether excessive levels of tin is a hazard that is reasonably likely to occur, i.e., if it is necessary for you to establish control measures to ensure that your juice will not contain harmful tin levels due to leaching of tin from the container into the juice.

1.3 Physical Hazards

1.31 Glass Fragments

We recommend that consideration of potential hazards associated with glass breakage be a part of your hazard analysis if you package your juice in glass. Glass fragments in juice caused by glass bottle breakage may result in serious injury and can be caused in a number of ways, including damage to bottles in transit to the juice processing facility, damage to bottles

during mechanized handling (cleaning, filling, or capping) of bottles, and thermal shock to the glass during hot filling or pasteurization. If you conclude in your hazard analysis that glass fragments are a hazard that is reasonably likely to occur in your juice, you must establish controls for glass fragments in your HACCP plan.

Glass fragments originating from facility related sources and not from glass containers, e.g., from a broken light bulb, may be addressed where applicable under your SSOPs (See 21 CFR 120.6 (a)(5)).

1.32 Metal Fragments

We recommend that consideration of potential hazards associated with metal fragments be a part of your hazard analysis if you conduct operations such as the grinding of fruit, or cutting operations, where metal fatigue or metal to metal contact can occur in your processing equipment. If your process includes such operations, we recommend that you classify metal fragments as a hazard that is reasonably likely to occur in the absence of data or experience about your operation that shows that your process does result in the presence of metal fragments in juice when there are no controls in place. For instance, if you have used a metal detector in your process for a year, and have had no occurrences of metal fragments in your juice, you could conclude that metal fragments are not a hazard that is reasonably likely to occur in your process. If you conclude in your hazard analysis that metal fragments are a hazard that is reasonably likely to occur in your juice, you must establish controls for metal fragments in your HACCP plan.

2.0 Evaluate All Potential Hazards

Step 2 -- The second step of a hazard analysis is to evaluate each of the potential hazards (from Step 1) by assessing the likelihood of occurrence and the severity of health consequences associated with the potential hazard. For instance:

- Microbial pathogens such as *E. coli* O157:H7, various *Salmonella* species, and the protozoan parasite *Cryptosporidium parvum*, have caused serious foodborne illness outbreaks due to consumption of contaminated juice, which resulted in hospitalizations and deaths. Any occurrence of pathogens such as these in juice is capable of causing severe adverse health effects, including death, particularly in the very young, the elderly, and immune-compromised persons. The juice HACCP regulation includes a 5-log pathogen reduction performance standard that requires you to establish controls in your HACCP plan for the "pertinent microorganism." Because a mandatory control measure for pathogens is part of the juice HACCP regulation, your responsibility in the hazard evaluation step is not to assess the severity of the illness or injury that a pathogen could cause (to determine whether control is necessary), but to determine which pathogen is the "pertinent microorganism" in your juice (that is, the most resistant pathogen among those potentially present), which is the pathogen that your process controls must be designed to eliminate. See section V.C.1.1 for more information on selecting the pertinent microorganism and establishing process controls to meet the 5-log pathogen reduction performance standard.
- Although potential hazards that may be introduced into food through pests in your facility may be of low to moderate severity, they are unlikely to occur if your facility carries out an effective pest control program as part of its SSOPs.
- Numerous U.S. government regulatory programs address aspects of pesticide usage, e.g., applicator licensure, usage instructions on the label, official monitoring of pesticide residues in foods, and enforcement actions against violators. Experience in the U.S. has demonstrated that domestically grown fruits and vegetables have a high level of compliance with U.S. pesticide tolerance regulations and that the occurrence of unlawful pesticide residues in food is likely to be infrequent and unlikely to have a severe public health impact. While pesticide compliance experience for imported fruits and vegetables is generally comparable to that for domestic produce, you should ensure that government controls in the foreign country that supplies your produce result in a high rate of compliance with U.S. pesticide tolerance regulations. If you can't achieve this assurance you should evaluate carefully whether pesticide residues pose a hazard that may warrant control under your HACCP plan.
- Exposure over time to high levels of patulin may pose a health hazard. Available information indicates that high levels of patulin may occur in apple juice if controls are not carried out to prevent this occurrence.

3.0 Determine Whether Potential Hazards Will Require Controls in Your HACCP Plan

Step 3 -- The third step of the written hazard analysis is to determine, based upon the information gathered in steps 1 and 2, whether each potential hazard will require controls in your HACCP plan pursuant to 21 CFR 120.8(a).

A hazard that will require control is referred to in the juice HACCP regulation as a hazard that is "reasonably likely to occur." Section 120.7(a)(2) describes such a hazard as "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."

A hazard that is "reasonably likely to occur" is one that presents an identifiable and significant food safety risk that you, acting as a responsible processor, would act to reduce to an acceptable level, prevent or eliminate, by establishing and carrying out control measures for that hazard. Generally, you will carry out your control measures at CCPs (which are specific points in the process for producing juice) identified in your HACCP plan.

3.1 Potential Hazards "Reasonably Likely to Occur"

If a potential hazard has a severe, acute public health impact (e.g., cuts in the mouth caused by ingestion of glass container fragments), that hazard presents a significant risk, even at an extremely low frequency of occurrence, and thus, should be identified as a hazard that is reasonably likely to occur.

Hazards that require exposure over time to cause harm would need to occur over time at levels of concern in the juice to be classified as a hazard that is reasonably likely to occur. The mycotoxin, patulin, which can occur at high levels in apple juice, is an example of a hazard that could result over time from exposure to a contaminant and thus, may need to be controlled through your HACCP plan.

3.2 Potential Hazards "Not Reasonably Likely to Occur"

Your HACCP team may identify a potential hazard for your juice, that upon further evaluation is determined not to require control. For example, processors of carrot juice may identify lead as a potential hazard because high lead levels have recently occurred in some carrot products apparently due to the carrots being grown in soils contaminated with lead from the past application of a no longer permitted, lead-containing pesticide to orchards formerly on the land. However, you may be able to establish that the land upon which your supplier grows carrots is not contaminated with lead, or that crops were never grown on that land that would have had lead-containing pesticides applied to them. Having established either of these premises, you could conclude appropriately that elevated levels of lead are not reasonably likely to occur in the carrots that you use to make juice. However, if you acquire a new supplier of carrots, you should reassess the potential for elevated levels of lead to pose a hazard in your juice as part of the re-validation of your hazard analysis required in 21 CFR 120.11 (b).

3.3 Hazards Related to Facility Sanitation

FDA recognizes that hazards controlled by most types of sanitation programs may be impractical to manage in a HACCP plan format because it is often difficult to determine appropriate critical limits and corrective actions for sanitation controls.

Therefore, when you conduct your hazard analysis, and identify hazards that derive from any of the eight areas listed in 21 CFR 120.6 (a), you may usually classify such hazards as "not reasonably likely to occur," and control those hazards under your SSOP program. As provided in 21 CFR 120.6 (d), you also have the option to control any of these sanitation- related hazards under your HACCP plan using a control measure implemented at a CCP.

Examples of potential hazards that may be controlled under your SSOP program include substances used on juice processing equipment, such as lubricants and sanitizing chemicals, or substances applied to juice packaging materials under the provisions of a food additive regulation, such as hydrogen peroxide that is used to sterilize packaging materials on aseptic packaging lines for juice. If you have SSOPs designed to ensure that the substance will be used in accord CGMPs or with the provisions of the applicable food additive regulation, you may, in your hazard analysis, cite the SSOP as a justification for determining that the hazard is not reasonably likely to occur. Examples of this approach are included in the Example Hazard Analyses in section VII A for pasteurized refrigerated apple juice (the sanitizer used for cleaning the holding tank) and for not-from-concentrate pasteurized orange juice (the lubricant used on the extraction equipment). In addition, the following partial hazard analysis summary table for an aseptic juice packaging operation (illustrating only the aseptic filling and packaging step) where hydrogen peroxide is used as a sterilant illustrates the same approach.

(1) Ingredient/Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for Column 3	(5) What preventative measure(s) can be applied to prevent/reduce/eliminate the hazard?	(6) Is this step a critical control point? (Yes//No)

(1) Ingredient/Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for Column 3	(5) What preventative measure(s) can be applied to prevent/reduce/eliminate the hazard?	(6) Is this step a critical control point? (Yes//No)
Aseptic filling and packaging	Hydrogen peroxide	No	Not reasonably likely to occur due to SSOP to ensure compliance with the maximum level of hydrogen peroxide residual allowed by regulation (21 CFR 178.1005; of 0.5 ppm in water filled and packaged in the system.)		

However, a special concern exists with respect to unsanitary food contact surfaces that can contaminate juice with residues of food processed on the equipment in prior runs that contain allergens. If the allergen containing food is not declared on the ingredient label, consumption of the juice and that can cause allergic reactions in sensitive individuals. Undeclared food allergens that arise from unsanitary food contact surfaces could pose a severe food safety hazard, if they occur in juice. As such, we recommend that these types of hazards should be classified as "reasonably likely to occur" and controlled in your HACCP plan if you determine that control measure(s) are necessary for the hazard. However, as provided in 21 CFR 120.6 (d), you may elect to control such a hazard under your SSOP program.

3.4 Controls for Allergens Arising from Food Contact Surfaces

As noted in the previous section, hazards that arise in juice processing from unsanitary food contact surfaces that can contaminate juice with residues of food allergens should be considered to be "reasonably likely to occur." We recommend that you control such hazards under your HACCP plan and not under your SSOPs when the hazard is amenable to control at a CCP because we believe that control at a CCP will afford a greater level of assurance of public health protection due to the validation and verification activities that are carried out for CCP controls and due to inclusion of the written CCP control procedures in the HACCP plan. To be amenable to control at a CCP, the control measure must lend itself to validation and to the establishment of critical limits. We may question the adequacy of a HACCP plan to control hazards that may arise from unsanitary food contact surfaces when the plan does not include rigorous SSOP controls, or where applicable (as discussed in the next paragraph), CCP controls for such hazards.

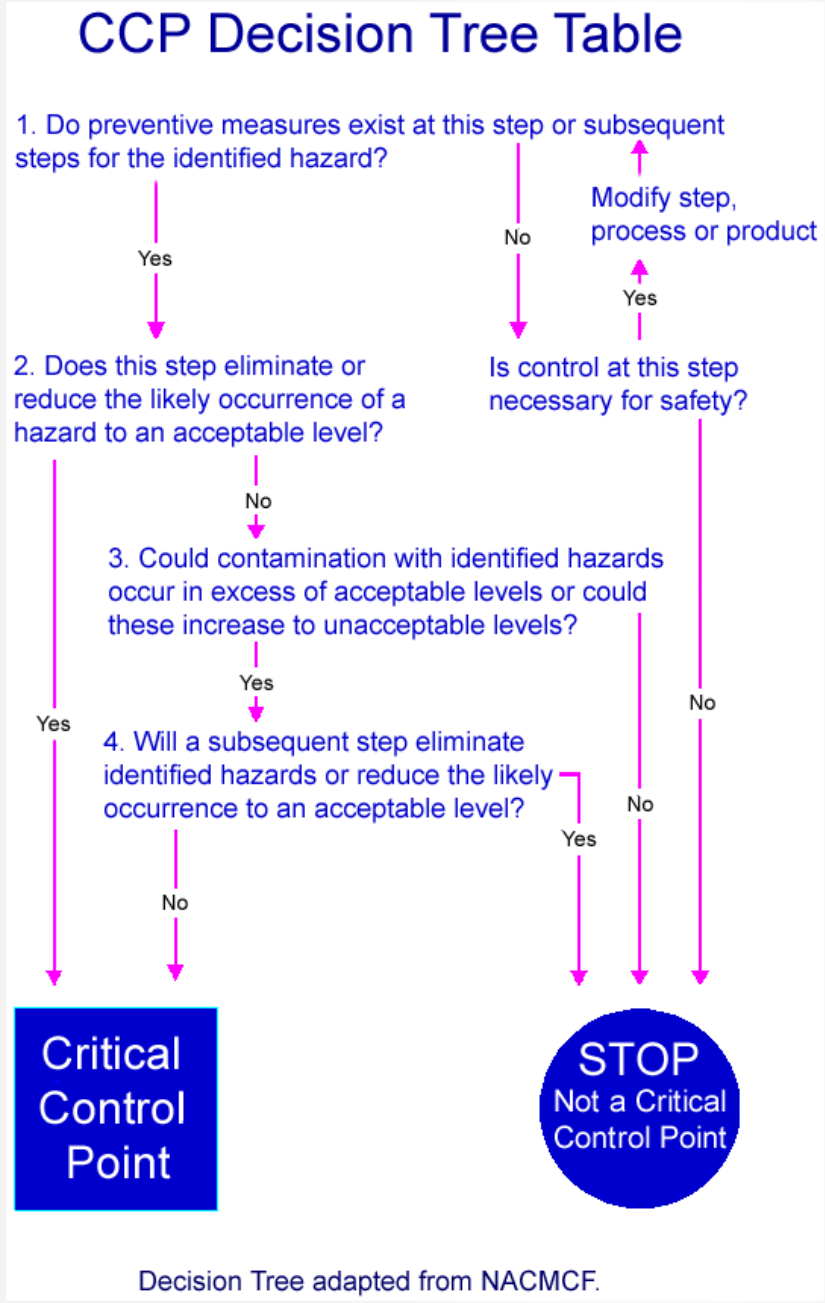
For example, if you produce juice on equipment that also is used to process milk, we recommend that you identify undeclared milk residues in your juice as a hazard that is "reasonably likely to occur." If a control measure for cleaning food contact surfaces to avoid contamination with milk residues from prior product runs is available to you and it can be validated, and critical limits can be established, we recommend that you incorporate such a control measure into your HACCP plan at a CCP rather than control the hazard under your SSOP program. If it is not possible to validate control measures for cleaning food contact surfaces, and critical limits cannot be established, your control activity would not be amenable to incorporation into a CCP and you would have to control the hazard through a rigorous SSOP procedure. Examples of a CCP and an SSOP for cleaning operations are given in Section VII. C.

4.0 Identify Control Measures and CCPs

Step 4 -- The fourth step in a written hazard analysis is to identify control measures and critical control points for hazards determined in step 3 to be reasonably likely to occur, and to review your current process to identify needed modifications to the process control measures are discussed in section V.

4.1 NACMCF CCP Decision Tree

This NACMCF CCP decision tree may assist you in determining critical control points for controlling the hazards that were identified in your hazard analysis as reasonably likely to occur.



4.2. Location of CCPs

A CCP may be established at any process step where you can effectively apply controls. See the Example Hazard Analyses and Example HACCP Plans in sections VII A and B. For instance, for a pasteurized apple juice process that includes controls for pathogens and for the mycotoxin patulin:

- CCPs for the control of patulin may be established at the receiving step at the processing facility at which time the shipment of apples can be checked to ensure that it originated from a supplier who has provided a guarantee that only apples harvested to exclude fallen fruit were supplied in the shipment, and at the culling or trimming steps, where bruised, damaged, moldy and rotten apples are removed from the product stream.
- A CCP may be established at the pasteurization step where treatment to achieve the 5-log pathogen reduction will be carried out.

Similarly, for a fresh orange juice process, for the control of pathogens:

- A CCP may be established at the step where oranges are received at the processing facility at which time the shipment can be checked to ensure that it originated from a supplier who has provided a guarantee that only tree-picked oranges were supplied in the shipment.

V. Control Measures

A. HACCP Control Measures

Under 21 CFR 120.8(a), you are required to implement HACCP control measures if you determine in your hazard analysis that a food hazard is reasonably likely to occur in your juice product.

Examples of HACCP control measures used in the processing of juice include measures carried out at CCPs specified in a HACCP plan such as the pasteurization of juice for the elimination of microbial pathogens; the culling or trimming of apples after storage to eliminate moldy, damaged, bruised, or rotten apples to ensure that patulin will not be present at levels of concern in the finished apple juice; and periodically monitoring processing lines for evidence of glass breakage.

B. Activities Not Considered to be HACCP Control Measures

Some activities firms may undertake in processing juice and in related functions are not HACCP control measures. These include Good Agricultural Practices (GAPs) and Current Good Manufacturing Practices.

1.0 GAPs

The HACCP regulation applies to firms engaged in the processing of juice. It does not apply to firms that conduct activities such as the growing, harvesting, and transporting of fruits and vegetables that will be processed into juice. Growers may voluntarily implement GAPs based upon FDA's GAPs guidance document which is available at http://www.foodsafety.gov/~dms/prodguid.html, and by mail from the address given in section I. C above. Because growers and transporters of raw agricultural ingredients of juice are not subject to the requirements of the HACCP regulation, GAPs measures voluntarily undertaken by these parties are not HACCP controls. However, if a hazard originating from the agricultural environment is determined to be reasonably likely to occur on your incoming fruit, e.g., patulin on incoming apples, or pathogens on incoming raw fruit, pursuant to 21 CFR 120.8 (a), that hazard must be identified in your hazard analysis and controlled through your HACCP plan. If control of such a hazard involves actions that will be carried out by your grower, e.g., supplying you with only tree-picked fruit or fruit that does not include fallen fruit, your control measure could be based upon a supplier guarantee to this effect implemented as part of your HACCP plan.

However, we encourage you to work with your suppliers to evaluate and modify agricultural practices in accordance with FDA's GAPs guidance document.

2.0 CGMPs

As noted above, juice processors are still required to comply with the CGMPs requirements of 21 CFR Part 110. One common misconception about HACCP is that some hazards that are reasonably likely to occur may be controlled under a firm's CGMP programs under 21 CFR Part 110. Because programs to comply with 21 CFR Part 110 are general in nature and are not designed to control specific hazards, they are not HACCP control measures. Therefore, you cannot use CGMP programs to control a specific hazard that, based upon your hazard analysis, you have concluded is reasonably likely to occur in your juice. You must use HACCP controls for any such hazard.

C. Control Measures for Biological Hazards

1.0 Minimum Requirement of 5-Log Pathogen Reduction

The 5-log pathogen reduction requirement in 21 CFR 120.24 describes the minimum level of pathogen "kill" that your pathogen control measures must consistently achieve. Processing experts evaluate treatments intended to destroy or inactivate pathogens in food in terms of "logs" of kill, where the term "log" is a shorthand expression of the mathematical term logarithm. A logarithm is "the exponent of the power to which a base number must be raised to equal a given number." If the base number is ten, it must be raised to the second power to equal 100, so the exponent is 2, i.e., 10 X 10 = 100. Again, if the base number is ten, it must be raised to the third power to equal 1000, so the exponent is 3, i.e., 10 X 10 X 10 = 1000.

The HACCP regulation requires you to use treatments capable of consistently achieving at least a 5-log reduction (using ten as the base number) in the level of the pertinent microorganism in your juice. The important thing to understand is that each log of kill is capable of causing a tenfold reduction in the number of organisms of the pathogen that the treatment is designed to kill, i.e., the "pertinent microorganism." A 1-log process would be one that is capable of reducing the level of the pertinent microorganism in the food by 10 fold, e.g., from 100 organisms (of the pathogen) per gram of food to 10

organisms (of the pathogen) per gram of food. A 2-log process further reduces the level of the target pathogen by another factor of 10, i.e., from 10 organisms (of the pathogen) per gram to 1 organism (of the pathogen) per gram of food. Thus, the 5-log performance standard means that you must treat your juice using a process capable of reducing levels of the pertinent pathogen in the juice by at least 100,000-fold (10 X 10 X 10 X 10 X 10 = 100,000).

This is illustrated in the following table:

Initial number of pertinent microorganism bacteria per gram of food	Log reduction	Decrease in pertinent microorganism bacteria levels	Percent of change	Final number of bacteria per gram of food
100,000 (10^5)	1	10-fold	90 %	10,000 (10^4)
100,000 (10^5)	2	10x10 = 100 fold	99 %	1,000 (10^3)
100,000 (10^5)	3	10x10x10=1000 fold	99.9 %	100 (10^2)
100,000 (10^5)	4	10x10x10x10=10,000 fold	99.99 %	10 (10^1)
100,000 (10^5)	5	10x10x10x10x10=100,000 fold	99.999 %	1 (10^0)

The initial number of pathogens present in your untreated juice is likely to be far less than 10^5 organisms per gram, i.e., only 10^1 or 10^2 organisms per gram. Applying a 5-log treatment to juice that may contain such levels of pathogens achieves a tolerable level of risk by ensuring that the process is adequate to destroy microorganisms of public health significance or to prevent their growth.

Thus, if you use pasteurization as your pathogen control measure, that treatment must be carried out to achieve consistently at least a 5-log reduction in the "pertinent microorganism." Likewise, if you use UV radiation as your pathogen control measure, that UV treatment must be carried out to achieve consistently at least a 5-log reduction in the "pertinent microorganism."

If you are a citrus juice processor and rely on, as your pathogen control measure, a series of surface sanitization treatments and an extraction process that limits juice/peel contact as provided for under 21 CFR 120.24 (b), these treatments must consistently achieve at least a 5-log reduction in the "pertinent microorganism."

Multiple processing steps, such as a series of surface sanitization treatments for citrus fruit, may be used to achieve the 5-log reduction. However, under 21 CFR 120.24 (b) and (c), all of the processing steps you perform to meet the 5-log pathogen reduction requirement must be carried out in a single production facility.

We recommend that all juice processors consult with a process authority (see "Process Validation" in section V.C.5) to establish their control measures for achieving the 5-log pathogen reduction required under the HACCP regulation.

1.1 What Does the "Pertinent Microorganism" Mean?

The "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice and is the pathogen that you must target for the 5-log pathogen reduction treatment (21 CFR 120.24(a)). By choosing the most resistant pathogen as your target, you are also treating the product for all other pathogens that are less resistant to the means of treatment.

One way to identify the pertinent microorganism for your juice is to consider whether there have been any illness outbreaks associated with this type of juice, and what microorganisms have caused the outbreaks. If certain pathogens have been demonstrated, i.e., through outbreaks, to be potential contaminants in certain juices, then the pertinent microorganism for your process typically should be one of these pathogens.

For example, *Salmonella* species have been the cause of several illness outbreaks related to orange juice and may be considered the "pertinent microorganism" for orange juice products. *E. coli* O157:H7, a bacterial pathogen, and *Cryptosporidium parvum,* a protozoan parasite, have both been the cause of outbreaks in untreated apple juice, and both should be identified as potential hazards in a hazard analysis for apple juice. Which of these two pathogens is determined to be the pertinent microorganism will depend upon which of the two is most resistant to the means of treatment, e.g., pasteurization, UV radiation, that you will use to achieve the 5-log reduction of pathogens that is required under the juice HACCP regulation. The pertinent microorganism for apple juice is discussed further in section V. C. 5.0.

Although *Listeria monocytogenes* has not been linked specifically to an illness outbreak from juice, it is ubiquitous in nature. For this reason, we recommend that *Listeria monocytogenes* be considered as a possible "pertinent microorganism" for juices that have not been associated with illness outbreaks caused by *Salmonella* species, *E. coli* O157:H7, or *Cryptosporidium parvum*. Alternatively, for juices other than apple juice, you may generically designate "vegetative bacterial pathogens" as your pertinent microorganism if your juice is an acidic juice, i.e., pH of 4.6 or less, no illness outbreaks believed to have been caused by non-bacterial pathogens have been attributed to that juice type, and you are processing your juice using a process that has been validated to achieve a 5-log reduction for *Salmonella* species*, E. coli* O157:H7, and *Listeria monocytogenes*, such as the general process which is discussed in section V.C.5.0 under "Process Validation."

Low-acid juices, such as carrot juice, that are distributed under refrigeration, and are not subject to the Low Acid Canned Foods regulation (21 CFR Part 113) may pose hazards associated with spore forming pathogens, specifically, toxins of non-proteolytic and proteolytic strains of *Clostridium botulinum*. Control measures for such juices are likely to involve multiple measures, e.g., a combination of a process step to destroy the non-proteolytic spores and measures to ensure that "Keep Refrigerated" labeling is used for the juice if the juice does not receive a treatment sufficient to destroy the proteolytic spores (Destruction of spores of the proteolytic strains requires a more severe heat treatment but germination and growth of these spores may be prevented by keeping the product under refrigeration during its lifecycle. Destruction of spores of the non-proteolytic strains requires a less severe heat treatment, but these spores can germinate and produce toxin even under refrigerated storage conditions).

1.2 Shelf Life and Moderate Temperature Abuse Conditions

The 5-log pathogen reduction treatment must last through the normal shelf life of the product when held under moderate temperature abuse conditions (21 CFR 120.24(a)). This requirement is intended to ensure the effectiveness of the treatment if any microorganisms that may be injured in processing, might be capable of surviving if held under optimal growing conditions. Normal handling of juice includes the movement of the juice from the plant to retail (e.g., transportation, warehouse storage) and consumer handling after purchase (e.g., transport home, setting out on a counter or table). Moderate abuse may occur when unusual circumstances occur during customary handling. For example, unloading a truck on a hot day where the product may sit on a loading dock for a short period of time could constitute moderate abuse. In addition, moderate abuse could occur if consumers purchase a product on a warm day, place it in their car, and run errands before refrigerating the product. Moderate abuse does not include exposure to warm temperatures for extended periods of time.

Your "process authority" (see "Process Validation" in section V.C.5) should be able to determine that the process you use, e.g., pasteurization, UV irradiation, will ensure that pathogens will not proliferate in your juice should it undergo moderate temperature abuse.

1.3 5-Log Treatment Performed on Juice after Extraction, with One Exception

You must meet the 5-log pathogen reduction requirement by treating the juice directly, i.e., after it has been extracted from the fruit, with one exception provided by 21 CFR 120.24(b). However, for citrus juices, you may meet this requirement by applying pathogen reduction treatments to the surface of the citrus fruit prior to extracting the juice. Such treatments usually are carried out through a series of washing, brushing, and sanitizing steps. Use of extraction methods that limit juice/peel contact may also be counted towards the 5-log reduction. If you use such treatments to meet the 5-log pathogen reduction requirement, you must also adhere to certain specific requirements in 21 CFR 120.24 (b) that are summarized in subsection 3.0 of this section.

2.0 Location of Juice Extraction, Processing, and Packaging

Pursuant to 21 CFR 120.24(c), you must carry out the 5-log pathogen reduction, whether it is via a one-step process or a multi-step process, in a single facility, and that facility must be the same facility in which the product is packaged in final form for sale. There are two potential exceptions discussed in the following paragraphs. If you do treat your juice at a different facility than the one in which the final packaging is carried out, the treatments applied at the first facility cannot be counted towards meeting the 5-log pathogen reduction requirement.

The first exception noted in the previous paragraph applies to producers and users of high degree Brix juice concentrate. In a letter dated January 22, 2002 (and a January 25, 2002 letter of correction), FDA stated that it would consider the exercise of enforcement discretion with respect to the "single facility" requirement as applied to producers and users of high degree Brix concentrate[6] where the following three conditions are satisfied: (1) the producer and user establish appropriate

prerequisite programs and SSOPs for the transport of high Brix juice concentrate; (2) the producer and user designate as a CCP in their respective HACCP plans the transport of high Brix concentrate from the production facility to a second facility for formulation and final packaging of concentrates; and (3) the producer and user establish control measures to prevent, reduce, or eliminate the risk of recontamination of the concentrate during transport (The January 22, 2002, letter and a correction to that letter dated January 25, 2002, are available at the website listed in section I. B.)

The second exception applies to the bulk transport and packaging of shelf-stable single strength juice that is transported in aseptic packaging. FDA also stated in the January 22, 2002, letter that it would consider using its enforcement discretion with respect to processors that transport in bulk and package shelf-stable single strength juice that is transported in aseptic packaging.

FDA also stated in the January 22, 2002, letter that it intended to develop and issue guidance that will contain FDA's basic recommendations for appropriate control measures for several transport modalities (modes of transportations), including tankers, mobile tank farms within cargo ships, single-use sanitary containers (e.g., bag-in-box containers), and reusable containers with single-use liners (e.g., 55 gallon drums with single-use liners). This guidance entitled "Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices," is available on the website listed in section I. B above.

You may extract juice from the fruit in one location and ship the untreated juice to a second location for processing (i.e., to achieve the 5-log pathogen reduction requirement) and packaging. If you do this, we recommend that you obtain assurance, e.g., a letter from the juice processor receiving the untreated juice, that the juice will be given the required 5-log treatment at the second location, and you should cite this assurance in your hazard analysis as the justification for not carrying out the 5-log reduction in your facility. We also recommend that the label of the untreated juice, or if transported in bulk, the invoice or other shipping documents, state that the juice has not received a treatment sufficient to yield a 5 log pathogen reduction.

3.0 Requirements for Certain Citrus Juices

If you produce a citrus juice and you choose to meet the 5-log pathogen reduction requirement by surface treatment of the fruit, the following additional requirements apply:

- The fruit must be tree-picked, cleaned, and culled prior to application of treatments to achieve the 5-log pathogen reduction (see 21 CFR 120.24(b)).
- All treatments to achieve the 5-log pathogen reduction, e.g., cumulative treatments, must be performed in a single facility. Final product packaging must also be performed in that same facility (see 21 CFR 120.24 (b)).
- Certain process verification requirements (testing of finished product for generic *E. coli*) set out in 21 CFR 120.25 are required. If *E. coli* is found in the processed juice, it may be an indication of failure of the HACCP system, or that the system may be approaching failure. See the discussion in the next section. A rapid method for testing the finished product for generic *E. coli* entitled "Comparative evaluation of a rapid method for detecting *Escherichia coli* in artificially contaminated orange juice," by Stephen D. Weagant and Peter Feng (FDA Laboratory Information Bulletin 4239, Vol. 17, March 2001) is available by mail at the address given in section I. C.

3.1 Compliance with Requirement to Use Tree-Picked, Culled Fruit

If you produce a citrus juice using surface treatments to meet the 5-log pathogen reduction requirement, FDA recommends that you do the following to meet the requirement that you use tree-picked and culled fruit:

- You obtain a written guarantee from your supplier for each fruit shipment stating that the shipment contains only tree-picked fruit, and establish a CCP at the receiving step for the citrus fruit, citing the existence of the guarantee as a critical limit to be met for acceptance of the lot of fruit. An additional critical limit at this CCP (the receiving step) should be that a sample of fruit from the shipment shows no evidence of inclusion of fallen fruit.
- You establish a CCP at a culling step in the process at which any damaged fruit is removed prior to any pathogen reduction treatments on the fruit surface. The culling step is important because damage to the peel of citrus fruit (e.g., punctures, cuts, splitting, rot, or mold) may allow pathogens to contaminate the edible portion of the fruit from which the juice is made.

Under such an approach, for the CCP at the receiving step:

- The existence of a supplier guarantee for each shipment of incoming fruit specifying that the shipment contains only tree-picked fruit would be one critical limit. A monitoring procedure would be to confirm visually the existence of the guarantee for each incoming shipment of fruit.

- The second critical limit would be that a sample of fruit from the shipment shows no evidence of fallen fruit. Monitoring could consist of visual inspection of fruit sampled from each incoming shipment to ensure that the fruit shows no evidence of inclusion of fallen fruit, e.g., flat dirty spots on the fruit.
- The corrective action procedure would be to reject any shipment of fruit from a supplier not accompanied by a guarantee, or any shipment that does not meet the inspectional criterion, e.g., shows evidence of containing fallen fruit.
- The verification procedure could consist of periodic auditing of the supplier to ensure that the supplier is following the provisions of the guarantee. Generally in HACCP, wherever you rely on guarantees or certificates from suppliers to control a hazard, we recommend that you couple these types of controls with a strong verification procedure, such as visiting the farm periodically or periodically testing the juice.

3.2 Positive *E. coli* Test Results for Citrus Juices Made Using Surface Treatment of Fruit to Achieve 5-Log Reduction

If your verification testing yields a single positive for *E. coli*, § 120.25(d) requires that you review monitoring records for the control measures used to attain the 5-log pathogen reduction standard and correct those conditions and practices that are not met. We recommend that you conduct these activities as quickly as possible. You also must look at results for the preceding six tests for that product; under 21 CFR 120.25(e), if a second positive result is found within seven consecutive tests, the control measures used to attain the 5-log reduction standard are inadequate and you must start immediate corrective action.

In the juice HACCP final rule, we also suggested that if you get a single positive test result, you should review your test results over a larger window of tests (more than just the last 7 tests) to see if these test results are an early warning that the process may be approaching failure. We stated that review should be sufficiently extensive to allow you to spot a trend towards loss of process control. Here, we provide how far back we recommend you review your records.

The 2-out-of-7 criterion, which is established in the final juice HACCP regulation, was chosen because it offers appropriate consumer protection while simultaneously having a low rate of "false alarms" (because the likelihood of 2 positives occurring by chance in 7 consecutive tests when citrus juice is appropriately treated is about 1 in 1000 (p=0.001)). As the window gets larger (i.e., you review a larger set of consecutive tests), the chance of finding two positives, even when juice is appropriately treated, increases. Therefore, looking at results over a larger window is not required and finding two positive results in the larger window does not impose any additional regulatory requirements.

However, as noted above, looking at test results over an extended time period may allow you to spot a trend towards loss of process control and take appropriate action before your system fails. How far back you choose to look may depend on a number of factors, including production volume, testing frequency, and experience. We recommend that you start by considering 2 positives in any series of 17 tests (or 3 positives in any series of 52 tests) as a potential warning. The likelihood of 2 positives occurring by chance in 17 consecutive tests, or 3 times in 52 tests, when citrus juice is appropriately treated is about 7 in 1000 (p=0.007).

Thus, a finding of 2 positives in 17 tests, or 3 positives in 52 tests, could be an indication that your controls are not functioning as intended and that they may fail at some point. You would then be able to investigate the operation of your control measures and take any necessary action to ensure that they are functioning as intended before a failure occurs.

As window width increases to 20, 25, and 30 tests, the probabilities of finding two positives when the system is functioning correctly are 9.4 in 1000 (p=0.0094), 14.6 in 1000 (p=0.0146), and 20.6 in 1000 (p=0.0206), respectively.

4.0 Heat Treated Shelf Stable Juices and Concentrates, and Other Non-Heat Treated Juices

Our recommendations for factors to consider when establishing control measures for heat treated shelf stable juices and concentrates, and other non heat- treated juices are discussed in 4.1, 4.2, 4.3, 4.4 and 4.5.

4.1 Heat Treated Shelf Stable Juices and Concentrates

If you use a single thermal processing step to produce a shelf stable juice, or a thermal concentration process that includes all of the ingredients of a juice, you are not required to include control measures in your HACCP plan for achieving the 5-log pathogen reduction. However, under 21 CFR 120.24(a)(2), you must include a copy of the thermal process or the concentration process in your written hazard analysis and you must establish controls in your HACCP plan for any chemical and physical hazards identified in your hazard analysis.

4.2 Example of a Process for a Shelf Stable Juice

The National Food Processors Association states that a typical hot fill/hold process used for shelf stable juices might be to treat the juice at 90 degrees C (194 degrees F) for 2 seconds, followed by filling at 85 degrees C (185 degrees F) and holding for 1 minute at that temperature. Based upon research it conducted for *E. coli* O157:H7, Salmonella species (spp.) and *Listeria monocytogenes* in fruit juices, NFPA calculated that this typical process used for shelf stable juices would achieve a 50,000 log reduction for these pathogens without taking into account the cumulative lethality during the cool down period. (See reference to publication by Mazzotta in section V. C. 5.0).

4.3 Thermal Concentration Processes

To obtain the exemption from the requirement to include controls in your HACCP plan to achieve the 5-log pathogen reduction, the juice HACCP regulation requires a copy of the process used to produce the thermally processed juice concentrate to be included in your hazard analysis. The thermal process must be applied to the concentrate and all of its ingredients.

We recommend that the copy of the thermal process used to achieve concentration describe the steps in the process, such as the pre-evaporation heat treatment and the evaporation steps. We also recommend that it describe the type of equipment used in each process step such as a "continuous flow tubular heat exchanger" for the pre-evaporation step and a "X effect high temperature short time evaporator" (X-representing the number of effects) for the evaporation steps. In addition, we recommend that it describe the product temperature and exposure time for the pre-treatment step, the product temperature for each of the evaporation effects, and the process time and temperature for the thermal process for any ingredient of the concentrate that is processed separately and then added to the concentrate.

To ensure the safety of a "thermally processed concentrate" we recommend all of the juice receive a pretreatment consisting of a thermal treatment of at least 80 degrees Centigrade for thirty seconds. Such a process delivers a degree of thermal inactivation of pathogens that is extraordinarily beyond the required 5-log reduction (see Reference #68 in the juice HACCP final rule). FDA is not likely to question whether a product processed in such a manner is a "thermal concentrate" and thus, qualifies for the exemption from a process control to achieve the 5-log performance standard for pathogen reduction.

However concentrates produced using unconventional processes that involve low temperatures might not receive enough heat to ensure a comparable level of inactivation of potentially harmful microorganisms that might be present in the juice. If we encounter a concentrate that is processed in such an unconventional manner, we may ask for additional data demonstrating that the process delivers a level of thermal inactivation of microorganisms that is comparable to that delivered by a conventional thermal concentration process. Absent providing such data, we may advise you of our view that the exemption from a process control to achieve the 5-log performance standard for pathogen reduction is not available for the product and that you should include control(s) (CCP(s)) in your HACCP plan for achieving the 5-log reduction.

4.4 Juices Subject to the Low-Acid Canned Foods and Acidified Foods Regulations

If you produce a juice that is subject to the requirements of 21 CFR Parts 113 or 114, i.e., the regulations for low acid canned foods and acidified foods, you do not have to include control measures in your HACCP plan for the potential hazards that are addressed through compliance with 21 CFR Parts 113 or 114, e.g., hazards associated with the formation of *Clostridium botulinum* toxin. You may identify such hazards as potential hazards in the hazard identification phase of your hazard analysis, but in the hazard evaluation phase, you may conclude that such hazards are not reasonably likely to occur because they are controlled through compliance with the requirements of 21 CFR Parts 113 or 114. However, the hazard analysis and HACCP plan should completely address any other hazards associated with such juices, i.e., any chemical and physical hazards such as metal or glass fragments.

4.5 Other Non-Thermal Treatments for Juice

If the treatment includes the use of a source of radiation, e.g., UV irradiation, pulsed light, FDA approval of the means of treatment for the control of microorganisms is required. Both UV radiation and pulsed light have been approved by FDA for the control of microorganisms, and the regulations specifying the conditions under which they may be safely used are at 21 CFR 179.39 (UV radiation) and 21 CFR 179.41 (Pulsed light).

If the treatment includes the use of a chemical anti-microbial agent, such as a sanitizer, to reduce pathogen levels on the surface of citrus fruit, the chemical agent must be approved by FDA for that use (i.e., to control or reduce levels of microorganisms) under the agency's food additive regulations in 21 CFR Parts 170-199, or it must be generally recognized as safe (GRAS) for such use.

If you use sanitizing agents as surface treatments on fruit used in the production of citrus juice, you should secure documentation from your supplier that the sanitizing agent is either GRAS, or is approved by the FDA for this use.

Treatment technologies that do not involve the use of a source of radiation or a chemical agent, e.g., high pressure processing, are not likely to require FDA approval. However you should verify any such assumption with your process authority (see following section).

Whether you use a form of radiation (UV radiation or pulsed light), a chemical treatment, or some other type of treatment for pathogen reduction purposes, the process used for pathogen control must be validated for this purpose according to the validation requirements in 21 CFR 120.11 of the juice HACCP regulation.

5.0 Process Validation

You must ensure that the process you will use has been validated, i.e., that at all times it will deliver, at a minimum, the required 5-log pathogen reduction (21 CFR 120.24(a)).

5.1 Role of a "Process Authority"

In order to ensure the validity of your process, FDA recommends that you employ or consult with a "process authority." A process authority is an expert in the processes for controlling pathogenic microorganisms in food, and as such, is qualified by training and experience to evaluate all aspects of your pathogen control measures, e.g., process time, temperature, type of equipment, etc., and to determine that your control measures, if properly implemented, will effectively control pathogens such as *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, and *Cryptosporidium parvum*.

Many different types of processes may be used to reduce the level of the organism of concern. For each of these processes, the critical control points and critical limits must be identified. A process authority should know what critical limits, such as time and temperature, would be effective for treating juice. Other processing factors such as flow rate, turbulence, pressure, concentration, composition, intensity, penetration depth, and absorbance may also be important to a process. Your process authority should be able to evaluate such other aspects of your processing system that could affect its performance.

Although your process authority will likely be your source for information on the critical limits for your pathogen reduction process, you will have to know what those limits are, e.g., the time and temperature parameters for a pasteurization process, or the amount of UV energy to which the juice is exposed; these values serve as the critical limits in your HACCP plan. We will need this information to be able to conduct an official review of your HACCP system.

You may employ a process authority as a member of your staff, or alternatively, you may be able to identify a process authority through your national or regional food processors trade association, or through educational institutions such as food science and technology departments in state universities. Some state government agencies, e.g., state departments of agriculture or public health, may have such experts on their staffs. Some processing equipment vendors employ or retain (as consultants) such experts who also have detailed knowledge about the performance capabilities of the vendor's equipment and can work with you to establish that the equipment will effectively control pathogens in your processing operation.

5.2 Validated Pasteurization Treatments for Juice

At this time there are some published studies on pasteurization processes for controlling pathogens in juice that we can comment on to assist you in developing your HACCP plan.

Study #1 Summary: A study done by the NFPA[(7)] has resulted in a recommended general thermal process of 3 seconds at 71.1 degrees C (160 degrees F), for achieving a 5-log reduction for *E. coli* O157:H7, *Salmonella,* and *Listeria monocytogenes* in fruit juices. The efficacy of this process was measured using single strength apple, orange, and white grape juices adjusted to a pH of 3.9. The authors noted that a pH in the range of 3.6 to 4.0 has been reported as a non-significant variable in the heat resistance of *E. coli* O157:H7. The authors also noted that the heat resistance of these vegetative bacterial pathogens might be considerably greater at pH values of 4.0 and higher. This process assumes that the pathogens will have increased thermal resistance due to their being acid-adapted.

Study #2 Summary: A study done at the University of Wisconsin[(8)] has shown that treatments of 68.1 degrees C (155 degrees F) for 14 seconds (recommended treatment conditions in Wisconsin) and 71.1 degrees C (160 degrees F) for 6 seconds (recommended treatment conditions in New York) are capable of achieving a 5-log reduction of acid adapted *E. coli* O157:H7 in apple cider (pH values of 3.3 and 4.1). The Wisconsin study also confirmed the adequacy of the treatment conditions of the NFPA study (71.1 degrees C (160 degrees F) for 3 seconds) for achieving a 5-log reduction for *E. coli* O157:H7 in apple cider.

FDA Comments/Recommendations: We believe that the process recommended in the NFPA study is adequate to ensure a 5-log reduction of the three stated vegetative bacterial pathogens, (*E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes*) at juice pH values comparable to those in the study. However, other validation studies may be needed for

juices that have pH values greater than 4.0. We also believe that either of the processes evaluated in the University of Wisconsin study is adequate to ensure a 5-log reduction of the three stated bacterial pathogens, (*E. coli* O157:H7, *Salmonella,* and *Listeria monocytogenes*) (at juice pH values comparable to those in the study) if any of these pathogens are the pertinent microorganism in your juice.

Neither of these two studies evaluated thermal processes for achieving a 5-log reduction for oocysts of the protozoan parasite *Cryptosporidium parvum* that has been a cause of illness outbreaks associated with the consumption of apple juice. In fact, the thermal destruction of *Cryptosporidium parvum* oocysts has not been as widely studied in the published literature as it has for the vegetative bacterial pathogens; however, the available scientific literature suggests that *Cryptosporidium parvum*[9] oocysts may be more resistant to thermal processing than the three vegetative bacterial pathogens. Therefore, we recommend that you consider *Cryptosporidium parvum* to be the pertinent microorganism when you are establishing a HACCP plan for apple juice.

For apple juice at pH values of 4.0 or less, we are recommending the following thermal processes to achieve a 5-log reduction for oocysts of *Cryptosporidium parvum* (in addition to the three aforementioned vegetative bacterial pathogens) based upon a conservative evaluation of the available scientific data;

- 160 degrees F for 6 seconds (recommended treatment conditions in New York),
- 165 degrees F for 2.8 seconds,
- 170 degrees F for 1.3 seconds,
- 175 degrees F for 0.6 seconds, or
- 180 degrees F for 0.3 seconds

Also, while it appears that *Cryptosporidium parvum* may be more resistant to thermal processing than the vegetative bacterial pathogens noted, in view of the limited data on the thermal destruction of *Cryptosporidium parvum*, processors may designate both *E. coli O157:H7* and *Cryptosporidium parvum* as the pertinent microorganism in their HACCP plans for apple juice, and use one of the recommended thermal processes given above for the a 5-log reduction of *Cryptosporidium parvum* oocysts, until more definitive data become available on the relative resistance to thermal processing of these two pathogens.

We also believe that the process that is typically carried out for milk pasteurization, 71.7 degrees C (161 degrees F) for 15 seconds, is adequate to achieve a 5-log reduction of oocysts of *Cryptosporidium parvum* and the aforementioned three vegetative bacterial pathogens when this process is used for apple juice (at juice pH values of 4.0 or less).

5.3 Equipment and System Considerations

Equipment and Systems that should be considered are discussed in 5.31, 5.32, 5.33, 5.34 and 5.35.

5.31 Pasteurization Equipment

If you use batch pasteurization equipment, we recommend that you continuously monitor both the time and temperature of the juice treatment as critical limits to ensure that your process is achieving the 5-log pathogen reduction.

If you use continuous (high temperature short time (HTST)) pasteurization equipment, we recommend that you designate the juice temperature and juice heating time as critical limits in your HACCP plan. Under your HACCP plan, we recommend that you continuously monitor the juice temperature; we do not recommend continuous monitoring of the heating time if the equipment (the positive displacement timing pump and holding tube length, volume and slope) is constructed to deliver a controlled flow rate of the juice through the heat exchanger to ensure that it is heated for the minimum required time. In this case, as a monitoring procedure for flow rate, we recommend that you periodically perform a visual check of the set point of the positive displacement pump to ensure that it is at the point that has been documented to deliver the proper flow rate. As a verification procedure, we recommend that you check the actual flow rate semi-annually (or whatever is needed to keep the system working properly) by performing testing of the timing pump to ensure that it is effectively controlling the flow rate.

A magnetic flow-based timing system is another type of flow rate timing system for an HTST pasteurizer. In such a system, we recommend that the flow rate (heating time), in addition to the juice temperature, be continuously monitored.

5.32 UV Processing Systems

UV systems for treating juice have recently begun to be commercialized. FDA approval in 2000 of UV radiation to treat juice to reduce human pathogens in (21 CFR 179.39) requires that the UV radiation be provided by low pressure mercury lamps emitting 90 percent of the emission at a wavelength of 253.7 nanometers (2,537 Angstroms), and that during the treatment, the juice undergo turbulent flow through tubes with a minimum Reynolds number of 2,200. If you are considering using UV radiation to process your juice, you should confirm with your process authority that the system you are considering meets the requirements of 21 CFR 179.39.

We also recommend that you consider the following questions in consultation with your process authority:

- Have you identified the appropriate pathogen as the "pertinent microorganism" considering that UV radiation is the means of treatment for achieving the 5-log pathogen reduction? For instance, if you are processing apple juice, you need to know whether *E. coli* O157:H7, *Crytopsporidium parvum*, or some other pathogen is more resistant to UV radiation to determine which of these is the pertinent microorganism. The relative resistance of pathogens to UV radiation may not be the same as it is for thermal treatment.
- Has the UV system been validated to achieve effectively a 5-log pathogen reduction for the "pertinent microorganism" (see previous bullet) in the juice that you will be processing?[10] The effectiveness of given UV treatment conditions can vary from one juice to another due to factors such as the opacity of the juice. The treatment parameters, e.g., flow rate, UV energy level, needed to achieve a 5-log pathogen reduction, may vary from one juice to another juice. We recommend that you consult with your process authority to ensure yourself that the system and processing parameters you will use have been validated to achieve a 5-log pathogen reduction in your juice.
- What are the critical limits for the process? Is the flow rate of the juice through the UV exposure chamber critical to the effectiveness of the process? Is the delivery of a minimum level of UV energy critical to the process? If so what are the critical flow rate and UV energy parameters? You need to know what the critical limits are to be able to enter them into your HACCP plan.
- What monitoring procedures will you have to carry out to ensure that the critical limits are met? Is it necessary to monitor flow rate continuously, or does the design of the equipment regulate the flow rate to not exceed the critical limit? What monitoring procedure, e.g., UV sensors, will indicate that the juice continually receives the critical level of UV energy? Is the system designed to shut down if a sensor fails or if a sensor indicates that a critical limit is not being met?
- What verification procedures will you have to carry out? These may include checking the UV sensors periodically to ensure that they are operating properly.
- What cleaning procedures should be carried out between runs to ensure that residues, e.g., particulates, do not accumulate in the equipment that would reduce the effectiveness of the treatment?
- What corrective action procedures will you specify in your HACCP plan? Your corrective action procedures should ensure that if the system fails, e.g., due to failure of a UV lamp, any juice that may not have received the 5-log pathogen reduction is segregated and, if necessary, treated again to ensure a 5-log reduction, and that the failed lamp is replaced.

5.33 High Pressure Processing Systems

High pressure processing, a technology in which pressure (in excess of 30,000 to 45,000 psig) is the principal anti-microbial agent, has been shown to be effective in reducing vegetative pathogens. Both semi-continuous and batch processes have been developed using high pressure processing. We recommend that the process time and pressure be critical limits for both types of processes. However, temperature may or may not need to be a critical limit. During high pressure processing, the temperature of the product does increase. This increase in temperature is dependent on the composition of the food product, the initial temperature of the product/vessel, the pressure transmitting fluid for batch systems, and the time the product is held at the processing pressure. Many high-pressure systems do not control the temperature of the product during treatment, and the temperature of the product tends to decrease with time due to heat loss to the surrounding pressure vessel. For many systems, a minimum initial temperature of the product/vessel may be specified and controlled. However, the temperature during the process may not be monitored as a critical limit. For batch systems, we recommend that changes in the composition of the pressure transmitting fluid should be controlled and checked periodically.

5.34 Dense Phase CO_2 Processing Systems

Dense phase carbon dioxide processing, a technology in which carbon dioxide under moderate pressure (1200-1500 psig) is the principal anti-microbial agent, has been shown to be effective in reducing vegetative pathogens. In the gas industry, supercritical and liquid carbon dioxide (CO_2) are known collectively as dense phase CO_2. Continuous processes have been developed using this technology. Pathogen challenge tests showed that microbial inactivation increases as CO2 concentration increases. It appears that pressure and residence time may be used to optimize the bactericidal effects of CO_2. For these processes, CO_2 concentration is critical to the process. The process is performed under ambient conditions, and temperature is not monitored as a critical factor.

5.35 Extraction Equipment for Certain Citrus Juice Processes

If you process citrus juice using surface treatment of fruit to achieve the 5-log pathogen reduction, it is important that the extraction of the juice be performed in a manner that avoids any potential for contamination of the juice by pathogens that may be present on the peel during the extraction operation. Juice extractors are available that have been designed to limit juice/peel contact during the extraction process for this purpose. We recommend that, as part of meeting the validation requirements of 21 CFR 120.11, you ensure that studies have been done to establish that contamination of juice by pathogens that may be present on the peel will not occur during the extraction operation. We recommend that such studies be included among the records you make available for official review under 21 CFR 120.12.

D. Control Measures for Chemical Hazards

There are no specific chemical hazards for which HACCP control measures are required explicitly under the juice HACCP regulation. If you identify a chemical hazard that is reasonably likely to occur in your juice, you will need to establish control measures for that hazard in your HACCP plan. However, because FDA has recently established an action level for patulin, a mycotoxin, which can occur in apple juice, we have included information on control strategies for patulin. The information in this section includes examples of control measures for incoming fruit based upon a supplier guarantee. These examples may be useful for devising control measures for other chemical hazards, such as lead and tin, if such control measures also are based upon a supplier guarantee.

We have also included information about appropriate controls to prevent cross contamination of juice by other foods, e.g., milk, that may cause allergic reactions in sensitive individuals when these other foods are produced on the same processing equipment.

1.0 Control Strategies for Patulin for Apple Juice Processors

This section discusses factors you may wish to consider in your hazard analysis to determine whether patulin is a hazard that is reasonably likely to occur in your juice. It also discusses control measures and CCPs you may wish to consider for your HACCP plan, should you determine that patulin is reasonably likely to occur in your juice.

The potential for high levels of patulin to occur depends on several factors. There is no single factor that will, in all cases, determine whether your apple juice may contain high levels of patulin. The most significant factors are:

- Whether the apples used include fallen fruit - Apple juice made from apples that include fallen fruit is more likely to contain high levels of patulin than juice made from apples harvested to exclude fallen fruit.
- The condition of apples at the time of harvest - Juice made from apples with visible damage (e.g., from birds or insects, mold, or rot), is more likely to contain high levels of patulin than juice made from apples without such visible defects. Proper agricultural control practices by the grower, e.g., insect control, anti-fungal applications when needed, can assist in minimizing mold growth and rot on apples.
- How apples are handled prior to storage - Patulin production can occur during the storage of apples, particularly in apples that are bruised in handling prior to and during storage.
- Storage conditions for apples - Apples stored without proper temperature and atmospheric control of the storage environment are more likely to contain high levels of patulin than apples stored under controlled conditions.
- Monitoring apples during storage for core rot - Patulin production in stored apples can be caused by core rot that is not visible by observation of the exterior of the apple. Lots of apples that are experiencing core rot may be identified by cutting and cross-sectional examination. Eliminating lots of apples with high levels of core rot from the juice production stream will reduce patulin levels in the juice.
- Culling or trimming apples prior to juice production - Growth of patulin producing molds is evidenced frequently by the appearance of visible mycelia or rot on the apple. Culling or trimming apples just prior to juice production to

eliminate damaged, bruised, moldy, and rotting apples will reduce patulin levels in the juice.

Not all apples are equally affected by these factors. For example, recently published research[11] indicates that different apple varieties, e.g., Red Rome, Granny Smith, and Red Delicious, may differ in how patulin levels in their juices are affected by factors such as whether fallen fruit is used or whether apples are culled prior to juice production.

1.1 Hazard Analysis

You may be able to gather a substantial amount of data pertinent to your juice and process and perform a comprehensive hazard analysis, considering all of the factors in the previous section, and determine that no controls (in rare instances), or relatively limited measures, are necessary to control patulin for your apple juice process.

For instance, you may determine, based upon data for the type of apples you use, that the use of apples that include fallen fruit would likely lead to excessive levels of patulin in your juice. You may opt to control for patulin via a CCP at the receiving step for apples based upon a supplier guarantee specifying that no fallen fruit is included among the apples supplied in the shipment. However, you also may determine that because you produce juice from apples that are stored only for very brief periods, during which data indicate that significant patulin production will not occur in the varieties of apple you use, the culling or trimming of apples prior to juice production is not necessary for the control of it, provided that you establish a control to ensure that apples are stored for a maximum period of time before juice production.

However, because patulin levels in juice can be affected by many factors as noted previously, not all processors may be able to acquire data or other information to perform a comprehensive hazard analysis considering all of the factors noted in the previous section. In such cases, it may be prudent for you to assume that patulin is a hazard that is reasonably likely to occur and to control for patulin by requiring a supplier guarantee for each shipment specifying that no fallen fruit is included among the apples supplied, and also by establishing a culling or trimming step in your process after the storage step, at which rotten, moldy, bruised, and damaged apples are removed from the production stream.

Thus, you might elect to have two CCPs for the control of patulin, the receipt of apples and the culling (or trimming) step prior to juice production. If you store apples for extended periods of time, we recommend a third control measure, inspecting apples taken from stored lots by cutting the apples and visually checking for core rot at various times during the storage period. Lots of apples showing significant levels of core rot may not be acceptable for juice production. These checks for core rot would constitute a third CCP. By establishing the three aforementioned controls, i.e., exclusion of fallen fruit, culling or trimming of rotten, moldy, bruised and damaged apples from production stream, and eliminating stored apples with high levels of core rot, it is likely that you will be able to adequately control patulin levels in your juice.

We suggest that you test some of your juice to show that your control measures will effectively control patulin. A commercial laboratory can do this testing for you. We suggest that an appropriate basis for determining that your control measures are effective is, if upon analysis of at least 3 samples of your juice for patulin taken during one year (each analyzed in duplicate and sampled under conditions where the occurrence of patulin is most likely, e.g., after apples are stored for the longest potential storage time), you find that all patulin levels are below FDA's action level and that the value achieved by adding 2 standard deviations to the mean is below FDA's action level of 50 parts per billion. This is illustrated in the following examples for hypothetical juices A, B and C:

Juice	Patulin level, Mean (std dev) (derived from 6 data points; 3 analyses during the year, each in duplicate)	Patulin level at mean plus 2x std deviations.	Is patulin being effectively controlled?
A	40.2 (7.2)	54.6	No
B	0.97 (1.67)	4.31	Yes
C	3.43 (31.9)	67.23	No

Processors in the same geographic region that use common varieties of apples and common production techniques may wish to consider pooling resources to test representative samples of their juices to develop baseline data on patulin for use in their hazard analyses.

If there are significant changes in your process or in factors that may affect patulin levels, e.g., a change in the variety of apples you use to make juice, a change in your storage practices, a new supplier, or abnormal weather conditions, we also recommend that you re-validate your hazard analysis by testing juice made under the new conditions.

1.2 Control Measures

If the receiving of apples is a CCP:

A supplier guarantee specifying that only apples harvested to exclude fallen fruit were supplied in the shipment is likely to be an effective control measure for patulin. Under such an approach:

- The existence of the supplier guarantee for each shipment of incoming fruit specifying that only apples harvested to exclude fallen fruit were supplied in the shipment would be the critical limit. For a small processor who harvests apples from his own orchard, we recommend, in lieu of a supplier guarantee, that the processor's apple pickers be instructed not to harvest fallen fruit and the processor confirm that the workers are adhering to the instructions.
- A monitoring procedure would be to confirm visually the existence of the guarantee for each incoming shipment of apples.
- The corrective action procedure would be to reject any shipment of fruit not accompanied by a guarantee from the supplier.
- The verification procedure could consist of periodic auditing of the supplier to ensure that the supplier is following the provisions of the guarantee, or testing the juice periodically to confirm that it does not contain high levels of patulin. We recommend that processor's who rely on guarantees or certificates from suppliers to control a hazard couple these types of controls with a strong verification procedure, such as visiting the farm periodically or periodically testing the juice.

If culling or trimming apples after storage is a CCP:

- The culling or trimming of the fruit during the sorting step after storage to eliminate moldy, rotten, bruised, and damaged (e.g., from birds or insects) fruit is likely to be an effective control measure.
- The use of only apples or apple portions free of mold, rot, bruising, and other damage would be the critical limit.
- A monitoring procedure would be to inspect apples at the sorting step to ensure that the apples are free of rot, mold, bruising, and other damage.
- The corrective action procedure would be to cull or trim any apples that show mold, rot, bruising, or other damage. In practice, we recommend that you establish visual or other criteria for what constitutes a damaged apple that should be culled. We further recommend that criteria be established based upon validation data showing that juice made from apples culled using the criteria do not contain unacceptable levels of patulin.
- The verification procedure could consist of periodically testing the juice to confirm that the juice does not contain high levels of patulin and reviewing records of monitoring, corrective action, and verification.

1.3 If You Make Apple Juice from Purchased Concentrate

If you make apple juice from purchased concentrate, your concentrate supplier is responsible under his/her HACCP program for controlling patulin if it is reasonably likely to occur in the concentrate. In such a situation, it is reasonable for the processor who, for example, purchases concentrate and processes it into single strength apple juice, to conclude in his hazard analysis that patulin is not reasonably likely to occur because it is controlled under the HACCP plan of the concentrate supplier.

2.0 Control Measures for Allergens that Can Contaminate Juice from Improperly Cleaned Shared Processing Equipment

If you process juice on equipment that also has been used to process a food that can cause allergic reactions, we recommend that you implement CCP or rigorous SSOP controls that will ensure that the equipment has been cleaned properly before it is used to process juice. (See discussion about when FDA recommends use of a CCP vs. an SSOP for contaminants from food contact surfaces in section IV. C. 3.3.) A list of eight foods that can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies is found in section IV C. 1.22.

For example, if you process milk on equipment also used to process juice, we recommend that you clean the equipment to eliminate the milk residues before using the equipment to process juice.

An appropriate SSOP might be to establish a procedure for cleaning your equipment with a cleaning solution, e.g., a pre-rinse, followed by a caustic wash, followed by a rinse. The procedure could include maintaining a log of what foods, e.g., milk, eggnog, soy drinks, were processed on your equipment, the sequence in which the foods were processed, and

how/when the equipment was cleaned. Your operator could check that log prior to starting any production run for juice. Your control could provide that the equipment would not be used for juice until the prescribed cleaning procedure was carried out, and recorded in the log (See Example SSOP in section VII C). We recommend that you initially validate the effectiveness of the cleaning procedure by conducting tests for milk protein residue on the equipment after running the cleaning. We also recommend that you establish a procedure to monitor the efficacy of the cleaning process, e.g., swabbing the equipment surfaces and testing the swabs for milk protein residue.

A CCP procedure could similarly be based upon a pre-rinse, caustic wash, followed by rinse procedure. We do recommend that the parameters of the procedure such as time, temperature, and percent caustic, initially be validated for the effective removal of milk protein from the processing equipment and monitoring of the parameters as critical limits be carried out (See Example CCP in section VII C).

Whether an SSOP or a CCP is used, you should consider whether the equipment's design makes cleaning difficult absent disassembly of the equipment. If necessary to achieve effective cleaning, we recommend that you disassemble the equipment as part of the cleaning process.

E. Control Measures for Physical Hazards

1.0 Physical Hazards

There are no specific physical hazards, e.g., glass or metal fragments, for which control measures are explicitly required under the juice HACCP regulation. The necessity for control measures for any potential physical hazard is dependent upon a finding in your hazard analysis that the specific hazard is reasonably likely to occur in your juice. FDA has issued a Compliance Policy Guide (CPG Section 555.425) (see section I. C for availability information) describing when hard or sharp foreign objects in food, such as glass or metal fragments, could pose a health hazard. If it is reasonably likely that your juice may become contaminated with hard or sharp foreign objects that meet the criteria in this CPG, we recommend that you regard the object as a potential hazard in your juice.

1.1 Glass Fragments

We can recommend several ways to establish control measures for glass fragments in juice.

One way is the use of on-line glass detection equipment such as x-ray detection. In this method, the product itself is continuously monitored after the last step at which glass inclusion is reasonably likely to occur (e.g. after bottling and sealing of the juice). This could be, for example, at a process step designated for x-ray examination. The critical limit might be designated as "no glass fragments in the finished product." The following illustrates the elements that might be entered into your HACCP plan.

- What is the critical limit? No glass fragments in finished product (Note: FDA's Health Hazard Evaluation Board has supported regulatory action against product with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. See also FDA Compliance Policy Guide 555.425).
- What will be monitored? The presence of glass fragments in containers passing the CCP
- How is monitoring done? Use of x-ray equipment or other defect rejection system
- How often? Continuous; each container is subjected to detection. For x-ray equipment and other defect rejection systems, we recommend that you confirm that the device is operating correctly, at least at the start of each production day
- Who will perform the monitoring? For x-ray detection and other defect rejection systems, the equipment itself performs monitoring. We recommend that you check at least once per day to ensure that the device is operating.

Another way to control glass fragments, applicable in operations where the containers are manually (not mechanically) handled and sealed, involves inspecting glass containers visually before they are filled to ensure that glass fragments are not present in the containers. An appropriately trained individual at a container inspection step in the process may do this. We recommend that there be a check at the start of production to ensure that the appropriate personnel are assigned to the processing step where the inspection will occur. The critical limit might be designated as "no glass fragments in empty glass containers at the container inspection step."

A third way to control glass fragments is visual inspection at steps in the process where glass breakage can result in glass entering the juice, such as the glass container receiving, glass container storage, mechanical conveying, mechanical filling, and mechanical capping. The inspection looks for any evidence of glass breakage in those areas. CCPs might be identified as

the glass receiving and storage steps and the mechanical conveying, filling and capping steps. The critical limit might be designated as "no broken glass at the CCPs for glass inclusion." If broken glass is observed, the line is stopped, the glass is removed, and the product that has moved through that area since the last inspection is placed on hold for further action as appropriate, e.g. to be run through off-line glass detection equipment, to be destroyed, to be diverted to non-food use, or to be re-run through a process that includes a glass detection step.

- What is the critical limit? No broken glass at the CCPs for glass inclusion
- What will be monitored? The presence of broken glass on or near equipment at the CCPs
- How is monitoring done? Visual check of the glass handling areas for broken glass
- How often? We recommend that you check before starting operations each day, check at least every four hours during operation, check at the end of operations each day, and check whenever there is an equipment or other malfunction that could increase the likelihood that glass containers could be damaged
- Who should perform the monitoring? Any person who has a thorough understanding of the proper condition of the glass handling equipment and surrounding area may perform monitoring. In assigning the responsibility for this monitoring function, we recommend that you consider the complexity of the equipment and the level of understanding necessary to evaluate its condition.

If broken glass is observed at a CCP, we recommend that the corrective action procedure be to stop the line, remove the broken glass, and then place on hold any product that has moved through the area where the glass breakage was observed since the last inspection, for further action as appropriate, e.g., to be run through off-line glass detection equipment, to be destroyed, to be diverted to non-food use, or to be re-run through a process that includes a glass detection step.

1.2 Metal Fragments

We can recommend several possible ways to establish control measures for metal fragments in juice.

One way involves the use of on-line metal detection equipment. With this method, the equipment continuously monitors the product after the last step at which metal inclusion is reasonably likely to occur (e.g., after bottling and sealing of the juice) at a process step designated for metal detection. The critical limit might be designated as "no metal fragments in the finished product." The following illustrates some of the elements that might be entered into your HACCP plan.

- What is the critical limit? No metal fragments in finished product (Note: FDA's Health Hazard Evaluation Board has supported regulatory action against product with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. See also FDA Compliance Policy Guide 555.425).
- What will be monitored? The presence of metal fragments in containers passing the CCP.
- How is monitoring done? By the use of metal detection equipment.
- How often? Continuously. Each container is subjected to detection. We recommend that you confirm that the device is operating correctly at least at the start of each production day.
- Who should perform the monitoring? Monitoring is performed by the equipment itself. We recommend that a check be made at least once per day to ensure that the device is operating correctly.

A second way to control metal fragments involves the use of a separation device such as a screen after the last step at which metal inclusion is reasonably likely to occur, at a process step designated for screening. For this approach (see example HACCP plans for Pasteurized Refrigerated Apple Juice and Not-from-concentrate Orange Juice in section VII):

- The critical limit might be designated as "screen is functional."
- Monitoring may be done by a daily visual check for screen integrity.
- We recommend that verification include periodic calibration testing to ensure that the screen retains its separation capability for metal particles of a specific size. In establishing this size, we recommend that you consider that FDA's Health Hazard Evaluation Board has supported regulatory action against product with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. (See also FDA Compliance Policy Guide 555.425).

A third way to control metal fragments involves visually inspecting equipment for damage or missing parts at process steps such as extraction and grinding, where such damage or loss of parts could lead to metal fragments in your juice. This approach may only be feasible for relatively simple equipment that can be fully inspected visually in a reasonable time period. Under this approach, CCPs might be identified as the fruit grinding and extraction steps in a process. The critical

limit might be designated as "no broken or missing metal parts from equipment at the CCPs for metal inclusion." If broken or missing metal parts are observed, the line is stopped, the equipment is repaired and, if necessary, adjusted or modified, and the product that has moved through that area since the last inspection is placed on hold for further action as appropriate, e.g., to be run through off-line metal detection equipment, to be destroyed, to be diverted to non-food use, or to be re-run through a process that includes a metal detection step. The following illustrates the elements that might be entered into your HACCP plan.

- What is the critical limit? No broken or missing metal parts from grinding (or extraction) equipment
- What will be monitored? The presence of broken or missing metal parts on or near the grinder
- How is monitoring done? By visual check of the grinder and immediate vicinity for broken or missing metal parts
- How often? Check before starting operations each day, check at least every four hours during operation, check at the end of operations each day, and check whenever there is an equipment or other malfunction that could increase the likelihood that metal inclusion could occur.
- Who will perform the monitoring? Any person who has a thorough understanding of the proper condition of the equipment and surrounding area may perform monitoring.
- If broken or missing metal parts are observed at a CCP, the corrective action procedure would be to stop the line, repair, adjust, and modify the equipment as necessary; the product that has moved through that area since the last inspection is placed on hold for further action as appropriate, e.g., to be run through off-line metal detection equipment, to be destroyed, to be diverted to non-food use, or to be re-run through a process that includes a metal detection step.

F. Table of Most Likely Hazards/Control Measures for Juice

The following table lists the hazards that you are most likely to address under your HACCP program, some of the control measures you may use for those hazards, and where to find information in this guidance about those control measures.

Table 1. Most Likely Hazards/Control Measures for Juice

Hazard Identity	Hazard rationale	Possible control measures[12]	For additional controls information see section ...

Hazard Identity	Hazard rationale	Possible control measures[12]	For additional controls information see section ...
Pathogens[13]/biological	Unless you produce one of the types of juice listed in footnote #12, or a low acid juice not subject to the Low Acid Canned Foods regulations (21 CFR Part 113) one of the pathogens listed in footnote #13 is likely to be the "pertinent microorganism" for your required 5-log pathogen reduction treatment.	1. Pasteurization 2. UV radiation 3. Pulsed light 4. High pressure processing 5. Dense phase CO_2 processing 6. For fresh citrus juice only: Supplier guarantee for each shipment (only tree-picked fruit was supplied), culling to remove damaged fruit that may have pathogens in edible portion, washing/sanitizing fruit surface, extraction process that minimizes juice/peel contact	• V. C. 1.1 - Pertinent microorganism • V. C. 5.0 - Process validation • V. C. 5.31 - Pasteurization Equipment • V. C. 5.32 - UV Processing Systems • V. C. 5.33 - High Pressure Processing Systems • V. C. 5.34 - Dense Phase CO_2 Processing Systems • V. C. 3.1 and 3.2 - Fresh citrus juices, also Example HACCP plan for fresh citrus juice in VII. B. 2.0.
Patulin/chemical	Patulin is a mycotoxin that can occur on rotten, moldy, bruised or damaged apples, and may occur at hazardous levels if such apples are used to make juice	1. Supplier guarantee for each shipment; only apples harvested to exclude fallen fruit were supplied 2. Cull or trim apples after storage to remove rotten, moldy, bruised and damaged apples	V. D. 1.2 and Example HACCP Plan for apple juice in VII. B. 1.0.
Milk residue (an undeclared allergen) in juice/chemical	May occur in juice processed using equipment also used to process milk or dairy products	CCP or SSOP control for adequate cleaning of processing equipment between a milk run and a juice run	V. D. 2.0 and Example CCP and SSOP in VII. C.
Fragments from glass containers/physical	Glass fragments in juice can pose a risk of injury if ingested	Check processing line for evidence of glass breakage (if containers are mechanically handled) Pass product through x-ray equipment or other defect rejection system Pass product through separation device such as a screen Check containers prior to filling for glass breakage (if containers are manually handled)	V. E. 1.1
Metal Fragments	Metal fragments in juice can pose a risk of injury if ingested	Check equipment for evidence of broken or missing metal parts that may enter the juice Pass product through metal detection equipment Pass product through separation device such as a screen or magnet (if the metal is ferrous, e.g., a steel grinder blade)	V. E. 1.2

VI. Preparing for HACCP

A. Getting people ready

In implementing your HACCP system, you will rely on people to perform a variety of tasks that will begin well before you produce any juice under your HACCP system, e.g., the development of your hazard analysis and HACCP plan.

To carry out these tasks, your employees should familiarize themselves, as appropriate, with HACCP principles and acquire any necessary HACCP training. InPart B of this section, we have listed several sources of information about HACCP resource materials and HACCP training.

You also may wish to retain outside experts to assist your staff in these tasks. For instance, a process authority can provide specialized expertise to validate the processing parameters, e.g., time/temperature, that you will use to meet the 5-log pathogen reduction requirement.

Successful implementation of HACCP requires trained people who cooperate from the preliminary stages to the implementation and ongoing operation of the HACCP system. We strongly recommend that you begin with step 1 of NACMCF's 5 preliminary steps of HACCP, by assembling a HACCP team that includes plant level and corporate level personnel. (See the HACCP Principles and Guidelines publication discussed in section IV. B.)

B. HACCP Training and HACCP Resource Materials

1.0 Juice HACCP Alliance Training Curriculum

The Juice HACCP Alliance has produced a manual for a training curriculum designed to instill the principles of HACCP as applied to the processing of juice under the requirements of the juice HACCP regulation.[14] In a guidance document entitled "Standardized Training Curriculum for Application of HACCP Principles to Juice Processing" (see section I. C. for availability information) FDA has advised that this manual, the 1st Edition of the Juice HACCP Training Curriculum of the Juice HACCP Alliance (the standardized curriculum), is adequate for use in training individuals to meet the requirements of the juice HACCP regulation in 21 CFR 120.13 issued. FDA also stated that other curricula that are equivalent in coverage to that of the standardized curriculum may also be used to meet this training requirement (see 21 CFR 120.13(b)). The manual for the standardized curriculum is available for purchase from the National Center for Food Safety and Technology at the Illinois Institute of Technology, and is available for viewing and downloading at no cost at www.ncfst.iit.edu (http://www.ncfst.iit.edu) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

2.0 USDA/FDA HACCP Training Programs and Resources Database

The USDA and FDA created the HACCP Training Programs and Resources Database to support the increasing educational information needs of industry and food service professionals in implementing HACCP programs. This database provides up-to-date listings of HACCP training programs and HACCP resource materials. Its intended users are educators, trainers, field staff in Extension, Food Safety and Inspection Service (FSIS) personnel, FDA personnel, private sector food processing plants and organizations, and others interested in identifying HACCP training resources. The internet address http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml.

VII. Example Documents

This section includes example documents showing components of hazard analyses and HACCP plans for a pasteurized refrigerated apple juice, a fresh orange juice, and a not-from-concentrate pasteurized orange juice. Hazard analysis summary tables, and excerpts from HACCP plans for the three juices, and a hazard identification and evaluation exercise for apple juice are included. These are provided as examples for you to consider when you conduct your hazard analysis and write your HACCP plan. However, we recommend that as you develop your hazard analysis and HACCP plan, you consider whether other control measures, monitoring activities, and verification activities, etc., are appropriate for your particular process. Most importantly, in your hazard analysis, we recommend that you should consider the factors that are specific to your juice and your process, and any unique conditions in your facility, to identify appropriate control measures for your HACCP plan.

A. Hazard Analysis Examples

1.0 Hazard Identification and Evaluation Exercise for Apple Juice

1.1 Step 1. Hazard identification

The team develops a list of potential biological, chemical, and physical hazards that may be introduced, increased, or controlled at each step in the production process.

- **Vegetative and Protozoan Enteric Pathogens**
  - Enteric pathogens such as the bacterium *Esherichia coli* O157:H7 and the protozoan parasite *Cryptosporidium parvum* may be present on and in apples and can contaminate apple juice at the time the juice is extracted from the fruit.
- **Patulin**
  - High levels of patulin can occur in juice made from fallen apples or damaged apples that contain mold, rot, or other damage.
  - Patulin present in the extracted juice will carry through to the final product because patulin is not destroyed by pasteurization.
- **Metal Fragments**
  - Metal fatigue or worn/damaged blades in equipment used for grinding apples can introduce metal fragments into juice.
- **Pesticides**
  - Residues from unapproved pesticides or residues in excess of pesticide tolerances in juice could pose a potential hazard if they occurred over an extended period of time at levels capable of causing health effects from chronic exposure, or if they occurred for only a brief period of time at levels capable of causing acute health effects.

1.2 Step 2. Hazard evaluation

The team assesses the severity of the health consequences if a potential hazard is not properly controlled.

- **Vegetative and Protozoan Enteric Pathogens**
  - Epidemiological evidence indicates that *E.coli* O157:H7 and *Cryptosporidium parvum* can cause severe and life-threatening foodborne illness. Unpasteurized apple cider has been linked to illness outbreaks from these pathogens.
- **Patulin**
  - Exposure over a period of time to high levels of patulin may pose a health hazard.
- **Metal Fragments**
  - If large enough, metal fragments in juice can cause injury when ingested.
- **Pesticides**
  - Acute or chronic exposure to unapproved pesticide residues can cause a variety of adverse health effects, some of which could be severe.

The team determines the likelihood of a potential hazard occurring if not properly controlled.

- **Vegetative and Protozoan Enteric Pathogens**
  - Because the entire fruit will be extracted, there is a reasonable chance for the pathogen to be present in the extracted juice if it is present in or on the fruit.
- **Patulin**
  - Available data indicates that if dropped or damaged apples are used to make juice, high levels of patulin may be reasonably expected to occur in the juice.
- **Metal Fragments**
  - Without controls, there is no means in the process by which metal fragments from grinding equipment would be removed from the juice.
- **Pesticides**

- Harmful pesticide residues in the juice are not likely because in U.S. produce, unapproved pesticide residues occur infrequently and the public health impact is typically not severe.

The HACCP team decides that E.coli O157:H7, Cryptosporidium parvum, patulin, and metal fragments are hazards that are reasonably likely to occur in the apple juice.

2.0 Example Hazard Analysis for Pasteurized Refrigerated Apple Juice

On the following page is an example of a "Hazard Analysis Summary Table" for a pasteurized refrigerated apple juice packed in plastic bottles. In the example, the process steps are simplified as compared with what may be performed in an actual process, but all critical process steps for this type of juice are included. For this example, we assumed that patulin was a hazard that was reasonably likely to occur if fallen fruit was used to make the juice or if the apples were not culled or trimmed after storage to remove rotten, moldy, damaged, or bruised fruit. See the discussion in section V. C. 5.2 about why two pathogens are identified as the pertinent microorganism in this hazard analysis.

Pasteurized Refrigerated Apple Juice

Procedures/Steps

Incoming Materials

- Locally grown fresh apples are received directly from farms.
- Packaging materials are delivered in clean, well-maintained and covered vehicles.

Processing

- Fruit is unloaded and placed into cold storage.
- Fruit is transferred from cold storage to the processing area, and dumped onto a slotted hopper where stems, leaves and other extraneous materials are removed.
- From the slotted hopper, the fruit goes to a flume tank containing sanitizer treated water.
- Fruit is elevated, dewatered, and moved over inspection rollers where visually defective apples are culled and fruit is rinsed with potable water.
- Fruit continues on to a wet scrubber where it is brushed and sprayed with treated water. Fruit then passes along a rubberized roller where it is partially dried.
- Fruit is elevated, rinsed in potable water, drained, and dropped into a hammermill grinder.
- After grinding, the slurry goes to a continuous belt press where the pomace and juice slurry are separated.
- The juice slurry is screened to separate the juice from the pulp, achieve a particle size compatible with the pasteurizer manufacturer's recommendations, and to remove metal fragments.
- The juice is pumped to a holding tank.
- The juice is pasteurized in a plate heat exchanger, which heats the juice to a predetermined temperature, holds the juice for a set time, and cools the juice as it exits.
- The juice is pumped into a refrigerated bulk storage tank.

Packaging and Shipping

- Juice is filled into High Density Polyethylene (HDPE) blow-molded bottles of various sizes. Bottles are capped, labeled, coded, cased, palletized and stored refrigerated until shipping.

Table 2. Hazard Analysis Summary Table(for Pasteurized Refrigerated Apple Juice)

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled, or enhanced at this step	(3) Are any potential food-safety hazards significant? (Yes/No)*	(4) Justify your decision for Column 3	=(5) What control measure(s) can be applied to prevent the significant hazards? =	(6) Is this step a Critical Control Point? (Yes/No)

Receiving (raw apples)	**Biological(B)** - Vegetative and protozoan enteric pathogens (i.e., *E.coli* O157:H7 and *Cryptosporidium parvum*)	Yes	History of outbreaks for apple juice.	Pasteurization	No
	Chemical(C) - 1. Pesticides	No	In U.S. produce unapproved pesticide residues occur infrequently and public health impact is typically not severe.		No
	2. Patulin	Yes	May have adverse effects	Supplier guarantee (apples harvested to exclude fallen fruit) and culling or trimming defective (i.e., moldy, rotten, bruised and damaged) apples.	Yes
	Physical(P) - None				
Receiving (plastic bottles/caps)	**B** - None				
	C - None				
	P - None				
Dry Storage **(plastic bottles/caps)**	**B** - None				
	C - None				
	P - None				
Cold Storage	**B** - Growth of pathogens such as salmonella and *E. coli* O157:H7 due to temperature abuse	No	Growth not likely due to the pH of apples.		
	C - Patulin	Yes	Patulin levels may increase in storage.	Cull or trim defective apples	No
	P - None				
Remove Debris **(slotted hopper)**	**B** - None				
	C - None				
	P - None				
Wash (flume tank)	**B** - Contamination with pathogens such as salmonella from water	No	Not likely to occur due to SSOP for water quality		
	C - None				
	P - None				
Cull	**B** - None				
	C - Patulin	Yes	Patulin levels are reduced by culling defective apples.	Cull or trim defective apples.	Yes
	P - None				
Brush/Wash	**B** - None				
	C - None				
	P - None				
Partially Dried	**B** - None				
	C - None				

	P - None				
Grind	**B** - None				
	C - None				
	P - Metal fragments	Yes	Metal fatigue, worn and damaged blades can cause contamination of slurry.	Screen	No
Press	**B** - None				
	C - None				
	P - None				
Screen	**B** - None				
	C - None				
	P - Metal fragments	Yes	Intact screen filters out the metal fragments	Screen	Yes
Holding Tank	**B** - None				
	C - Sanitizing chemicals	No	Not likely to occur because of SSOP for cleaning and sanitizing; residue levels not reasonably likely to cause illness.		
	P - None				
Pasteurize/Cool	**B** - Vegetative and protozoan enteric pathogens (*E. coli* O157:H7 and *Cryptosporidium parvum* are the pertinent microorganisms	Yes	Microbial contamination on incoming apples.	Pasteurization	Yes
	C - None				
	P - None				
Holding Tank	**B** - None				
	C - Sanitizing chemicals	No	Not likely to occur because of SSOP for cleaning and sanitizing; residue levels not reasonably likely to cause illness.		
	P - None				
Fill	**B** - None				
	C - None				
	P - None				
Cap	**B** - None				
	C - None				
	P - None				
Code/Case/Palletize	**B** - None				

	C - None				
	P - None				
Cold Storage	**B** - None				
	C - None				
	P - None				
Ship	**B** - None				
	C - None				
	P - None				

* For the purpose of this example hazard analysis, a "significant hazard" is one that meets the definition of a hazard that is reasonably likely to occur in §120.7(a)(2) of the juice HACCP regulation, i.e., it is one for which a prudent processor would establish controls, i.e., at CCPs in his HACCP plan.

3.0 Example Hazard Analysis for Fresh Orange Juice

On the following page is an example of a "Hazard Analysis Summary Table" for a fresh orange juice packed in plastic bottles for which the 5-log pathogen reduction process is achieved through surface treatment of the oranges. In the example, the process steps are simplified as compared with what may be performed in an actual process, but all critical process steps for this type of juice are included. A hazard identification and evaluation exercise is not shown for this juice, but for enteric pathogens, it would be similar to the one shown above for apple juice, except that *Salmonella* species would be identified as the pathogen of concern (the pertinent microorganism) because of the history of illness outbreaks caused by *Salmonella* in orange juice. For pesticides, the hazard identification and evaluation exercise would be identical to the one shown for apple juice. Patulin is not a concern for citrus juices. For this example, we assume that the processor has data of the type discussed in section IV. C. 1.32, indicating that there were no occurrences of metal fragments in the juice, and thus was able to conclude that the potential hazard of metal fragments from the extraction equipment was not reasonably likely to occur.

Fresh Orange Juice

Procedures/Steps

Incoming Materials

- Locally grown tree-picked oranges of various varieties are received either directly from the field or from local cold storage facilities.
- Packaging materials are delivered in clean, well-maintained, and covered vehicles.

Processing

- Fruit is visually inspected prior to unloading and placed into cold storage.
- Fruit is washed prior to primary culling.
- During primary culling, damaged fruit is culled out and disposed of (primary cull step).
- Fruit is rinsed with potable water.
- Fruit is sprayed with sanitizer solution.
- Fruit passes through a brush washer while being sprayed with a detergent/sanitizer.
- Fruit is graded (secondary cull step).
- Fruit is sprayed with a sanitizer solution and rinsed with potable water.
- Juice is extracted using a process that limits juice/peel contact.
- Juice is chilled using a tube-in-shell heat exchanger.
- Juice is batched in a chilled surge tank.

Packaging and Shipping

- Juice is filled into HDPE blow-molded bottles of various sizes. Bottles are capped, passed through a metal detector, labeled, cased, and stored refrigerated until shipping.

Table 3. Hazard Analysis Summary Table (for Fresh Orange Juice)

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food-safety hazards significant? (Yes/No)*	(4) Justify your decision for Column 3	(5) What control measure(s) can be applied to prevent/reduce/eliminate the hazard?	(6) Is this step a Critical Control Point? (Yes/No)
1. Receiving (raw fruit)	B - Pathogens (*Salmonella* spp. was determined to be the pertinent microorganism)	Yes	B - Pathogens in raw fruit have been known to cause illness	B - Supplier agreement specifying that only tree-picked fruit will be supplied, culling to remove damaged fruit that may contain pathogens in edible portion, brush washing and sanitizing fruit.	Yes
	C - Pesticides	No	C - In U.S. produce, unapproved pesticide residues occur infrequently and public health impact is typically not severe		No
	P - None	No			No
2. Inspect, Wash, Cold Storage	B - None	No			No
	C - None				
	P - None				
3. Primary cull	B - Pathogens	Yes	Pathogens in raw fruit have been known to cause illness	Cull visually damaged fruit, e.g., punctures, splitting, cuts, rot, mold in peel	Yes
4. Potable Water Rinse	B - Pathogens from water	No	Not likely to occur due to SSOP for water quality.		
	C - None				
	P - None				
5. Sanitize	B - Pathogens	Yes	B - Pathogens in raw fruit have been known to cause illness	Sanitized wash used to achieve portion of cumulative 5-log pathogen reduction	Yes
6. Brush Washing with Detergent/Sanitizer	B - Pathogens	Yes	B - Pathogens in raw fruit have been known to cause illness	Sanitized wash used with brusher used to achieve portion of cumulative 5-log pathogen reduction	Yes
7. Grading (secondary cull)	B - None	No			No
	C - None				
	P - None				
8. Re-sanitize	B - Pathogens	Yes	B - Pathogens in raw fruit have been known to cause illness	Sanitized wash used to achieve portion of cumulative 5-log pathogen reduction	Yes
9. Extract	B - None				No **
	P - Metal fragments	P - No	P - Processor has metal detector data for more than one year showing that no metal metal fragments capable of causing injury have occurred in juice from the extraction equipment		

10. Chill	B - None				No
	C - None				
	P - None				
11. Batch in chilled surge tank	B - None	No			No
	C - None				
	P - None				
12. Package, cap	B - None	No			No
	C - None				
	P - None				
13. Label, case, palletize	B - None	No			No
	C - None				
	P - None				
14. Store, ship	B - None	No			No
	C - None				
	P - None				

B=Biological; C=Chemical; P=Physical

*For the purpose of this example hazard analysis, a "significant hazard" is one that meets the definition of a hazard that is reasonably likely to occur in § 120.7(a)(2) of the juice HACCP regulation, i.e., it is one for which a prudent processor would establish controls, i.e., at CCPs in his HACCP plan.

** In this example hazard analysis, the extraction step was not determined to be a CCP because the extractor is of a design that facilitates the 5-log pathogen reduction by by limiting juice/peel contact during extraction, and is the only extractor in the facility. Should a different extractor be used in the facility, the processor would have to re-validate the HACCP plan under § 120.11 (b).

4.0 Example Hazard Analysis for Not-from-Concentrate Pasteurized Orange Juice

On the following page is an example of a "Hazard Analysis Summary Table" for a not-from-concentrate pasteurized orange juice in cartons. The orange juice is derived from oranges that are extracted at the facility, and from un-pasteurized juice received in tankers. FDA permits unpasteurized juice to be shipped in bulk if the processor receives assurance that another processor will treat the juice to achieve the 5-log pathogen reduction in the facility where final packaging is to be performed (see "The Juice HACCP Regulation Questions and Answers," at the web address given in section I. B above).

In the example, the process steps are simplified as compared with what may be performed in an actual process, but all critical process steps for this type of juice are included.

A hazard identification and evaluation exercise is not shown for this juice, but for enteric pathogens, it would be similar to the one shown above for apple juice, except that *Salmonella* species would be identified as the pathogen of concern (the pertinent microorganism) because of the history of illness outbreaks caused by *Salmonella* in orange juice. For pesticides, the hazard identification and evaluation exercise would be identical to the one shown for apple juice. Patulin is not a concern for citrus juices.

Metal fragments could occur in the orange juice, but they would originate from the extraction equipment in this example, because no grinding of fruit (as was performed in the apple juice process) is performed in this process. Metal fragments in the unpasteurized juice received in tankers would be handled under the HACCP Plan of the processor of that juice (see section V. D. 1.3).

Not-from-Concentrate Pasteurized Orange Juice

Procedures/Steps

Incoming materials

- Locally grown fresh oranges of various varieties are received directly from the field. Un-pasteurized juice is also received in tankers.
- Packaging materials are delivered in clean, well-maintained, and covered vehicles.

Processing

- At fruit receiving/bin staging, fruit is unloaded, de-stemmed.
- Fruit is rinsed with potable water.
- Fruit is graded (initial culling)
- Graded fruit is stored in bins.
- Upon removal from bins, fruit is rinsed and then brush washed with detergent/sanitizer.
- Fruit is rinsed with potable water.
- Fruit is graded (final culling).
- Fruit is sized and the juice is extracted.
- Pulp is removed from the extracted juice by finishers and the juice is pumped to a jacketed surge tank.
- Incoming juice (unpasteurized) from tankers is pumped to a jacketed storage tank.
- Juices are then blended in a surge tank for pasteurization.
- Juice is pasteurized using a tube-in-shell heat exchanger.
- Pasteurized juice is chilled and pumped to a jacketed surge tank.

Packaging and Shipping

- Chilled pasteurized juice is screened and filled into cartons
- Cartons are sealed, coded, cased, palletized, and put into refrigerated storage.
- Products are shipped in clean, well-maintained refrigerated tractor-trailers.

Table 4. Hazard Analysis Summary Table
(for Not-from-concentrate Pasteurized Orange Juice)

(1) **Ingredient/ processing step**	(2) **Identify potential hazards introduced, controlled or enhanced at this step**	(3) **Are any potential food-safety hazards significant? (Yes/No)***	(4) **Justify your decision for Column 3**	(5) **What preventative measure(s) can be applied to prevent/reduce/eliminate the hazard?**	(6) **Is this step a Critical Control Point? (Yes/No)**
1. Receiving/Staging (raw fruit)	B - Pathogens (*Salmonella* spp. were determined to be the pertinent microorganism)	Yes	B - Possible presence of pathogens on incoming fruit	B - Controlled at the pasteurization step.	No
	C - Pesticides	No	C - In U.S. produce, unapproved pesticide residues occur infrequently and public health impact is typically not severe		No
	P - None				
2. Destemming	B - None	No			No
	C - None				
	P - None				
3. Rinse	B - None	No			No
	C - None				

	P - None				
4. Primary Culling	B - None	No			No
	C - None				
	P - None				
5. Bin Storage	B - None	No			No
	C - None				
	P - None				
6. Rinse and Brush Wash w/Detergent Sanitizer	B - None	No			No
	C - None				
	P - None				
7. Potable Water Rinse	B - None	No			No
	C - None				
	P - None				
8. Final Culling	B - None	No			No
	C - None				
	P - None				
9. Sizing	B - None	No			No
	C - None				
	P - None				
10. Extraction	B - None				
	C - Lubricants	No	Not likely to occur due to preventative maintenance SSOP and use of food grade lubricants.		
	P - Metal fragments	Yes	Metal fragments from extraction equipment due to wear, metal fatigue, and breakage may cause injury if ingested	P - Controlled at screen step	No - controlled at screen step
11. Receipt of un-pasteurized juice in tankers	B - Pathogens, Salmonella spp.	Yes	Possible presence of pathogens in unpasteurized juice	B - Controlled at the pasteurization step	No
	C - None				
	P - None - (metal fragments are handled under shipper's HACCP plan)				
12. Blend	B - None	No			No
	C - None				
	P - None				
13. Pasteurize	B - Pathogens, *Salmonella* spp.	Yes	Possible presence of pathogens on incoming fruit and in unpasteurized juice	Pasteurization	Yes
	C - None				

	P - None				
14. Chill	B - None	No			No
	C - None				
	P - None				
15. Surge Tank	B - None	No			No
	C - None				
	P - None				
16. Screen	B - None				
	C - None				
	P - Metal fragments	Yes	Eliminates metal fragments introduced at extraction step	Screen	Yes
17. Fill in Cartons	B - None	No			No
	C - None				
	P - None				
18. Seal Cartons	B - None	No			No
	C - None				
	P - None				
19. Code, case, palletize	B - None	No			No
	C - None				
	P - None				
20. Store	B - None	No			No
	C - None				
	P - None				
21. Ship	B - None	No			No
	C - None				
	P - None				

B. HACCP Plan Examples

Included in this section are three examples of how to write components of a HACCP plan. The first example is for a pasteurized refrigerated apple juice, the second example is for a fresh orange juice, and the third example is for a not-from-concentrate pasteurized orange juice.

1.0 Example HACCP Plan for Pasteurized Refrigerated Apple Juice

The following table represents excerpts from a Summary HACCP Plan for a pasteurized refrigerated apple juice packed in plastic bottles. For this example, it is assumed that the pasteurization process is performed using a continuous (non-batch) system with a positive displacement (constant flow) timing pump. (See Discussion of Pasteurization Equipment in section V.C.5.11.) The excerpts included in this example are for the control of enteric pathogens, patulin, and metal fragments. An actual HACCP plan for such a product might be more detailed, but the summary table format lists all of the elements that we recommend be included in the plan.

Table 5. Excerpts from Summary HACCP Plan
(For Pasteurized Refrigerated Apple Juice)

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			A. What	B. How	C. Frequency	D. Who			
CCP1 Receiving	Patulin	A supplier guarantee specifying that the shipment includes only apples harvested to exclude fallen fruit.	Ensure supplier guarantee exists for each incoming shipment of fruit.	Supplier guarantee is visually confirmed.	Each incoming fruit shipment	Receiving manager	Reject fruit if not accompanied by supplier guarantee.	Review monitoring corrective action and verification records within one week of preparation Audit the supplier periodically for adherence to guarantee Periodically test juice for patulin levels	Supplier guarantee Receiving log Supplier audit report Patulin test results
CCP 2 Culling	Patulin	Undamaged apples[15]	Moldy, rotten, bruised or otherwise damaged apples	Visual inspection	Continuous	Culling inspector	Stop belt and remove damaged fruit AND Adjust belt speed if necessary	Review monitoring, corrective action, and verification records within one week of preparation Periodically test juice for patulin levels	Culling log Patulin test results
CCP 3 Screen	Metal inclusion	Screen is intact and in place	Integrity of screen	Visual	Daily	Production Employee	Segregate product and rework to eliminate metal pieces, run product through metal detector, divert to nonfood use, or destroy AND Replace screen.	Calibrate screen to ensure metal pieces 7 mm or greater do not pass screen, semi-annually. Review monitoring corrective action and verification records within one week of preparation	Screen integrity log Screen calibration log

CCP 4 Pasteurize	*E. coli* O157:H7 and *Cryptosporidium parvum*	Minimum 160° F and 6 seconds (provides a 5-log reduction)	1.Temperature of juice 2. Flow rate	1.Temperature recorder 2. Visual check of positive displacement pump setting	Continuous monitoring with visual check hourly Daily	Pasteurizer operator Pasteurizer operator	Segregate and hold affected product for evaluation, destroy, or divert to nonfood use AND Adjust pasteurizer (temperature or flow rate) to achieve the critical limit. AND Reprocess any product that did not undergo 5-log pathogen reduction	Documentation of process establishment; Check the accuracy of the temperature recording device (TRD) against a mercury and glass thermometer daily; Calibrate the mercury and glass (MIG) thermometer annually; Flow rate test and resealing of pump speed monthly; Review monitoring, corrective action, and verification records within one week of preparation.	Operator's log Recorder Thermometer Chart TRD, MIG and pump check and calibration records

2.0 Example HACCP Plan for Fresh Orange Juice

The following table represents excerpts from a HACCP plan for fresh orange juice packed in plastic bottles. For this example, surface treatment of the orange peel is performed to achieve the 5-log pathogen reduction. The excerpts in this example show five critical control points (steps 1, 3, 5, 6, and 8 in the summary table shown in the Hazard Analysis example for this juice) for ensuring that the incoming fruit is properly culled to remove damaged fruit that may contain pathogens in the edible portion of the fruit, that the orange peel is effectively sanitized to achieve a cumulative 5-log pathogen reduction before extracting the juice.

Processing steps other than those cited as critical control points are also important to ensuring a safe juice. For example, the effectiveness of the pathogen reduction process depends upon ensuring that juice is not contaminated by any pathogens that may be present on the peel during the extraction operation. For this hypothetical process, it was assumed that the juice was extracted using an extraction process, which limits juice/peel contact during the extraction operation.

2.0 Example HACCP Plan for Fresh Orange Juice

Table 6. Excerpts from Summary HACCP Plan

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			

CCP 1 (biological) Receiving	Pathogens-*Salmonella*	A supplier guarantee specifying that the shipment includes only tree-picked oranges.	Ensure supplier guarantee exists for each incoming shipment of fruit.	Supplier guarantee is visually confirmed.	Each incoming fruit shipment	Receiving manager	Reject fruit if not accompanied by supplier guarantee.	Review monitoring corrective action and verification records within one week of preparation. Audit the supplier annually for adherence to guarantee.	Supplier guarantee Receiving log Supplier audit report
CCP 2 (biological) Primary cull	Pathogens-*Salmonella*	Undamaged fruit	Damaged peel, e.g., punctures, cuts, splitting, rot, mold	Visual inspection	Continuous	Culling inspector	Stop belt and remove damaged fruit. AND Adjust belt speed if necessary.	Review monitoring, corrective action, and verification records within one week of preparation.	Culling log
CCP 3 (biological) Sanitize	Pathogens-*Salmonella*	1. Minimum of 200ppm of available chlorine 2. 30 sec contact time	1. Free available chlorine 2. Belt speed (RPM)	1. Low concentration alarm 2. Measure belt marking speed with stopwatch	1. Continuous 2. Daily	1. Operator 2. Operator	1. Stop line, adjust sanitizer strength to achieve critical limit, AND segregate and hold affected product for evaluation, destroy or divert to nonfood use Stop line, adjust belt speed to achieve critical limit, AND segregate and hold affected product for evaluation, destroy or divert to nonfood use	Test alarm daily Review monitoring corrective action and verification records within one week of preparation. Review of required testing for biotype 1 *E. coli.*	Log of alarm test, belt speed test *E. coli* test results

CCP 4 (biological) Brush wash with Detergent/Sanitizer	Pathogens-*Salmonella*	Minimum of 200ppm of available chlorine Contact time ___ seconds (processor should include appropriate entry in HACCP plan)	Strength of sanitizer Belt speed ___ RPM (processor should include appropriate entry in HACCP plan)	Chlorine test kit or equivalent	At the beginning of the operation and hourly thereafter	Operator	Stop line, adjust sanitizer strength or belt speed to achieve critical limit, AND segregate and hold affected product for evaluation, destroy, or divert to nonfood use.	Review monitoring, corrective action, and verification records within one week of preparation. Review of required testing for biotype 1 *E. coli.*	Operator test log *E. coli* test results
CCP 5 (biological) Re-sanitize	Pathogens-*Salmonella*	Minimum of 200ppm of available chlorine Contact time ___ seconds (processor should include appropriate entry in HACCP plan)	Strength of sanitizer Belt speed ___ RPM (processor should include appropriate entry in HACCP plan)	Chlorine test kit or equivalent	At the beginning of the operation and hourly thereafter.	Operator	Same as CCP 4	Same as CCP 4	Same as CCP 4

3.0 Example HACCP Plan for Not-from-concentrate Pasteurized Orange Juice

The following table represents excerpts from a Summary HACCP Plan for a not-from-concentrate pasteurized orange juice packed in cartons. For this example, it is assumed that the pasteurization process is performed using a continuous (non-batch) system with monitoring of the flow rate of the juice through the heat exchanger. (See Discussion of Pasteurization Equipment in section V.C 5.31) The excerpts included in this example are for the control of enteric pathogens and metal fragments. An actual HACCP plan for such a product might be more detailed, but the summary table format lists all of the elements that we recommend be included in the plan.

Table 7. Excerpts from Summary HACCP Plan

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			

CCP 1 Pasteurization	Pathogens-*Salmonella*	Minimum 160 deg. F AND Min. 3 sec. Hold loop	Temperature Flow rate	Chart recorder Flow meters	Continuous with hourly visual check. Continuous with daily visual check.	Operator Operator	Isolate affected product. Reprocess, destroy, or divert (to non-food use) the affected product Adjust pasteurizer to achieve critical limit.	Documentation of process establishment. Check accuracy of temperature recording device against mercury in glass thermometer daily. Calibrate MIG thermometer annually. Weekly fill test for flow rate. Review monitoring, corrective action, and verification records w/in one week of preparation.	Operator inspection log Calibration records Fill test log
CCP 2 Screen	Metal fragments	Screen is intact and in place	Integrity of screen	Visual	Daily	Production employee	Segregate product and rework to eliminate metal pieces, run product through metal detector, divert to nonfood use, or destroy AND Replace screen.	Calibrate screen to ensure metal pieces 7 mm or greater do not pass screen, semi-annually. Review monitoring, corrective action, and verification records within one week of preparation.	Screen integrity log. Calibration log.

C. Example CCP and SSOP for prevention of occurrence of undeclared milk residues in juice

- **Example SSOP Item**

  This example SSOP illustrates how contamination of juice with milk residues due to cross contact from the use of processing equipment also used to process milk or dairy products may be prevented. Such an SSOP would be applicable in a facility that processes both dairy beverages, e.g., milk, and juice.

  Goal: All surfaces of equipment that contact juice during processing are pre-rinsed, then cleaned with caustic cleaning solution and rinsed, prior to processing juice on any equipment that has been used to process milk during the previous production run.

  Procedure: An equipment log is to be maintained for each piece of processing equipment, e.g., pasteurizer, filler, that may contact milk, dairy products, or juice that indicates what foods were processed using the equipment and the time of the processing. The log also will record all cleanings of the equipment, and will denote the cleaning procedure, e.g., pre-rinse, then caustic followed by rinse, and the time of the cleaning. The efficacy of the cleaning procedure will be monitored by swabbing the surfaces of the equipment and testing the swabs for milk protein residue.

  The production supervisor will review the equipment log prior to every juice production run to determine whether milk was processed during the previous production run on the equipment to be used for the juice run. If milk was processed in the previous run, the supervisor will verify that the equipment has been cleaned using the prescribed procedure.

Weekly Equipment Log

Equipment	Food Processed (date/time)	Swab Test Result

Pasteurizer #1		
Pasteurizer #2		
Filler #1		
Filler #2		
Holding Tank #1		
Holding Tank #2		

Example CCP Item

This example CCP illustrates how contamination of juice with milk residues due to cross contact from the use of processing equipment also used to process milk may be prevented. Such a CCP would be applicable in a facility that processes both dairy beverages, e.g., milk, and juice.

Critical Control Point (CCP)	**Hazard(s)**	**Critical Limits**	**Monitoring**				**Corrective Action**	**Verification**	**Record keeping**
			What	**How**	**Frequency**	**Who**			
Product changeover from product containng a known food allergen to product that does not contain that allergenic material. Equipment cleaning after producing the allergen-contain-ing product, prior to producing the non-allergen (or different allergen) containing product.	Chemical - undeclared food allergen Product changeover presents an unintentional opportunity for product that contains an allergen(s) to cross-contact product that doesn't contain that particular allergen, thus resulting in an undeclared allergen.	Validated cleaning process parameters: e.g., values for pre-rinse time & temperature; alkali cleaner %, time, and temperature; and/or rinse time and temperature - whatever values for control measures that are critical for allergen control	Critical cleaning parameters	Monitoring devices used to measure cleaning parameters	Every time the cleaning process is performed	Operator	**During cleaning:** If monitoring indicates non-compliance with the critical limits, use alternate methodolo-gy to clean the equipment surfaces to remove the residue prior to running the non-allergen (or different allergen) containing product, and document the cleaning on the equipment inspection log. **After production** If records review indicates that critical limits may not have been met, place the entire production of product on hold and assess for allergen hazard.	Review monitoring, corrective action and verification records w/in one week of preparation. Calibration of all monitoring, corrective action and verification instruments. Periodic check to verify the CCP is effective and under control (e.g., testing of CIP solution, final product, or certain equipment swabs for allergenic protein).	Monitoring, corrective action and CCP verification records

Notes:

[1] This guidance has been prepared by the Division of Plant Product Safety in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] Except for high Brix juice concentrates and certain shelf-stable juices as discussed in section V. C. 2.0.

[3] Comments on the draft of this guidance requested clarification on how to classify probable hazards, i.e., "reasonably likely to occur," or "not reasonably likely to occur," that fall under the realm of facility sanitation related hazards that may be addressed under SSOPs or under the HACCP plan (at the processor's option). We believe that it is only necessary to classify this type of hazard as "reasonably likely to occur" when you have opted to control the hazard through your HACCP plan at a CCP, as we have recommended in Section IV. C. 3.3 for undeclared allergens in juice arising from inadequately cleaned processing equipment previously used to process milk. If you have opted to control a facility sanitation related hazard through your SSOPs, it is not necessary to classify it as reasonably likely to occur.

[4] An action level is a guideline that FDA uses in considering whether the level of a contaminant in a food may constitute a health hazard sufficient to warrant regulatory action by FDA against the product.

[5] Food allergens (see CPG chapter 555.250) are naturally occurring proteins in certain foods that cause abnormal responses of the immune system involving the production of allergen specific IgE antibodies in some individuals.

[6] In the January 22, and January 25, 2002 letters, FDA described high degree Brix juice concentrate as a concentrate that is diluted and repackaged as either frozen juice concentrate for consumer use or as institutional concentrate, and also stated that high degree Brix juice concentrates that are diluted to single strength and repackaged are not covered under the FDA policy stated therein.

[7] Mazzotta, Alejandro S., Thermal Inactivation of Stationary-Phase and Acid-Adapted *Escherichia coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* in Fruit Juices, Journal of Food Protection, Vol. 64, No. 3, 2001, pp. 315-320

[8] Mak, Peggy P., Ingham, Barbara H., and Ingham, Steven C., Validation of Apple Cider Pasteurization Treatments against Escherichia coli O157:H7, Salmonella, and Listeria monocytogenes, Journal of Food Protection: Vol. 64, No. 11, 2001 pp. 1679-1689.

[9] See Deng, Ming Qi, and Cliver, Dean O., Inactivation of *Cryptosporidium parvum* Oocysts in Cider by Flash Pasteurization, Journal of Food Protection, Vol. 64, No. 4, 2001, pp. 523-527, and Harp, James A., Fayer, Ronald, Pesch, Bruce A., and Jackson, George J., Effect of Pasteurization on Infectivity of Cryptosporidium parvum Oocysts in Water and Milk, Applied and Environmental Microbiology, Vol. 62, No. 8, 1996, pp. 2866-2868.

[10] See Hanes, D.E., Orlandi, P.A., Burr, D.H., Miliotis, M.D., Robl, M.G., Bier, J.W., Arrowood, M.J., Churey, J.J., Jackson, G.J., and Worobo, R.W., Inactivation of *Crytposporidium parvum* Oocysts in Fresh Apple Cider by UV Irradiation, Applied and Environmental Microbiology, Vol. 68 No. 8, 2002, pp. 4168-4172.

[11] Jackson, Lauren S., Beacham-Bowden, Tina, Keller, Susanne E., Adhikari, Chaitali, Taylor, Kirk T., Chirtel, Stewart J., and Merker, Robert I., Apple Quality, Storage, and Washing Treatments Affect Patulin Levels in Apple Cider, Journal of Food Protection: Vol. 66, No. 4, 2003, pp. 618-624

[12] The juice HACCP regulation requires control measures that will achieve a 5-log reduction in the "pertinent microorganism" for all juices except shelf stable juices, juice concentrates, and juices subject to the low acid canned foods or acidified foods regulations.

[13] Pathogens include enteric pathogens (e.g., *E. coli* O157:H7, *Cryptosporidium parvum*, *Salmonella* spp.) and *Listeria monocytogenes*, which is ubiquitous in nature.

[14] The Juice HACCP Alliance was formed through the voluntary participation of industry, government, and academic members interested in guiding the juice industry to the higher level of food safety assurance provided by HACCP. The Alliance was coordinated through the efforts of the National Center for Food Safety and Technology at the Illinois Institute of Technology. Staff from the FDA participated as technical advisors in the development of the curriculum.

[15] In practice, this processor should establish visual criteria for what constitutes a damaged apple that should be culled. The criteria should be established based upon validation data showing that juice made from apples culled using the criteria do not contain unacceptable levels of patulin.

This document supercedes Draft Guidance: Juice HACCP Hazards and Controls Guidance *First Edition* (September 12, 2002)

Related Information

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