

Juice HACCP Final Rule



Donald A. Kautter, Jr.
Consumer Safety Officer
Division of HACCP Programs
Washington, D.C.
United States of America

FDA's Juice Initiative

Outline:

- **Public debate and alternatives considered to reduce risks**
- **(Very) basic HACCP Principles**
- **Key elements of the juice HACCP Final Rule**

Juice HACCP – Public Debate/Education

Juice Public Meeting – December, 1996

**National Advisory Committee on
Microbiological Criteria for Foods
(NACMCF)**

Juice HACCP – Public Debate/Education

Juice Public Meeting – December, 1996

- **Purpose:**
 - **Consider industry practices, current science regarding risks, alternative ways to reduce risk, and additional consumer education**
- **Participants:**
 - **Government, academia, industry, and consumer representatives**

Juice HACCP – Public Debate/Education

Juice Public Meeting – December, 1996

- **NACMCF Recommendations:**
 - **Need for active safety intervention, especially for fresh juices**
 - **Use of safety performance criteria**
 - **Cumulative 5 log reduction in a target microorganism or**
 - **Reduction in yearly risk of illness to less than 1 in 100,000**

Juice HACCP – Public Debate/Education Citrus Juice Technical Workshops November 1998

- **Purpose:**
 - **To explain how citrus juice processors could attain a 5-log reduction in the pertinent pathogen in citrus juices**

Juice HACCP – Public Debate/Education Apple Juice Workshop

July 1999

- **Purpose:**
 - **To explain the agency's regulations requiring warning statements on certain juice products and to address pathogen reduction interventions that may be effective for apple cider**

Juice HACCP – Public Debate/Education

Juice Public Meeting - December 1999

NACMCF

- **Purpose:**
 - **To discuss recent research and other information related to performance criteria for fresh citrus juices and to discuss the potential for internalization of pathogens into citrus fruit as well as information relative to the application and measurement of the 5-log reduction**

Juice HACCP – Public Debate/Education

Juice Public Meeting - December 1999

NACMCF Recommendations on citrus juice:

- **5-log does not have to start with extracted juice but processors should not start a cumulative reduction until after the fruit is cleaned and culled,**
- **One way to minimize microbial infiltration would be by controlling the temperature of the wash water,**

Juice HACCP – Public Debate/Education

Juice Public Meeting - December 1999

NACMCF Recommendations on citrus juice:

- **The entire 5-log process must occur under one firm's control and in one processing facility,**
- **Juice shipped in bulk (tankers/totes) is not juice in a final package form and must undergo a 5-log reduction process after transport and prior to final fill and packaging, and**

Juice HACCP – Public Debate/Education

Juice Public Meeting - December 1999

NACMCF Recommendations on citrus juice:

- **As part of a HACCP verification program, firms should conduct microbial testing on the final product if the 5-log reduction process relies in part on fruit surface decontamination.**

Juice HACCP

Alternatives Considered:

- Increased inspection
- cGMPs
- Mandatory pasteurization
- Labeling
- Education
- HACCP

Juice HACCP

HACCP – Alternative of Choice:

- Follows the recommendations of NACMCF
- HACCP is the most effective approach and is science based
- HACCP incorporates the best of the other alternatives:
 - Manufacturer responsible for self-verification
 - cGMP's provide prerequisite foundation to HACCP
 - Encourages innovations for effective control measures

HACCP

Five Preliminary Steps of HACCP:

- Assemble a HACCP Team
- Describe the food and its distribution
- Identify the intended use and consumer of the food
- Develop a flow diagram
- Verify the flow diagram

HACCP

Seven Principles of HACCP:

- **Conduct a Hazard Analysis**
- **Determine the Critical Control Points (CCPs)**
- **Establish Critical Limits**
- **Establish Monitoring Procedures**
- **Establish Corrective Actions**
- **Establish Verification Procedures**
- **Establish Record Keeping and Documentation Procedures**

HACCP

Foundation for Juice HACCP Regulation:

- **Consistent with NACMCF Recommendations**
- **Consistent with FDA Seafood HACCP regulation**
- **Consistent with USDA's HACCP regulation for meat and poultry products**
- **Modifications from Seafood HACCP:**
 - **Written hazard analysis**
 - **Distinction/clarification between validation and verification**
 - **Imports – written hazard analysis**
 - **Performance standard**
 - **End product testing for fresh citrus juice producers**

Juice HACCP

Definition of Juice:

- **Aqueous liquid used in a beverage expressed or extracted from one or more fruits or vegetables**
- **Puree used in a beverage of the edible portion of one or more fruits or vegetables**
- **Concentrate of such liquid or puree**

Juice HACCP

Applicability:

- Any juice sold as such or used as an ingredient in beverages must be processed in accordance with the HACCP requirements in Part 120
- Juices not processed according to Part 120 will be considered adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act
- The requirements of Part 120 shall apply to any juice, whether in interstate or intrastate commerce

Juice HACCP

Effective Dates:

- **January 22, 2002 for all juice processors except:**
 - **January 21, 2003 for small businesses**
 - **January 20, 2004 for very small businesses**

Juice HACCP

Activities not covered by the Regulation:

- **Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing**
 - **Processors should apply existing Agency guidance in these areas to minimize hazards**
- **The operation of a retail establishment**

Juice HACCP

Retail Establishment Definition:

“..an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. “Provides” includes storing, preparing, packaging, serving, and vending.”

Juice HACCP

Section 120.5:

**cGMP Regulations in 21 CFR
Part 110 still apply and are
mandatory**

Juice HACCP

Section 120.6: Sanitation Standard Operating Procedures (SSOPs)

- Each Processor shall have and implement SSOPs that address:
 - Safety of the water
 - Condition and cleanliness of food contact surfaces
 - Prevention of cross contamination
 - Maintenance of hand washing/sanitizing and toilet facilities

Juice HACCP

Section 120.6: Sanitation Standard Operating Procedures (SSOPs)

- Each Processor shall have and implement SSOPs that address:
 - Protection of food and materials from adulteration
 - Proper labeling, storage and use of toxic compounds
 - Control of employee health conditions
 - Exclusion of pests

Juice HACCP

Section 120.6: Sanitation Standard Operating Procedures (SSOPs)

- **Monitoring/Records:**
 - Each processor shall maintain SSOP records that document the monitoring and corrections related to the 8 sanitation SOP procedures
 - Controls may be in the SSOPs or in the HACCP plan

Juice HACCP

Section 120.7: Written Hazard Analysis

- Identification of food hazards
- An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur
- Identification of the control measures that can be applied
- Review of current processes to determine if modifications are necessary
- Identification of critical control points

Juice HACCP

Section 120.7: Written Hazard Analysis

Hazards to consider:

- **Biological (microbial)**
 - **Microbial**
 - **Parasitic**
 - **Viral**

Juice HACCP

Section 120.7: Written Hazard Analysis

Hazards to consider:

- **Chemical:**
 - **Chemical contamination**
 - **Unlawful pesticide residues**
 - **Decomposition in food where a food hazard has been associated with decomposition**
 - **Natural toxins**
 - **Unapproved use of food or colors additives**
 - **Presence of undeclared ingredients that may be allergens**

Juice HACCP

Section 120.7: Written Hazard Analysis

Hazards to consider:

- **Physical:**
 - **Sticks**
 - **Wood**
 - **Glass**
 - **Metal**
 - **Plastic**
 - **Rocks**

Juice HACCP

Section 120.8:HACCP Plan

- **Must be developed by a trained individual(s) and be written**
- **Specific to each location**
- **Specific to each type of juice processed, except:**
 - **may group types of juice together, and**
 - **may group types of production methods together, if the hazards and CCP controls, etc. are essentially the same**

Juice HACCP

Section 120.8:HACCP Plan

Contents of the HACCP Plan:

- List all food hazards that are reasonably likely to occur**
- List the CCPs**
- List the critical limits that shall be met at each CCP**
- List the monitoring procedures**
- Include any corrective action plans**
- List the validation and verification procedures**
- Provide for a record keeping system**

Juice HACCP

Section 120.10: Corrective Actions

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by using the corrective action plan in their HACCP plan or take steps to ensure that:

- No product enters commerce that is injurious to health or is otherwise adulterated and**
- The cause of the deviation is corrected**

Juice HACCP

Section 120.10: Corrective Actions

If a processor does not have a corrective action plan that is appropriate for the deviation, the processor shall:

- Segregate and hold affected product
- Perform or obtain a review to determine the safety of the product
- Take action to ensure that the affected product does not enter commerce
- Take action to correct the cause of the deviation
- Perform or obtain timely verification to determine whether modification of the HACCP plan is required

Juice HACCP

Section 120.11: Verification and Validation

- Every processor shall verify that the HACCP system is being implemented according to design
- Every processor shall validate that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur
- In the absence of a HACCP plan, the processor shall reassess the adequacy of the hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists

Juice HACCP

Section 120.11: Verification and Validation

- **Types of Verification:**
 - Review of consumer complaints
 - Calibration of process monitoring instruments
 - Review of CCP monitoring records within 7 days
 - Review of corrective actions within 7 days
 - End-product or in-process testing at the option of the processor except that processors of citrus juice that utilize surface treatment of fruit must perform end-product testing (Section 120.25)

Juice HACCP

Section 120.12: Records

- **Required Records:**
 - **Records documenting the implementation of the prerequisite program SSOPs**
 - **The written hazard analysis**
 - **The written HACCP plan**
 - **Records documenting the ongoing application of the HACCP plan that include:**
 - **monitoring of CCPs and their critical limits**
 - **corrective actions**
 - **Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis**

Juice HACCP

Section 120.12: Records

- **General Requirements:**
 - The name of the processor or importer and the location of the processor or importer
 - The date and time of the activity that the record reflects
 - The signature or initials of the person performing the operation or creating the record
 - Where appropriate, the identity of the product and the production code
 - Actual values and observations must be recorded

Juice HACCP

Section 120.13: Training

- **Activities Performed by Trained Individuals**
 - Developing the hazard analysis
 - Developing the HACCP Plan
 - Verifying and modifying the HACCP Plan
 - Performing the record review

Juice HACCP - Imports

Section 120.14:

**Application of requirements to
imported products**

Juice HACCP - Imports

**Section 120.14 (Importer Requirements):
Every importer of juice shall either:**

- **Obtain the food from a country that has an active Memorandum of Understanding (MOU) with the Food and Drug Administration that covers the food and documents the equivalency of compliance of the inspection system of the foreign country with the U.S. system; or**

Juice HACCP - Imports

Section 120.14 (Importer Requirements):

Every importer of juice shall either:

- Have and implement written procedures for ensuring that the food that such importer receives for import into the United States was processed in accordance with the requirements of this part (the HACCP rule).

Juice HACCP - Imports

These procedures shall provide, at a minimum:

- **product specifications that are designed to ensure that the juice or juice product is not adulterated; and**
- **affirmative steps to ensure that the products being offered for entry into the US were processed under controls that meet the requirements of the Juice HACCP rule**

Juice HACCP - Imports

These steps may include any of the following:

- **obtaining from the foreign processor the HACCP plan and prerequisite program records related to the lot being offered for import;**
- **obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party;**

Juice HACCP - Imports

These steps may include any of the following:

- **regularly inspecting the foreign processor's facilities to ensure compliance with the rule;**
- **maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan and a written guarantee that the food was processed according to the requirements;**

Juice HACCP - Imports

These steps may include any of the following:

- **periodically testing the imported food, and maintaining, in English, a copy of a written guarantee that the food was processed in accordance with the rule; or**
- **other such verification measures as appropriate that provide an equivalent level of compliance with the requirements.**

Juice HACCP - Imports

Other items:

- **Competent third party**
 - an importer may hire a competent third party to assist with or perform any or all of the verification activities
- **Records**
 - the importer must maintain records, in English, that document the performance and results of the affirmative steps discussed previously

Juice HACCP

Section 120.24: Process Controls

In order to meet the requirements of this regulation, processors of juice products must include in their HACCP plans control measures that will consistently produce, at a minimum, a 5-log reduction in the pertinent microorganism of concern

- this organism is the most resistant microorganism of public health concern likely to occur in the juice

Juice HACCP

Section 120.24: Process Controls

Exemptions from 120.24:

- A juice processor that is subject to 21 CFR part 113 or part 114
- A juice processor using a single thermal processing step sufficient to achieve shelf-stability or a thermal concentration process that includes thermal treatment of all ingredients
 - Must include a copy of the thermal process used to achieve this process in the written hazard analysis

Juice HACCP

Section 120.24: Process Controls

- All juice processors will meet the 5-log requirement through treatments that are applied directly to the juice except:
 - Citrus juice processors may use treatments on the fruit surfaces, provided that the reduction process begins after culling and cleaning and the reduction is accomplished within a single production facility

Juice HACCP

Section 120.24: Process Controls

- **Cleaned:** washed with water of adequate sanitary quality
- **Culled:** separation of damaged fruit from undamaged fruit

Juice HACCP

Section 120.24: Process Controls

- All juice processors must perform final product packaging within a single production facility operating under cGMPs
- Processors claiming an exemption shall also process and perform final product packaging of all juice subject to the exemption within a single production facility operating under cGMPs

Juice HACCP

Section 120.25: Process Verification for Certain Processors

- Juice processors that rely on treatments that do not come into direct contact with all parts of the juice to achieve the 5-log reduction must analyze the finished product for biotype I *Escherichia coli*

Juice HACCP

Section 120.25: Process Verification for Certain Processors

- If a subsample is determined to be positive for *E. coli*, the processor:
 - Must review monitoring records for the control measures used to attain the 5-log reduction and correct those conditions that are not being met.
 - May test for pathogens
 - Must take corrective actions if review of records or testing indicates that the 5-log reduction standard was not met

Juice HACCP

Section 120.25: Process Verification for Certain Processors

- If two samples in a series of seven are positive for *E. coli*, the control measures used to attain the 5-log reduction are inadequate and the processor must immediately:
 - Use an alternate process to achieve the 5-log reduction until corrective actions are completed
 - Perform a review of the monitoring records for control measures to attain the 5-log reduction standard

Juice HACCP

Juice Hazards and Controls Guide

Juice HACCP Alliance