



# Juice HACCP Training Curriculum, First edition

August 2002

*Developed by the **Juice HACCP Alliance**  
as recognized by the Food and Drug Administration*

# THE JUICE HACCP ALLIANCE

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## ***Foreword: The Juice HACCP Alliance***

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 group was coordinated through the efforts of the National Center for Food Safety and Technology (NCFST), at Illinois Institute of Technology (IIT), with the support of the Food and Drug Administration (FDA).

The first task of the alliance was to produce the manual for a juice training curriculum. Much of the curriculum material originally appeared in the document "HACCP: Hazard Analysis and Critical Control Point Training Curriculum", developed by the Seafood HACCP Alliance for Education and Training. Donn Ward of North Carolina State University chaired the Editorial Committee made up of HACCP and seafood specialists from around the nation. The Juice HACCP Alliance was granted permission to use these materials from the Seafood HACCP Alliance.

Extensive changes have been made to the 3<sup>rd</sup> edition of the seafood text to reflect the needs of juice processors and the special requirements of the new juice regulations published in 21 CFR 120. This includes addressing the requirement for 5-log reduction of the most pertinent pathogen in juices. Minor changes have been made to reflect the requirement for documented and monitored prerequisite programs in the regulation. The seafood HACCP curriculum structure has been largely retained due to demonstrated success and familiarity with the curriculum among trainers.

Due largely to the efforts of National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the concept of HACCP is becoming standardized throughout the nation, and due to CODEX harmonization, throughout the world. It is expected that future revisions of the juice HACCP curriculum will parallel the NACMCF standards. From the beginning, it was the intention of the Juice HACCP Alliance to harmonize with HACCP training programs provided for the seafood and dairy industries. Future commodity-specific training programs are encouraged to focus on HACCP, based on the NACMCF principles, followed by orientation to the particular needs of the commodity. This will facilitate future training and will allow the use of alternative delivery systems for training in HACCP.

## ***Foreword: The Juice HACCP Alliance***

This manual emphasizes certain basic concepts in HACCP. HACCP is a food safety program that operates in an environment of properly implemented prerequisite programs that are properly monitored and documented. Corrections are made when necessary. Potential hazards – those which could cause illness or injury to the consumer in the absence of their control - are identified and evaluated in light of these prerequisite programs to determine their likelihood of occurrence. A prerequisite program may be found to reduce the likelihood of occurrence of a potential hazard. However, hazards that are reasonably likely to occur must be controlled by critical control points. The combination of the prerequisite programs and the HACCP plan comprises the HACCP system. This system is to be verified according to the plan.

In order to ensure that training instills the concepts above, the Juice HACCP Alliance recommends that this course be presented by a trainer who has training and experience with NACMCF HACCP principles. Train-the-trainer courses have been designed to ensure consistency in the use and application of these materials and exercises, to convey regulatory perspective, and to provide practical, juice-specific applications that lead to juice HACCP plan development.

This alliance owes a special debt of gratitude for the exceptional efforts of Drs. Peter Slade and Kathy Knutson of the NCFST/IIT for leadership, coordination and the final editing of the text. We also appreciate the efforts of Ms. Jodi Skrip and Dr. Sam Palumbo (NCFST/IIT) for respectively preparing and reviewing draft versions of the text.

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## ***Introduction: About the Course***

### **About the Course Manual**

This course manual and accompanying generic HACCP plans and overheads were developed by the Juice HACCP Alliance — a group comprised of federal and state food-inspection officials, university food-science educators and juice-industry representatives. The course was designed to meet the HACCP training requirements established under 21 CFR Part 120.13 of the U.S. Food and Drug Administration's mandatory juice HACCP inspection program.

Part 120.13 requires that certain HACCP activities must be completed by a "HACCP-trained individual." A HACCP-trained individual is one who has successfully completed training in the application of HACCP to juice products (at least equivalent to that received under a "standardized curriculum" recognized by FDA) or has acquired the knowledge through job experience. The Juice HACCP Alliance course is the standardized curriculum by which FDA will evaluate other training courses.

### **Maintaining Course Integrity**

Because this course will be used to evaluate HACCP-training equivalency, it is imperative that course instructors adhere to the course format and material to the extent possible. The course is divided into three components. The first teaches the student the seven principles of HACCP. The second component explains the juice HACCP regulations and guidance materials available to help develop a HACCP plan. The last component is a class exercise where students are divided into small groups and asked to conduct a hazard analysis and develop a HACCP plan for one or more processing models, like those found in Appendix IV. Each of these components is necessary to give students an adequate foundation to establish their company's HACCP mandate. Instructors are urged not to delete the material in the course because this defeats the course objective of standardizing the training experience. However, instructors may wish to augment the course with examples pertinent to their region.

It is noteworthy that component one, dealing with the seven principles, was designed to address the HACCP training needs for any FDA-regulated food product. In some instances, non juice product examples are used to demonstrate the application of HACCP principles. Additional discussion on juice specific hazards is provided in the Juice HACCP Hazards and Controls Guide published by the FDA, separate from this training curriculum.

### **Tools for Developing HACCP Plans**

The course material incorporates teaching tools to assist students in conducting a hazard analysis and developing a HACCP plan. A fictional juice processing firm (the XYZ Juice Co.) that produces refrigerated pasteurized apple juice is used to illustrate how a HACCP plan may be developed. It is important that instructors understand (and that they help students understand) that the model developed for XYZ Juice Co. as well as other models are illustrative. The Juice HACCP Alliance does not suggest that the models represent the only way or necessarily the best way to develop HACCP plans for the products in question.

## ***Introduction: About the Course***

A hazard-analysis worksheet is introduced in Chapter 5. In Chapter 6, a decision tree is used to help determine which steps in the production of refrigerated pasteurized apple juice are critical control points (CCPs). It must be remembered that tools such as the decision tree are not perfect since not all products and processes fit neatly into the tree. In some circumstances, the decision tree may not lead to an appropriate answer. Students must be taught to factor in all pertinent data and information about the plant operation and the characteristics of the product to determine if and where a CCP exists.

The development of XYZ Juice Co.'s HACCP plan continues in Chapters 7 to 11. A HACCP plan form is used to identify critical limits, monitoring activity, corrective actions, verification procedures and records associated with the CCPs.

The forms and worksheets are completed step-by-step as the instructor covers each chapter. The manual provides the forms and worksheets along with responses. Instructors are urged to have students use the blank worksheets and forms found in Appendix IX to fill in their own answers before turning to the completed forms in the manual. Students may then be instructed to check their answers against those found at the end of each chapter.

### **Instructor's Notes:**

Instructors may wish to begin the program by introducing themselves and asking each student to give his/her name, title, affiliation or the nature of the company or organization. Students may be from the private sector or from government agencies. If the student is from industry, the types of products each processes and handles might be discussed briefly.

After the introduction, the instructors should cover meeting logistics: directions to bathrooms, phones, food establishments, smoking areas, etc. Students should be informed that the course is designed to provide a morning and afternoon break each day. Instruction should proceed with the introduction provided in Chapter 1.

## **Course Agenda: The Juice HACCP Alliance**

### **Day One**

#### **Welcome**

Introduction to the Course and HACCP.....	Chapter 1
Hazards – Biological, Chemical, and Physical.....	Chapter 2
Prerequisite Programs and Preliminary Steps .....	Chapter 3
<b>Break Out Session:</b> Exercise One. Prerequisite Programs and Preliminary Steps Team Presentations and Class Discussion Commercial Processing Example: Refrigerated Pasteurized Apple Juice .....	Chapter 4
Principle 1. Hazard Analysis .....	Chapter 5
<b>Break Out Session:</b> Exercise Two. Hazard Analysis	

### **Day Two**

#### **Team Presentations and Class Discussion on Exercise Two**

Principle 2. Determine the Critical Control Points .....	Chapter 6
Principle 3. Establish Critical Limits .....	Chapter 7
Principle 4. Critical Control Point Monitoring .....	Chapter 8
Principle 5. Corrective Actions .....	Chapter 9
<b>Break Out Session:</b> Exercise Three. Critical Control Points Team Presentations and Class Discussion	
Principle 6. Verification Procedures .....	Chapter 10
Principle 7. Record-Keeping Procedures .....	Chapter 11
<b>Break Out Session:</b> Exercise Four. The HACCP Plan Team Presentations and Class Discussion	

### **Day Three**

The Juice HACCP Regulation .....	Chapter 12
Sources of Information on Preparing HACCP Plans .....	Chapter 13

### **Final Discussion**

Course Evaluation and Examination

#### **Notes:**

Instructor's Note:  
Schedule lunch and breaks as  
appropriate.

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# **CHAPTER 1: INTRODUCTION TO THE COURSE AND HACCP**

Notes:

Overhead 1

## **Objectives**

In this module you will learn:

- Objective of the course
- Format of the course
- Expectations of the participant
- Meaning and importance of HACCP

### **Course Objective**

In January 2001, the Food and Drug Administration (FDA) issued juice regulations based on the principles of Hazard Analysis and Critical Control Point (HACCP). The FDA issued these regulations to ensure safe processing and importing of juice. These regulations specify that certain critical jobs in juice processing must be performed by individuals trained in HACCP. These persons are responsible for developing and modifying the HACCP plan and reviewing records. This course contains the information necessary for you or a team to meet the HACCP training requirements. It is also designed to provide inspectors with the knowledge they need to evaluate HACCP plans and practices.

### **Course Format**

This juice HACCP course is divided into three distinct segments:

1. HACCP fundamentals.
2. An orientation to the requirements of the juice HACCP regulation.
3. Work sessions to develop a juice HACCP plan.

The first segment defines the seven principles of HACCP. Learning these principles will give a clear understanding of the fundamentals on which HACCP is based. As each principle is discussed, the class will develop a HACCP plan for pasteurized, refrigerated apple juice using the fictional XYZ Juice Co. as a model. This will help you to understand HACCP principles and how they interrelate.

The second segment explains the juice HACCP regulation and the guidance materials that are available to help you develop a HACCP plan. The manual also presents information about juice-specific hazards.

**Notes:**

The third segment demonstrates how to develop a juice HACCP plan. During this part of the course, the class will be divided into teams to write a HACCP plan based on a narrative and flow chart.

**What is Expected of the Participant**

HACCP is a common-sense technique used to control food safety hazards. It is an important safety management system and can be integrated into any operation. However, HACCP can seem complicated and demanding until its concepts are understood. Therefore, you are encouraged to ask questions and to contribute first-hand experiences to discussions. This manual includes exercises that require class participation throughout the training. Keep in mind that the more you contribute to these exercises, the less complicated the HACCP system will seem, and the easier it will be to design and implement a HACCP plan later.

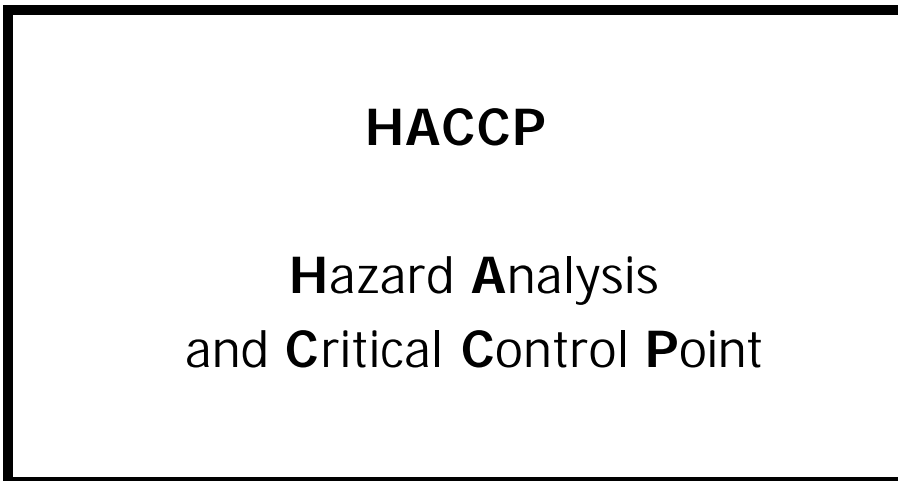
**How to Use This Manual**

This manual is yours. Become familiar with it. Learn where the definitions are, where the forms are that will help you develop a HACCP plan, and where to find other basic information. Make as many notes and marks in the text as needed to assist in creating and understanding a HACCP plan. Use the manual as a reference. This manual does not have a copyright. Make as many copies of its forms as necessary or copy the whole manual to share with others in your company.

**Meaning and Importance of HACCP**

Many people may not have heard the term "HACCP" until recently. However, it is neither a new term nor a new concept.

Overhead 2



HACCP is merely an acronym that stands for Hazard Analysis and Critical Control Point. But the concept behind this term is important.

Overhead 3

Notes:

## HACCP

- Is preventive, not reactive
- Is a management tool used to protect the food supply against biological, chemical and physical hazards

HACCP is a preventive system of hazard identification and control rather than a reactive one. Food processors can use it to ensure safer food products for consumers. To ensure safer food, the HACCP system is designed to identify hazards, establish controls, and monitor these controls. Hazards can be in the form of harmful microorganisms, chemical adulterants, or physical contaminants.

Overhead 4

## Origins of HACCP

- Pioneered in the 1960s
- First used when foods were developed for the space program
- Adopted by many food processors in the U.S.

The Pillsbury Co. pioneered the application of the HACCP concept to food production during its efforts to supply food for the U.S. space program in the early 1960s. Pillsbury decided that their existing quality control techniques did not provide adequate assurance against contamination during food production. The company found that end-product testing necessary to provide such assurance would be so extensive that little food would be available for space flights.

Notes:

Overhead 5

## HACCP

- Is not a zero-risk system
- It is designed to minimize the risk of food safety hazards

The only way to ensure safety, Pillsbury concluded, would be to develop a preventive system that kept hazards from occurring during production. Since then, Pillsbury's system has been recognized worldwide as the method of choice for control of food safety hazards. It is not a zero-risk system, but it is designed to minimize the risk of food safety hazards. The FDA first required HACCP-based controls for food processing in 1973 for canned foods to protect against *Clostridium botulinum*, the bacterium that causes botulism.

Overhead 6

## Recommendation

"The HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors."

National Academy of Sciences, 1985

## Chapter 1. Introduction to the Course and HACCP

In an assessment of the effectiveness of food regulation in the United States, the National Academy of Sciences (NAS) recommended in 1985 that the HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors.

Overhead 7

# National Academy of Sciences Recommendation led to formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

This recommendation led to the formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). This committee standardized the HACCP principles used by industry and regulatory authorities. The committee's work is the basis of this standardized curriculum.

Overhead 8

## Seven Principles of HACCP

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

### Notes:

Explanatory Note:  
NACMCF is continuing to refine the HACCP principles in an effort to make them more user-friendly and effective. In August 1997, NACMCF adopted revised HACCP guidelines. To the extent possible, many of the changes have been incorporated into this manual. Most obviously, Principles 6 and 7 were switched, thereby making record-keeping Principle 7. Additionally, "preventative measures" was changed to "control measures."

Instructors and students should be aware of the dynamic nature of HACCP and not be surprised or confused as the principles are refined.

**Notes:**

NACMCF adopted the following seven HACCP principles. They are:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

These principles will be explained in more detail in the following sessions. The juice HACCP regulation and other domestic and international HACCP control systems are based on these principles.

Overhead 9

## International Use

- *Codex Alimentarius*
- European Union
- Canada

HACCP has been endorsed worldwide by organizations such as *Codex Alimentarius* (a commission of the United Nations), the European Union, and by several countries including Canada, Australia, New Zealand and Japan.

Overhead 10

## HACCP

A system for food safety control

HACCP is a preventive system for ensuring food safety, but it is not a stand-alone system. HACCP must be built upon key prerequisite programs, such as Good Agricultural Practices (GAPs) and mandatory Good Manufacturing Practices (GMPs) (e.g., sanitation and personal hygiene programs) to make it work.

**Notes:**

Overhead 11

## **Traditional inspection methods for food safety control versus The HACCP approach**

The HACCP concept is used by regulators during inspections of food processors to focus their attention on the parts of the process that are most likely to affect the safety of the product.

The inspection of plants operating under HACCP plans differs from traditional inspection methods of food safety control. Traditional methods evaluate processing practices on the day or days of inspection. The HACCP approach allows regulators to look at what happens in the plant through time by also examining the firm's monitoring and corrective action records.

Overhead 12

### **HACCP Approach Complements Traditional Inspection Methods**

- HACCP:
  - Emphasizes process control
  - Concentrates on points in the process that are critical to the safety of the product
  - Stresses communication between the regulator and industry

**Notes:**

With HACCP, the emphasis is on understanding the process system. This requires the regulator and industry to communicate and to work with one another. The inspector will be verifying the HACCP plan by determining that significant food safety hazards have been properly identified and that industry is consistently controlling these hazards. The inspector will accomplish this by first surveying the plant and then reviewing the HACCP plan and records. In addition to HACCP inspections, regulators will continue to look for compliance in areas such as sanitation, economic fraud, food standards, etc.

Overhead 13

**“HACCP systems represent a systematic approach to the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur in a particular food in a particular production process.”**

**Bernard A. Schwetz, D.V.M., Ph.D.  
Acting Principal Deputy Commissioner, FDA  
October 10, 2001**

Acting FDA Commissioner Dr. Bernard Schwetz on October 10, 2001 said, “HACCP systems represent a systematic approach to the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur in a particular food in a particular production process.” He also noted that “(implementation of HACCP regulations for fruit and vegetable juices) will prevent at least 6,000 illnesses per year.”

In defining the roles of industry and the regulatory agencies in HACCP, the NACMCF document indicates "It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate this process." Or, in other words, the role of the government is to ensure that industry adheres to their role.

**“It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate the process.”**

**NACMCF, June 1993**

As you learn more about HACCP, there will be many new definitions that you will need to understand. To assist you, the most common HACCP definitions are found in the following two pages. Refer back to these pages as needed and add other terms as appropriate that will help you in developing and implementing your own HACCP plan. Other terms specific to the juice HACCP regulation are included in Chapter 12.

The next sessions will explain the basics of HACCP. It first starts by defining major terms used in HACCP and the juice HACCP regulation.

### **Glossary**

- **Cleaned:** Washed with water of adequate sanitary quality.
- **Continuous Monitoring:** Uninterrupted collection and recording of data such as temperature on a strip chart.
- **Control:** To prevent, eliminate, or reduce.
- **Control Measure:** Any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
- **Corrective Action:** Procedures followed when a deviation occurs.
- **Critical Control Point (CCP):** A point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
- **CCP Decision Tree:** A sequence of questions asked to determine whether a point, step or procedure in the process is a CCP.
- **Critical Limit:** A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food hazard.
- **Culled:** Separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, culled means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.
- **Deviation:** Failure to meet a critical limit.

Notes:

- **Fallen Fruit:** 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, drops.
- **Five-log (5-log) Reduction:** A treatment of juice (or citrus fruit if using surface treatments) using a process that will achieve at least a 100,000 fold (5-log) decrease in the numbers of the pertinent pathogen.
- **HACCP:** A systematic approach to the identification, evaluation and control of food safety hazards.
- **HACCP Plan:** The written document that is based upon principles of HACCP and that delineates the procedures to be followed.
- **HACCP System:** The result of the implementation of the HACCP plan.
- **HACCP Team:** The group of people who are responsible for developing, implementing and maintaining the HACCP system.
- **HACCP-Trained Individual:** An individual who performs certain functions related to the development of the hazard analysis and HACCP plan and the verification, validation, corrective action, and record review requirements of the regulation, who has received training based on a standardized curriculum that FDA recognizes as adequate, or its equivalence.
- **Hazard:** A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
- **Hazard Analysis:** The process of collecting and evaluating information on hazards associated with the food under consideration to decide what hazards are significant and must be addressed in the HACCP plan.
- **Importer:** Either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
- **Juice:** 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.
- **Juice Concentrate:** 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:** 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.
- **Operating Limit:** A criterion that is more stringent than a critical limit and that is used by an operator to reduce the risk of a deviation.
- **Performance Standard:** A goal that processors should achieve but with flexibility on how processors accomplish them.
- **Pertinent Pathogen:** The most resistant microorganism of public health concern that may occur in juice.
- **Prerequisite Programs:** Procedures, including current Good Manufacturing Practices (cGMPs), that address operational conditions providing the foundation for the HACCP system.

## Chapter 1. Introduction to the Course and HACCP

- **Process Adjustment:** Action taken by an operator to bring the process back within operating limits.
- **Processing:** Activities that are directly related to the production of juice products. Processing does not include: (1) harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing, and/or (2) the operation of a retail establishment.
- **Processor:** Any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.
- **Retail Establishment:** Is 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.
- **Shall:** Is used to state mandatory requirements.
- **Shelf-stable Product:** A product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.
- **Severity:** The seriousness of a hazard (if not properly controlled).
- **Should:** Is used to state recommended or advisory procedures or to identify recommended equipment.
- **Validation:** That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the identified food hazards.
- **Verification:** Those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

### Acronyms

- **CCP:** Critical control points
- **cGMP:** current Good Manufacturing Practice
- **CL:** Critical limit
- **FDA:** Food and Drug Administration
- **GAP:** Good Agricultural Practice
- **HACCP:** Hazard analysis and critical control point
- **MIG:** Mercury-in-glass (thermometer)
- **NAS:** National Academy of Sciences
- **NACMCF:** National Advisory Committee on Microbiological Criteria for Foods
- **PPM:** Parts per million
- **SOP:** Standard operating procedure
- **SSOP:** Sanitation standard operating procedure

Notes:

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## CHAPTER 2: HAZARDS-BIOLOGICAL, CHEMICAL AND PHYSICAL

Overhead 15

### Objectives

In this module you will learn to develop awareness of:

- Biological hazards
- Chemical hazards
- Physical hazards
- Characteristics of certain microorganisms

To perform a hazard analysis for the development of a HACCP plan, food processors must gain a working knowledge of potential hazards. The HACCP plan is designed to control all identified food safety hazards that are likely to occur. Such hazards are categorized into three classes: biological, chemical and physical.

Overhead 16

### Definition

**Hazard:** a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control

Biological hazards include harmful bacteria, viruses or parasites (e.g., *Salmonella*, hepatitis A and *Cryptosporidium*). Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Physical hazards include foreign objects in food that can cause harm to the consumer, such as glass or metal fragments.

Notes:

Explanatory Note:  
Whether a particular hazard listed in this chapter will need to be addressed in a HACCP plan will depend on an evaluation of the likelihood of occurrence of the hazard and its likelihood to cause illness or injury in the absence of its control.

This evaluation is explained in the next chapter. This chapter is intended as a general discussion on hazards. For information on juice-specific hazards, refer to the Hazards and Controls Guide.

Explanatory Note:  
Students may ask why some hazards are classified as chemical rather than biological. The best answer is tradition. It is important to stress, however, that the significant issue is not the actual classification of a hazard, but accurate identification and control.

**Notes:**

It is important to understand that, for the purposes of HACCP, hazards only refer to the conditions or contaminants in food that can cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. All of these defects must be controlled in food processing. However, they often are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a HACCP plan.

Overhead 17

**In HACCP, “hazard” does not refer to**

**undesirable conditions, e.g.:**

- Violations of regulatory standards not directly related to food safety
  - Spoilage
  - Economic fraud
  - Standards of identity

**or inadvertent but tolerable levels of contamination, e.g.:**

- Insect
- Hair
- Filth

It is not within the scope of this course to go into detail on foodborne hazards. That topic is too large and would be covered better in a separate microbiology, toxicology and/or food processing course. However, this chapter will increase awareness of the kinds of hazards that may occur in foods. This awareness will prepare participants for recognizing what is and is not appropriate to control with HACCP. Food processors may find it necessary to work with technical experts to develop a HACCP plan.

**Biological Hazards**

Foods can contain biological hazards. These hazards can come from raw materials or from food processing steps used to make the final product. Table 2.8 (at the end of the chapter) provides a list of biological hazards.

***Microorganisms***

Organisms too small to be seen with the naked eye are called *microorganisms*. Microorganisms are found everywhere: air, dirt, fresh and salt water, skin, hair, animal fur and plants.

Microorganisms are classified into various groups. A few groups important in foods include yeasts, molds, bacteria, viruses and protozoa. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to deal with them.

Although thousands of kinds of microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms, or *pathogens*, will be discussed in more detail later.

## Chapter 2. Hazards-Biological, Chemical and Physical

Many microorganisms are beneficial. Certain kinds of yeasts, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Particular kinds of yeasts are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health.

People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and protozoa daily without ill effect. Therefore, when foods are processed and preserved, food processors and regulators need only be concerned with certain microorganisms, particularly pathogens.

Overhead 18

- **Microorganisms can be beneficial, even essential**
- **Some can be pathogenic; these concern food processors and public health officials**

Bacteria, one type of microorganism too small to be seen without a microscope, are alive and have certain needs in order to live and grow. Without a supply of adequate food and water and the appropriate temperature, bacteria stop growing and multiplying. Some die; others stop functioning until their needs are met. Some preservation methods control the water or nutrients in food, making these essential elements unavailable to bacteria.

Overhead 19

### **What Do Microorganisms (Other than Viruses) Need?**

- Food
- Water
- Proper temperature
- Air (O<sub>2</sub>) - no air - minimal air
- Proper acidity

Notes:

Notes:

Different bacteria respond differently to air. Like most plants and animals, many microorganisms need air to live and will die or stop growing if deprived. However, many bacteria can function without air. Some are poisoned by it. Unfortunately, pathogens exist in each of these categories. Although some bacteria can be controlled by the amount of air they receive, it is not an effective way of controlling all pathogens.

Microorganisms multiply in different ways. The most common method, especially for yeasts, bacteria and protozoa, is to grow large and divide. One bacterium splits into two, two into four, four into eight, eight into sixteen, and so on. By doubling, microorganisms multiply quickly. Under ideal conditions, some bacteria double every 20 minutes. Potentially, one bacterium can multiply to more than 30,000 in five hours and to more than 16 million in eight hours. Fortunately, most bacteria grow more slowly than this and can be slowed even more by controlling the food, water and temperature that they need to grow and multiply.

Overhead 20

**Bacteria reproduce by dividing in two.**

Overhead 21

**Some Microorganisms Form By-Products**

- **Yeasts** - produce carbon dioxide and/or, alcohol useful for making bread and alcoholic beverages
- **Lactic acid bacteria** - produce lactic acid in making yogurt, cheese, fermented meat products
- ***Staphylococcus aureus*** - enterotoxin

**Most spoiled foods do not present a health risk, and not all food that appears normal is safe to consume.**

Microorganisms form by-products during growth. The more they grow, the more by-products they form. Some of the by-products are desirable in the right foods. For example, when yeasts grow in dough, they produce carbon dioxide, acids and flavors. The dough rises, and we make bread. However, when the same yeasts grow and produce the same by-products in another food, such as fruit juice, it may not be desirable. Then we call it spoilage. Such spoilage is undesirable, and processors strive to avoid it in food. In addition, some by-products produced by pathogens are toxic and can cause disease.

**Food spoilage or decomposition that can result in a food safety problem should be prevented or controlled by a HACCP program.**

Food contaminated by pathogens or by toxic microbial by-products may not look, smell or taste bad, but can make a person sick. Food spoilage or decomposition that can result in food safety problems should be prevented or controlled by a HACCP program.

During the processing of foods, the amounts and types of microorganisms can increase, remain constant, or be reduced. Even though processing can be used to destroy harmful microorganisms, some non-harmful microorganisms can survive the treatment.

**Notes:**

*Example:* Certain juices may be pasteurized, or heat-treated, to destroy pathogens. After pasteurization, the juice is free of vegetative pathogens; however, some nonpathogenic microorganisms may survive.

Overhead 24

## Microbiological Hazards

- Bacteria
- Viruses
- Protozoa

Among the five groups of microorganisms described earlier, mainly bacteria, viruses and protozoa include the kinds of microorganisms that can make food unsafe for consumption. Generally, yeast and molds do not pose a biological hazard in food. Some molds produce hazardous toxins, but these toxins are considered chemical hazards.

Overhead 25

## Foodborne Illness Caused By Bacterial Pathogens

- Infection
- Intoxication

### **Bacterial Hazards**

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication. Foodborne infections are caused by swallowing living pathogens that grow within the body, usually in the ntestinal tract. They differ from foodborne intoxications, which are illnesses caused by swallowing preformed toxins (i.e., toxins are produced by microorganisms in the food before it is eaten).

Bacterial hazards can also be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g., *Clostridium* and *Bacillus* spp.) may pass through a dormant stage in their life cycle called a spore. When the bacterium exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to nonsporeforming bacteria. Because they are dormant, spores are not hazardous as long as they remain as spores. Unfortunately, if they survive a processing step designed to kill nonsporeforming, vegetative bacteria, they may become a hazard in the food if they are allowed to grow. When sporeformers are a concern, the process steps used to control them are often much more severe than if only nonsporeformers need to be controlled.

Overhead 26

### Examples of Sporeforming Bacteria (Pathogenic)

- *Clostridium botulinum*
- *Clostridium perfringens*
- *Bacillus cereus*

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### Examples of Non-Sporeforming, Vegetative Bacteria (Pathogenic)

- *Campylobacter jejuni*
- Pathogenic *Escherichia coli* (e.g., *E. coli* O157:H7)
- *Listeria monocytogenes*
- *Salmonella* spp. (e.g., *S. Typhimurium*, *S. Enteritidis*)
- *Shigella* spp. (e.g., *S. dysenteriae*)
- Enterotoxigenic *Staphylococcus aureus*

Notes:

## Notes:

Table 2.1. Examples of Bacterial Hazards Found in Food

Microorganism	Why a hazard?
<i>Clostridium botulinum</i> (sporeformer)	Causes an intoxication that affects the central nervous system and causes shortness of breath, blurred vision, loss of motor capabilities and death.
<i>Listeria monocytogenes</i> (nonsporeformer)	Causes an infection with mild flu-like symptoms. Severe forms of listeriosis are possible in people with weakened immune systems, causing septice-mia, meningitis, encephalitis and stillbirths.
<i>Salmonella</i> spp. (nonsporeformer)	Causes an infection with the following symptoms: nausea, vomiting, abdominal cramps, diarrhea, fever and headache. Death is possible in people with weak immune systems.

**Viral Hazards**

Like other microorganisms, viruses exist everywhere. They are very small particles that cannot be seen with a light microscope and cannot reproduce by themselves. Although they are alive, viruses differ from other microorganisms in what they need to live and how they multiply. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell using material from it. Viruses only grow once they enter a suitable host. Only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water and frozen foods for months.

## Viral Hazards

- What are viruses?
- Where do they come from?
- How do they reproduce?
- How can they be controlled?
- What are some examples?

Viruses can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers, but see Table 2.2 for description of usual symptoms). Transmission of viruses to foods is usually related to poor hygienic practices. People who have viruses shed the virus particles in feces. Food handlers with viruses can transmit them to food if they forget to properly wash and sanitize their hands. This route can also result in contamination of food with bacterial hazards.

Table 2.2. Examples of Viral Hazards Found in Food

Microorganism	Why a hazard?
Hepatitis A virus	Causes fever and abdominal discomfort, followed by jaundice.
Norwalk virus	Headache and low-grade fever may also occur.
Rotavirus	Causes nausea, vomiting, diarrhea and abdominal pain (gastroenteritis).

Notes:

Overhead 29

## Viruses

- Hepatitis A
- Norwalk Virus Group
- Rotavirus

### Parasitic Hazards (e.g. Protozoa)

Parasites are organisms that need a host to survive, living on or within it. Thousands of kinds of parasites exist worldwide. Only about 20 percent can be found in food or water, and less than 100 types are known to infect people through consumption. There are two types of parasites that can infect people through food or water: protozoa and parasitic worms. Protozoa are single -cell animals and most cannot be seen without a microscope.

Table 2.3 lists the parasitic protozoa most likely to be found in the U.S. food supply. For most foodborne parasites, the food is part of their natural life cycle (e.g., nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to a parasite's survival are a proper host (i.e., a given parasite does not infect all organisms) and a suitable environment.

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## Parasites in Food

- Parasites are organisms that need a host to survive
- Thousands of kinds exist worldwide, but only about 100 types are known to infect people through food consumption
- Mainly protozoa
- Role of fecal material

Chapter 2. Hazards-Biological, Chemical and Physical

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts. Methods of preventing transmission of parasites to foods by fecal contamination include:

- Good personal hygiene practices by food handlers,
- Elimination of insufficiently treated animal waste to fertilize crops, and
- Proper sewage and water treatment.

Consumer exposure to parasites depends on food selection, cultural habits and preparation methods. Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food. However, consuming raw foods containing infective parasites can pose a hazard.

Table 2.3. Examples of Parasite Hazards Found in Food

Protozoan parasite	Why a hazard?
<i>Cryptosporidium parvum</i>	Causes watery diarrhea, coughing, low grade fever, and severe intestinal distress. It lasts 2-14 days. Carriers may also be asymptomatic. The most severe symptoms are confined to immunodeficient individuals.
<i>Cyclospora cayetanensis</i>	Causes disease symptoms that mimic those of cryptosporidiosis (described above). The incubation period ranges between 2 and 11 days, with a mean of about 7 days. Diarrhea is prolonged but self-limiting, lasting a mean of 43±24 days. Other symptoms may include loss of appetite, fatigue, and weight loss.
<i>Entamoeba histolytica</i>	Causes dysentery (severe, bloody diarrhea).
<i>Giardia lamblia</i>	Causes diarrhea, abdominal cramps, fatigue, nausea, flatulence (intestinal gas) and weight loss. Illness may last for one to two weeks, but chronic infections can last months to years.

Notes:

## Notes:

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## Parasitic Protozoa

- *Cryptosporidium parvum*
- *Cyclospora cayetanensis*
- *Entamoeba histolytica*
- *Giardia lamblia*

### Chemical Hazards

Chemical contamination can happen at any stage in food production and processing. Some chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. These chemicals are not hazardous if properly used or controlled. Potential risks to consumers increase when chemicals are not controlled or the recommended treatment rates are exceeded. The presence of a chemical residue may not always represent a hazard. The amount or type of the chemical may determine whether it is a hazard or not. Some may require exposure over prolonged periods to have a toxic effect. Regulatory limits are set for some of those contaminants.

Chemical hazards can be separated into three categories:

1. Naturally-occurring chemicals.
2. Intentionally-added chemicals.
3. Unintentional or incidental chemical additives.

The types of chemicals included in these categories are listed in Table 2.9 at the end of the chapter.

#### ***Naturally-Occurring Chemicals (including allergens)***

These chemicals are derived from a variety of plants, animals or microorganisms. In most cases, these naturally-occurring chemicals are found prior to or during harvest. Although many naturally-occurring toxins are biological in origin, they are traditionally categorized as chemical hazards.

**Explanatory Note:**

Some of these limits (such as for aflatoxin) can be found in Title 21 of the Code of Federal Regulations and in the FDA Compliance Policy Guides.

Table 2.4. Examples of Foods Containing Naturally-Occurring Chemical Hazards

Source	Why a hazard?
Egg, milk, nuts, seafood, soy	Certain varieties or species produce an allergic reaction in sensitive people.
Apple, nuts, cereal grains	Certain molds can form mycotoxins, e.g., Aflatoxin <i>Alternaria</i> toxins Fumonisin Ochratoxin Patulin Vomitoxin
Elderberry	Some parts of this plant are toxic

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## Types of Naturally-Occurring Chemical Hazards

- Allergens
- Mold toxins (mycotoxins)
- Toxic plant components

***Intentionally-Added Chemicals***

Some chemicals are intentionally-added to food at some point during production and processing. These chemicals are intended to be used at safe levels, but could present a hazard if those levels are exceeded.

**Notes:**

Explanatory Note:  
Allergic reactions are caused by proteins (allergens) that react with the body's natural immune system. This type of chemical hazard is of concern to individuals who are sensitive to the allergen\*. However, some other food components that may cause adverse reactions in sensitive individuals, e.g. sulfites and FD&C Yellow No. 5, may need to be addressed in the hazard analysis.

\* It is particularly important that foods formulated with components that are known to produce these types of reactions have these ingredients clearly identify on the label. HACCP controls, i.e., CCPs, must be established to ensure that foods formulated with components that are known to produce serious allergenic reactions must have the allergenic ingredients declared on their labels. CCP or SSOP controls may be necessary to prevent contamination of foods with allergens, e.g. when juice is processed on lines that are also used to process dairy foods such as milk.

Explanatory Note:  
Certain food additives must have prior approval before they can be used in foods. Before using a new food additive, food processors should review the appropriate regulations for approval status and any limitations on its use.

Indirect food additives require appropriate regulatory approval and may include lubricants, cleaning compounds and sanitizers.

Notes:

Table 2.5. Examples of Food Additives That May Become Chemical Hazards if Used Improperly

Source	Why a hazard?
FD&C Yellow No. 5 (food coloring)	Can produce an adverse reaction in sensitive people.
Sodium nitrite (preservative)	Can be toxic in high concentrations.
Vitamin A (nutritional supplement)	Can be toxic in high concentrations.
Sulfiting agents (preservative)	Can cause an intolerance reaction in sensitive individuals.

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## Intentionally-Added Chemicals - Food Additives

- Direct (allowable limits under cGMPs)
  - Preservatives (e.g., sodium benzoate and sulfiting agents)
  - Nutritional additives (e.g., calcium)
  - Color additives

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## Intentionally-Added Chemicals - Food Additives (cont'd)

- Indirect
  - Packaging materials
  - Processing plant chemicals
    - Lubricants (food grade)
    - Sanitizers

## **Unintentional or Incidental Chemical Contaminants**

- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, and other residues)
- Prohibited substances (21 CFR Part 189)
- Toxic elements/compounds (e.g., lead, tin, copper, zinc, arsenic, mercury, cyanide)

## **Unintentional or Incidental Chemical Contaminants (cont'd)**

- Cross-contaminating food allergens from inadequately cleaned shared processing equipment
- Processing plant chemicals (e.g., lubricants, cleaners and sanitizers)

### **Notes:**

Explanatory Note:  
A partial list of prohibited substances can be found in Title 21 CFR Part 189 of the Code of Federal Regulations, "Substances Prohibited from Use in Human Food."

**Notes:*****Unintentional or Incidental Chemical Contaminants***

Chemicals can become part of a food without being intentionally-added. For example, certain juices containing a high level of nitrate can cause excessive levels of tin from the container to leach into the juice. These incidental chemicals might already be part of a food ingredient or packaging material when it is received. Incidental chemicals, such as sanitizers, may come into direct contact with ingredients or the product. Most incidental chemicals have no effect on food safety, and others are only a concern if present in excessive amounts. Incidental chemicals may also include inadvertent addition of prohibited substances such as poisons or insecticides that may not be allowed at any level.

Cross-contamination with food allergen residues or inadequately cleaned shared processing equipment is also a concern with the processing of juices, e.g., processing of juice on dairy lines. The potential for milk protein allergens crossing into the juice must be controlled in a HACCP system, either within the HACCP plan or under SSOPs.

Table 2.6. Examples of Incidental Contaminants That May Become Chemical Hazards

Source	Why a hazard?
Agricultural chemicals (e.g., pesticides, herbicides)	Many are approved for use on food. However, if improperly used or applied, some can be acutely toxic or may cause health risks with long-term exposure.
Cleaning chemicals (e.g., acids, caustics)	Can cause chemical burns if present in the food at high levels.
Equipment components (e.g., copper pipe fittings)	Acidic foods can cause leaching of heavy metals from pipes and joints (e.g., copper and lead).
Maintenance chemicals (e.g., lubricants)	Some chemicals that are not approved for food use may be toxic.
Packaging materials (e.g., tin)	High nitrite levels in food can cause excessive detinning of uncoated cans resulting in excessive levels of tin in food.

**Physical Hazards**

Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after consumption, and the source of the hazard is often easy to identify. Table 2.10 at the end of the chapter lists the types of materials that can be physical hazards in foods.

Table 2.7. Examples of Materials That May Become Physical Hazards

<b>Material</b>	<b>Why a hazard?</b>
Glass	Cuts, bleeding, choking; may require surgery to find or remove.
Plastic	Cuts, bleeding, choking; may require surgery to find or remove.
Metal	Cuts, bleeding, broken teeth; may require surgery find or remove.

Notes:

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## Physical Hazard

- Any potentially harmful extraneous matter not normally found in food

## Notes:

Table 2.8. Examples of Biological Hazards

<b>Bacteria</b>
<b>Sporeformers</b>
<i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Bacillus cereus</i>
<b>Nonsporeformers</b>
<i>Campylobacter jejuni</i> Pathogenic <i>Escherichia coli</i> (e.g., <i>E. coli</i> O157:H7) <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. (e.g., <i>S. Typhimurium</i> , <i>S. Enteritidis</i> ) <i>Shigella</i> spp. (e.g., <i>S. dysenteriae</i> ) <i>Staphylococcus aureus</i> <i>Vibrio</i> spp. (e.g., <i>V. cholerae</i> , <i>V. parahaemolyticus</i> , <i>V. vulnificus</i> ) <i>Yersinia enterocolitica</i>
<b>Viruses</b>
Hepatitis A Norwalk virus group Rotavirus
<b>Parasitic Protozoa</b>
<i>Cyclospora cayentanensis</i> <i>Cryptosporidium parvum</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i>

Chapter 2. Hazards-Biological, Chemical and Physical

Table 2.9. Examples of Chemical Hazards

Notes:

<b>Naturally-Occurring Chemicals</b>
Mycotoxins (e.g., aflatoxin, <i>Alternaria</i> toxin, fumonisin, ochratoxin, patulin, vomitoxin)
Elderberry leaves, guanabana seeds
Pyrolizidine alkaloids
Phytohemagglutinin
<b>Intentionally-Added Chemicals</b>
Undeclared ingredients
Allergens (e.g., egg, milk, nuts, soy)
Food additives
Direct (allowances under food additives regulations)
Preservatives (e.g., nitrite, propionate, sodium benzoate, sorbate, sulfiting agents)
Nutritional additives (e.g., calcium, niacin, vitamins)
Color additives
Indirect
Packaging materials (e.g., inks, bleaching agents)
Lubricants (food grade)
Cleaners and sanitizers
<b>Unintentional or Incidental Chemical Contaminants</b>
Agricultural chemicals (e.g., fertilizers, fungicides, herbicides, pesticides, other residues)
Prohibited substances (21 CFR Part 189)
Toxic elements and compounds (e.g., arsenic, copper, cyanide, lead, mercury, tin, zinc)
Polychlorinated biphenyls (PCBs)
Plant chemicals (e.g., cleaning compounds, lubricants, sanitizers)

Notes:

Table 2.10. Examples of Physical Hazards and Common Sources

<b>Material</b>	<b>Sources</b>
Glass	Bottles, jars, light fixtures, thermometers, gauge covers
Plastic	Bottles, jars, equipment, and packaging material
Metal	Machinery, agricultural fields, buckshot, wire, staples, building materials, employee personal effects

## **CHAPTER 3: PREREQUISITE PROGRAMS AND PRELIMINARY STEPS**

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### **Objectives**

In this module you will learn:

- The role of prerequisite programs
- Preliminary steps involved in developing HACCP plans

### **Prerequisite Programs**

HACCP is not a stand-alone program but is one part of a larger system of control procedures. For HACCP to function effectively, it should be accompanied by prerequisite programs such as those discussed in this chapter.

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**GAP** - Good Agricultural Practice

**GMP** - Good Manufacturing Practice

**SSOP** - Sanitation Standard Operating Procedure

**HACCP** - Hazard Analysis and Critical Control Point

HACCP systems are designed to identify and control food safety hazards associated with food from the time a company receives raw material through processing to distribution to the consumer. HACCP systems must be built upon a firm foundation of compliance with Good Manufacturing Practices (GMPs) (21 CFR Part 110) acceptable sanitation standard operating procedures (SSOPs) and appropriate industry practices. GMPs and sanitation procedures affect the processing environment and should be considered prerequisite programs to HACCP.

Notes:

Explanatory Note:  
This chapter is not intended to be an exhaustive discussion of all elements that could be included in prerequisite programs.

## Notes :

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## Definition

**Prerequisite programs:** procedures, including GMPs and SSOPs, that address operational conditions providing the foundation for the HACCP system

The GMPs define measures of general hygiene as well as measures that prevent food from becoming adulterated due to unsanitary conditions. The GMPs are broadly focused and encompass many aspects of plant and personnel operations. SSOPs are procedures used by food processing firms to help accomplish the overall goal of maintaining GMPs in the production of food. Typically, SSOPs describe a particular set of objectives associated with sanitary handling of food, the cleanliness of the plant environment, and the activities conducted to meet those objectives.

When SSOPs are well-designed and fully and effectively implemented, they are valuable in reducing the likelihood of occurrence of a hazard. Identification of critical control points may be influenced by the effectiveness of prerequisite programs including GMPs and SSOPs. For example, SSOPs can help reduce the likelihood of occurrence of a hazard by: (1) preventing product cross-contamination, (2) providing handwashing and sanitizing stations near the processing area to facilitate proper employee hygiene, and (3) ensuring appropriate equipment maintenance and cleaning and sanitizing procedures. SSOPs can likewise be used to help control chemical contamination from sanitizers and other chemicals found in food processing operations.

In some situations, properly implemented SSOPs may lead to a determination that a CCP is unnecessary. In some instances, plant sanitation, employee hygiene and strict handling procedures are often as important in preventing cross-contamination as other steps, such as pasteurization, that might be identified as CCPs in HACCP plans.

When SSOPs are in place, the focus of the HACCP plan becomes the hazards associated with the product or the process which must be controlled and not the manufacturing plant environment. If sanitation controls are included as part of a HACCP plan, they must lend themselves to all aspects of a CCP such as establishing critical limits, monitoring, corrective actions, verification and record-keeping procedures, to be discussed.

Cleaning and sanitizing post-pasteurization handling equipment, such as a filler, is an example of a sanitation control that might be handled as a CCP within a HACCP plan. The system's effectiveness can be monitored, critical limits can be established, monitoring records can be maintained, and appropriate corrective actions can be established when the critical limits are not met. On the other hand, a processor's *general* cleaning and sanitizing program should be included in its SSOPs rather than its HACCP plan. Procedures for these will be considered later.

Explanatory Note:  
The juice HACCP regulation requires that each processor has and implements SSOPs. The eight areas of sanitation identified in the juice HACCP regulation (discussed in Chapter 12) must be monitored and documented by all processors regardless of whether a firm has a written SSOP or is required to have a HACCP plan.

### Chapter 3. Prerequisite Programs and Preliminary Steps

Even without HACCP, the level of plant sanitation and cGMPs must comply with regulatory requirements. Contrary to popular perception, sanitation control is not limited to cleaning equipment. Although clean equipment and a clean working area are essential for producing safe foods, so are personnel practices, plant facilities, pest control, warehouse practices, and equipment and operation design. Each should be addressed in a written sanitation procedure designed to comply with existing regulations.

An important component in any sanitation program is monitoring. Methods for monitoring sanitation practices will vary according to the type and size of a food processing operation. Oftentimes a simple checklist can describe the sanitation procedures and at the same time provide a mechanism to document results. The frequency of checks will vary as necessary to assure that the SSOPs remain in control. For example, in certain processing plants, the safety of the processing water may be checked annually. However, the water from other plants may require more frequent checks because of their location. Grounds surrounding a plant may require only periodic checks to ensure that they do not attract and harbor pests, but cooler-storage areas and floor drains may need daily inspection. Relatively more frequent checks might be required for work surfaces, hand-wash stations and employee attire. The Juice HACCP Regulation requires monitoring and documentation to cover at least the eight key sanitation conditions and practices.

Any correction necessary to maintain control of the SSOPs must also be documented. These corrections are documented as part of the SSOP records. An example of an SSOP checklist is given in Chapter 4.

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## **Eight Key Sanitation Conditions and Practices**

1. Safety of water.
2. Condition and cleanliness of food-contact surfaces.
3. Prevention of cross-contamination.
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities.
5. Protection from adulterants.
6. Labeling, storage and proper use of toxic compounds.
7. Employee health conditions.
8. Exclusion of pests.

### ***Examples of Common Prerequisite Programs***

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This had traditionally been accomplished through the application of GMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.

Notes:

**Notes :**

Common prerequisite programs may include but are not limited to:

- Facilities. The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.
- Supplier Control. Each facility should ensure that its suppliers have in place effective cGMP and food safety programs.
- Specifications. There should be written specifications for all ingredients, products, and packaging materials.
- Production Equipment. All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.
- Cleaning and Sanitation. All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.
- Personal Hygiene. All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.
- Training. All employees should receive training in personal hygiene, cGMPs, cleaning and sanitation procedures, personal safety, and their role in the HACCP program. Companies may wish to maintain records of employee training activities.
- Chemical Control. Documented procedures should be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants and pesticides or baits used in or around the plant.
- Receiving, Storage and Shipping. All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to ensure their safety and wholesomeness.
- Traceability and Recall. All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.
- Pest Control. Effective pest-control programs should be in place.

Other examples of prerequisite programs might include quality assurance procedures, standard operating procedures for sanitation, processes, product formulations and recipes, glass control, procedures for receiving, storage and shipping, labeling, and employee food and ingredient handling practices.

### **Preliminary Steps in Developing a HACCP Plan**

HACCP is often thought of in terms of its seven basic principles. However, HACCP also includes preliminary steps. Failure to properly address the preliminary steps may lead to ineffective design, implementation and management of the HACCP plan.

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## **Preliminary Steps**

1. Assemble HACCP team.
2. Describe food and its distribution.
3. Identify intended use and consumers of food.
4. Develop process flow diagram.
5. Verify flow diagram.

### ***Preliminary Steps***

There must be clear management commitment to successfully design and implement a HACCP program. Assembling a HACCP team is an important step in achieving this. The team should consist of individuals with different specialties. The team may include personnel from maintenance, production, sanitation, and quality assurance. The HACCP team should include members who are directly involved with the plant's daily operations.

The team documents the prerequisite programs, writes the SSOPs, develops and validates the HACCP plan, and implements and verifies the HACCP system. The team should have access to technical expertise and knowledge about food safety hazards and their control. The team should be led by a HACCP-trained individual. When issues arise that cannot be resolved internally, it may be necessary to enlist outside experts or other resources.

Although a single person may be able to analyze hazards and develop a HACCP plan successfully, many companies find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process, but the biggest concern is with implementation and “buy-in.” The team approach also encourages ownership of the plan, builds company involvement and brings in broader, cross-functional expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various operations, including owners, should be members. Universities, cooperative extension services, consulting groups, model plans and published guidance can provide additional assistance.

Notes:

**Notes :*****Description of the Product, Its Ingredients and Intended Use***

Once a HACCP team is established, the members first describe the product and its ingredients, the method of distribution, the intended customer (e.g., general public, infants, elderly) and consumer use of the product (e.g., consumed without further cooking). This information is normally tabulated or charted to become part of the permanent record.

*Example:* Refrigerated pasteurized apple juice

Apple juice has a pH of 3.6-3.8 and is unlikely to support the growth of pathogens. Pathogenic bacterial sporeformers will not germinate at this pH. Vegetative pathogens which occur in the raw juice are destroyed by pasteurization. Refrigerated storage maintains the quality and shelf-life of the product without further preparation. The product is sold in 28 oz plastic bottles to be consumed by the general public.

***Development and Verification of the Process Flow Diagram***

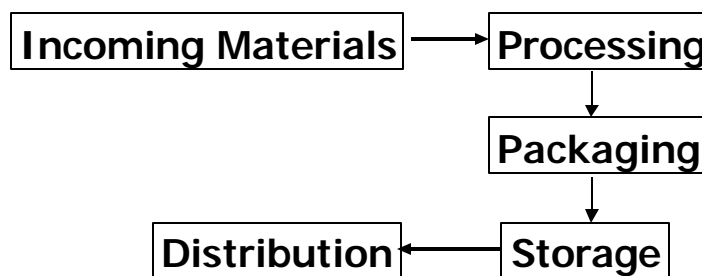
A flow diagram shows in simple block or symbol form the steps required to manufacture and distribute a food product. This provides an important visual tool that the HACCP team can use to complete the remaining steps of the HACCP plan. A clear and simple, but complete, diagram of the process is all that is needed.

It is important to include all the steps within the facility's control, including receiving and storage steps for all raw materials. The flow diagram should be clear and complete enough so that people unfamiliar with the process can quickly comprehend the process.

Since the accuracy of the flow diagram is critical in order to conduct a hazard analysis, the steps outlined in the diagram must be verified in the plant. If a step is missed, a significant food safety hazard may not be addressed.

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## The Following is an Example of a Basic Flow Diagram:



The HACCP team should walk through the facility and make any required changes in the flow diagram. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

Explanatory Note:  
This depicts a schematic flow diagram. A real-world flow diagram would be much more detailed.

### Chapter 3. Prerequisite Programs and Preliminary Steps

In addition to the above, experience has shown that the following items need to be addressed in establishing a HACCP system.

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- **Management commitment**
  - Training resources
  - Personnel time
  - Funding
  - Delegation of authority
- **Employee training**

#### *Management Commitment*

For a HACCP plan to work, it is extremely important to have the support of top company officials such as the owner, director and chief executive officer. Without it, HACCP will not become a company priority or be effectively implemented.

#### *Employee Training*

Education and training are important elements in developing and implementing a HACCP program. Employees who will be responsible for the HACCP program must be adequately trained in its principles. This course is designed to meet that need.

Notes:

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## **CHAPTER 4: COMMERCIAL PROCESSING EXAMPLE: REFRIGERATED PASTEURIZED APPLE JUICE**

Notes :

To facilitate our discussion of HACCP, the XYZ Apple Juice Co. is introduced. With this fictitious company as a base, evolution of a HACCP plan for apple juice will be discussed and illustrated. Keep in mind that the HACCP plan developed for XYZ Apple Juice Co. is primarily intended to demonstrate the procedures used in plan development. Since HACCP plans are very product, process and plant specific, XYZ Apple Juice Co.'s plan may not be suitable for other firms.

Processing narratives can help explain the current processing steps needed to produce a product covered by a particular HACCP plan. They offer a historical, working reference for the processor and facilitate communication with the staff and inspectors. For these reasons, a written narrative should accompany a HACCP plan.

### **Refrigerated Pasteurized Apple Juice Processing Narrative**

Company: XYZ Apple Juice Co.

Final Product: Refrigerated pasteurized apple juice

Procedures/Steps:

#### **INCOMING MATERIALS**

- Locally grown fresh apples: Winesap, Paula Reds, MacIntosh, Red and Golden Delicious are purchased directly from farms. Apples are received bulk in wooden boxes containing approximately 40 bushels and upon receipt are visually examined for gross filth. Following acceptance, the apples are assigned a lot number, and placed in refrigerated storage. Furthermore, a supplier agreement specifying that the apples are tree-picked is in effect for each incoming shipment of apples.
- Packaging materials are delivered in clean, well-maintained and covered vehicles. All materials are checked for integrity and order specifications. They are then assigned lot numbers and placed into a dry-storage warehouse/room.

#### **PROCESSING**

- Apples are transferred from refrigerated storage to the processing area. Apples are dumped from bulk boxes onto a slotted hopper where stems, leaves, and other extraneous materials are removed.
- From the slotted hopper, the apples go into a flume tank containing treated water.
- Apples are elevated, dewatered and moved to the processing facility over inspection rollers where visually defective apples are removed.

[Note: Defective apples are diverted, not to be used for human consumption.]

- Accepted apples continue on to a wet scrubber where they are brushed and sprayed with treated water. Then, the apples pass across a rubberized roller where they are partially dried.

**Notes :**

Explanatory Note:  
Processing aids for filtration and clarification are not included in this model. It is important these steps are evaluated in a hazard analysis.

- Apples are 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.

[Note: Pomace is diverted for non-human food use.]

- The juice slurry is screened to separate the juice from the pulp and to achieve a particle size compatible with the pasteurizer manufacturer's specifications.

[Note: Pulp is diverted for non-human food use.]

- The juice is collected and pumped to a balance tank where juice is held until it goes to the pasteurizer. The positive displacement timing pump and holding tube are constructed to deliver a constant flow rate of the juice through the heat exchanger to ensure that it is heated for the minimum required time.
- 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 and from there pumped to the filler.

### **PACKAGING**

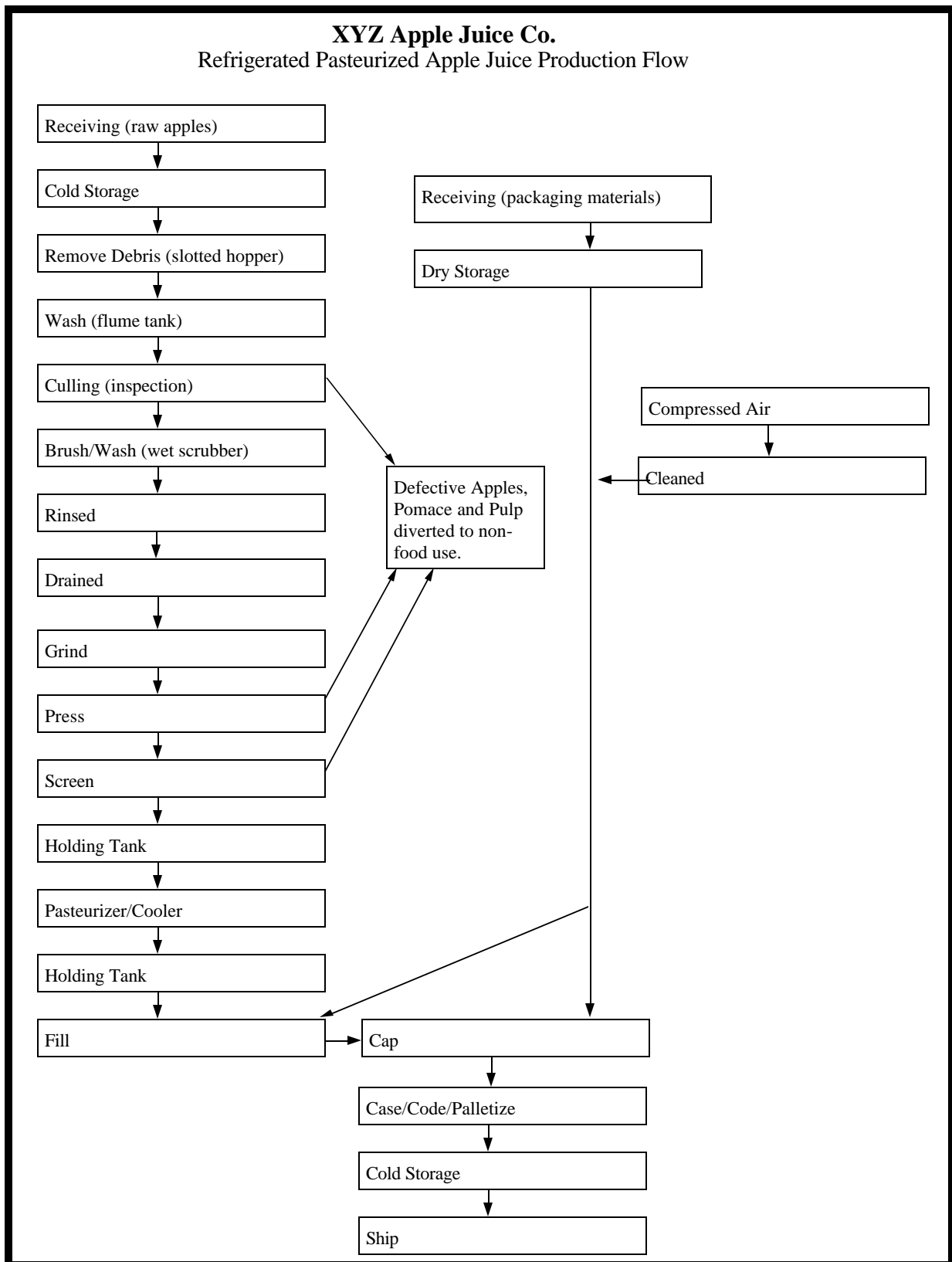
- Plastic containers are cleaned using compressed air. Each primary container is identified by the production date, code, and lot number.
- Juice is pumped into a reservoir on the filler and gravity-fed into 1-gallon plastic containers that are pre-labeled.
- Immediately after filling, caps are mechanically applied to the plastic containers.
- Filled, dried containers are check weighed and packed into shipping cartons as required by the customer. Each shipping carton is marked with a code identical to the code on the primary containers within the carton. Each shipper carton is palletized in accordance with customer or company specifications. Pallets are then conveyed to a storage cooler.

### **STORAGE/SHIPPING**

- All finished product is placed into cooler storage without delay. All product is stored and shipped on a first-in, first-out basis.
- Finished product is shipped by common carrier in clean, well-maintained refrigerated tractor-trailers.

Figure 4.1. Process Flow Diagram for XYZ Apple Juice Co.

Notes :



**Notes :**

**Sanitation Standard Operating Procedure (SSOP)**

Although sanitation monitoring requirements are new, sanitation standards have been in place for many years as part of FDA's current Good Manufacturing Practice Regulation – 21 CFR Part 110 or the GMPs. There are many courses available that teach the basics of sanitation and how to comply with the GMPs.

With the advent of HACCP, many have recognized that sanitation is a prerequisite to HACCP and provides a foundation for safe food production. In writing the Juice HACCP regulation, FDA recognized that monitoring of sanitation conditions would be necessary to achieve and maintain improvements in sanitation in juice processing operations.

The regulation requires monitoring in eight key areas of sanitation. Not every area is relevant to all facilities. The following example SSOP addresses the sanitation concerns for a fictional refrigerated pasteurized apple juice company, the XYZ Apple Juice Co. SSOPs will vary from facility to facility because each is designed differently. In this model, the XYZ Apple Juice Co. has distinct quality assurance, maintenance, and production departments.

**1. Safety of Water**

- A. Goal: Water that comes into direct contact with food or food-contact surfaces is derived from a safe and sanitary source or is treated to make it safe.

Procedure:

XYZ Apple Juice Co. will use well water. The water is treated to make it potable. The well is considered a public water source and is tested every quarter for coliforms by a certified external laboratory.

- B. Goal: There are no cross-connections between the potable water system and any non-potable system.

Procedure:

- 1) The quality control supervisor will perform a monthly inspection to determine that no cross connections exist between potable water and waste systems. The results of the inspections will be recorded on the monthly sanitation audit form.
- 2) A certified external agency will perform an annual inspection of the well seal and will test all in-place backflow prevention devices.

- C. Goal: The water used in the flume tank and washer/brusher is sanitized at a level sufficient to prevent cross-contamination of apples.

Procedure:

The flume tank water is changed on a daily basis, and chlorine is added at an initial level of 100 ppm. The chlorine level is monitored on an hourly basis for active chlorine using an appropriate test kit. During active use, chlorine levels are maintained at a detectable residual level.

Explanatory Note:  
FDA's regulation requires records of eight key sanitation operations. XYZ Apple Juice Co. has identified 15 goals in their SSOPs to meet these requirements. In practice, these goals may not be appropriate or the same for all operations.

The brusher/washer water is sanitized with chlorine dioxide and metered into the supply line. The chlorine level is monitored prior to start and every 4 hours of operation using an appropriate chlorine test kit. During active use, chlorine levels are maintained at a detectable residual level.

## 2. Food Contact Surfaces

- A. Goal: All food-contact surfaces of plant equipment and utensils, are designed of such material and workmanship to be easily cleaned and maintained in a sanitary condition. Such surfaces will be constructed of nontoxic materials and designed to withstand the environment of its intended use and the action of the cleaning compounds and sanitizing agents.

Procedure:

Presently, all plant equipment and utensils meet current recommended state and federal standards. Prior to replacing any major piece of equipment, the quality assurance, production and maintenance departments will meet to evaluate the equipment. The evaluation will determine whether replacing the equipment will impact adjacent processing steps. Specifications of all equipment will be reviewed to ensure it is capable of withstanding the intended use and can be easily cleaned. The same evaluation will be conducted on materials used in the modification of the physical plant. Orders to purchase minor equipment and utensils used in the process will be reviewed by the line supervisor placing the order and the quality assurance department. If necessary, the supervisor of the contracted cleaning company will be contacted to consider the impact of present methods of cleaning and sanitizing plant equipment and utensils. The results of these evaluations will be kept on file. The quality control supervisor will evaluate the condition of plant equipment and utensils monthly. The results of these evaluations will be recorded on the monthly sanitation audit form.

- B. Goal: All utensils and surfaces of equipment that contact food during processing are cleaned and sanitized with effective cleaning and sanitizing preparations in the following frequencies:
- 1) Cleaned and sanitized at the end of the day's operations;
  - 2) Sanitized before the day's operations begin.

Procedure:

All process lines, regardless of the intended purpose, will be cleaned and sanitized at the end of the day's operation. At the end of the production day, XYZ Apple Juice Co. employees will remove any buildup of debris or other materials from the facility. In addition employees will clean and sanitize all equipment, utensils and the facility. A food-grade alkaline detergent will be used for cleaning, followed by a 100 ppm chlorine rinse. The concentration of the chlorine sanitizer will be checked by the quality control representative before it is used. The results will be recorded on a daily sanitation audit form.

### Notes :

Explanatory Note:  
Processing will not resume until the plant conditions are determined to be satisfactory.

**Notes :**

Before the production day begins, the facility, equipment and utensils will be sanitized using a 100 ppm chlorine rinse. The concentration of the chlorine sanitizer will be checked by the quality control representative before it is used. The results will be recorded on a daily sanitation audit form. The quality control representative will conduct a preoperational sanitary inspection. A representative of the cleaning crew will be present and, if necessary, immediately eliminate any discrepancy noted. The observations will be recorded on a daily sanitation audit report.

- C. Goal: Gloves and outer garments that contact food or food-contact surfaces are made of an impermeable material and are kept clean and sanitary.

Procedure:

The company will issue line workers rubber aprons and work gloves. The line supervisor will ensure that his or her employees are issued this gear. Employees are not allowed to use personal gear in place of these items unless authorized by the line supervisor and foreman. Employees are required to maintain this gear in a sanitary and operable condition and, if necessary, must replace it through the line supervisor. Supervisors must require all employees to comply. In addition, the quality control representative will check this gear at the beginning of each day's operations. Observations will be recorded on a daily sanitation audit form.

### **3. Prevent Cross-Contamination**

- A. Goal: Employees' hands, gloves and outer garments, utensils, food-contact surfaces of equipment that come into contact with waste, the floor, or other unsanitary objects do not touch food products without first being adequately cleaned and sanitized.

Procedure:

- 1) Employees will be trained on how and when to properly wash and sanitize hands. Training will be documented and kept on file.
- 2) The foreman will maintain handwashing stations.
- 3) The foreman will maintain separate utensil wash stations.
- 4) Should the filler line become contaminated by any form of waste or floor splash, the supervisor or designated person will immediately stop the filler. The section affected will be cleaned, sanitized and then inspected by a quality control representative before production starts again. Results will be recorded on the daily sanitation audit form.
- 5) Supervisors, maintenance workers, quality control and production personnel, including those who handle waste, touch the floor or other insanitary objects, must clean and sanitize their hands and gloves before handling product.
- 6) Utensils and equipment food-contact surfaces that have come in contact with the floor, waste or other insanitary objects must be washed and sanitized before being used in contact with product.

- B. Goal: Food, food-contact surfaces and packaging materials will be protected from contaminants that may be sprayed, dripped, drained or drawn into food.

Procedure:

- 1) The maintenance department is responsible for establishing a regular maintenance program for the facility's ventilation system. This ensures adequate ventilation, airflow and air pressure that prevents or inhibits the formation of condensates in the processing and storage areas. Condensates can lead to contamination of product, product-contact surfaces or packaging materials.
- 2) Supervisors must also ensure that no floor splash occurs in processing areas during cleaning or sanitizing during production hours. They must also make sure that the area is cleaned, sanitized and inspected before restarting production. The food processing area will be inspected for possible sources of contamination, including condensate, by the quality control supervisor each day during operation and the results recorded on a daily sanitation audit form.

#### 4. Maintain Handwashing and Toilet Facilities

- A. Goal: Handwashing stations are located in all processing areas where good sanitary practices require employees to wash and sanitize their hands. These facilities must be equipped with hand-cleaning preparations, hot and cold running water, and disposable towels, and properly managed waste receptacles.

Procedure:

- 1) Handwashing stations will be located at all entrances to the process floor. These will be used upon entry to the process floor.
- 2) The handwashing stations will be checked by a quality control representative daily for adequate supplies before operation begins. Employees will be instructed to inform their supervisor when any of the supplies need replenishing. These activities will be recorded on a daily sanitation audit form.

- B. Goal: Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.

Procedure:

- 1) Separate toilet facilities are provided for male and female employees in the break area and adjacent to the processing area. Each restroom is equipped with double doors opening inward and is well-ventilated. An adequate number of toilets must be provided.
- 2) Restrooms will be equipped with handwashing facilities, soap dispensers and stocked with soap and disposable towels.

Notes :

**Notes :**

- 3) During production hours, line supervisors check, on a rotational basis, that toilet facilities are sanitary and well-stocked. Following production, the janitorial staff is responsible for cleaning and sanitizing toilet facilities and for restocking.
- 4) The maintenance department keeps toilet facilities operable and in good repair.
- 5) The condition of the restrooms will be inspected daily by the quality control supervisor. The results will be recorded on the daily sanitation audit form.

## **5. Protection of Food from Adulterants**

- A. Goal: Food, food-contact surfaces and food packaging materials shall be protected from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments or other chemical or physical contaminants.

Procedure:

- 1) All cleaning compounds and sanitizing agents used within the processing environment will be clearly identified and stored away from the process area and any other lubricants or chemicals. The cleaning supplies company will provide the quality assurance department with a material safety data sheet (MSDS) for all compounds and agents stored at the plant.
- 2) All food-grade lubricants will be stored separately from nonfood-grade lubricants and be properly labeled.
- 3) The Stun'em Pesticide Co. will not store any pesticides in the plant. The company will provide a MSDS for any pesticides used for pest control.
- 4) The maintenance department will store and properly label all nonfood-grade lubricants within the maintenance area. No fuels will be stored within the facility. All gas fuels (i.e., oxygen and acetylene) shall be stored in portable tanks outside the plant and will be brought inside only when production is stopped. If it becomes necessary to use such fuels during production, maintenance personnel will raise barriers to ensure that the process is not contaminated. When finished, the area will be thoroughly cleaned, sanitized and inspected before production starts again.
- 5) The quality control supervisor will inspect the processing area daily during operation for possible contamination sources and to make sure toxic compounds are labeled and stored properly. The results will be documented on the daily sanitation audit form.

## **6. Proper Labeling, Storage and Use of Toxic Compounds**

- A. Goal: Any toxic compounds allowed in the plant shall be identified, held, used and stored in a manner that protects against contamination of food, food-contact surfaces or packaging materials.

Explanatory Note:  
Provision of MSDS sheets is a legal requirement. The QA department will make MSDS available and accessible to all employees.

Procedure:

The quality control supervisor will inspect the processing area daily during operations for possible contamination sources and to make sure toxic compounds are labeled and stored properly. The results will be documented on the daily sanitation audit form.

## 7. Employee Health Conditions

- A. Goal: Anyone who has or may have, by medical examination or supervisory observation, an illness, infected wound, an open lesion such as a boil or sore, or any other problem that might contaminate food, food-contact surfaces or packaging materials shall be excluded from any operations until the condition is healed or corrected.

Procedure:

- 1) As a part of new employee orientations, staff will be briefed on the need to notify immediate supervisors of any illness or injury that may lead to contamination of any part of the process. Employees must notify immediate supervisors if they have been exposed to a confirmed disease outbreak of *Salmonella* (such as typhoid), hepatitis A or *Shigella*, especially when employees are asymptomatic. In addition, employees will be informed that, if at all possible, they will be assigned duties that will not compromise the process. The results of the training will be documented and kept on file.
- 2) It is the responsibility of all supervisory personnel to observe the apparent well-being of their personnel. Employees will be reviewed for signs of medical problems daily before operations begin by the quality control supervisor. At any indication of injury or illness that may compromise the process due to contamination, the supervisor will remove that person from the line and report to the plant manager. If that employee cannot be assigned other duties, he or she will be sent home until the situation is alleviated or a medical authority states that he or she may return to work. Observations will be recorded on the daily sanitation audit form.

## 8. Exclusion of Pests

- A. Goal: No pests are in any area of a food plant.

Procedure:

The presence of rodents, insects, birds or other pests in the plant is unacceptable. The Stun'em Pesticide Co. has been contracted and is responsible for all facets of pest control within the plant as well as the grounds. MSDS's for all pesticides used by the company are on file. A representative of the company will meet monthly with the quality control supervisor and discuss facility pest control. In addition, the quality control supervisor will inspect the facility for the presence of pests daily before operation. Observations will be recorded on the daily sanitation audit form.

Notes :

**Notes :**

- B. Goal: The plant is designed to minimize the risk of pest contamination of the food, contact surfaces and food packaging material.

Procedure:

- 1) The quality control supervisor and representatives from the maintenance department will schedule a monthly review of the plant layout and structure to ensure that contamination of any aspect of the process does not occur from internal or external sources. Observations will be recorded on the monthly sanitation audit form.
- 2) Any modification to the physical facility requires the consultation of a certified sanitarian.

Explanatory Note:  
Although SSOP records are required, the regulation does not require that these records be periodically reviewed by the processor. Although not required, a periodic review, is nevertheless, a highly recommended practice.

Figure 4.2. Juice HACCP Daily Sanitation Monitoring Report Form

<b>Daily Sanitation Control Record</b> (page 1 of 2)												
<b>Report Date:</b>			<b>Firm Name:</b>									
<b>Line 1: Refrigerated Pasteurized Apple Juice</b>			<b>Firm Address:</b>									
Sanitation Area and Goal	Pre-Op Time	Start Time	Hourly Test								Post-Op Time	Comments and Corrections
			Actual Time									
1) Safety of Water (See Monthly/and Periodic Sanitation Control Record) • Hourly active chlorine test (ppm)												
2) Food Contact Surfaces (See Monthly Sanitation Control Record also) • Equipment cleaned and sanitized Line 1: (S/U) <input style="width: 50px;" type="text"/>  • Sanitizer Strength Sanitizer Type _____ Strength _____ ppm Line 1: (ppm) <input style="width: 50px;" type="text"/>  • Gloves and outer garments clean and sanitary Line 1: (S/U) <input style="width: 50px;" type="text"/>												
3) Prevent Cross-Contamination (See Monthly Sanitation Control Records also) Utensils and equipment food contact surfaces  • Workers must wash and sanitize hands and gloves before handling product (S/U)  • Inspection of food processing area by QC supervisor (S/U)  • Filler cleared and inspected by QC supervisor or designate after contamination  • Utensils and equipment food contact surfaces washed/sanitized after contact with unsanitary objects (S/U)											Actual time  Check off	
S = Satisfactory / U = Unsatisfactory												



## Monthly Sanitation Control Record

Report Date: \_\_\_\_\_

Firm Name: \_\_\_\_\_

Firm Address: \_\_\_\_\_

Sanitation Area	Decision	Comments/Corrections
<b>1) Safety of Water</b> <ul style="list-style-type: none"> <li>• No cross-connections in hard plumbing (S/U)</li> </ul>	<input style="width: 100px; height: 30px;" type="text"/>	
<b>2) Food Contact Surfaces</b> <ul style="list-style-type: none"> <li>• Processing equipment and utensils in suitable condition (S/U)</li> </ul>	<input style="width: 100px; height: 30px;" type="text"/>	
<b>2) Prevent Cross-Contamination</b> <ul style="list-style-type: none"> <li>• Maintenance program HVAC system (S/U)</li> </ul>	<input style="width: 100px; height: 30px;" type="text"/>	
<b>8) Exclusion of Pests</b> <ul style="list-style-type: none"> <li>• Representative of pest control company submits report and meets with QC supervisor to discuss (S/U).</li> <li>• QC and maintenance review plant layout and structure to exclude contamination (S/U).</li> </ul>	<input style="width: 100px; height: 30px; margin-bottom: 10px;" type="text"/> <input style="width: 100px; height: 30px;" type="text"/>	

S = Satisfactory / U = Unsatisfactory

**Additional Comments:**

**Signature or initials:** \_\_\_\_\_

<b>Periodic Sanitation Control Record</b>			
<b>Firm Name:</b>	<b>Date:</b>		
<b>Firm Address:</b>			
<b>Condition</b>	<b>S</b>	<b>U</b>	<b>Comments/Corrections</b>
<b>1. Safety of Water:</b> a. Well seal inspection (annually). b. Test in-place back flow prevention devices (annually).			
<b>3. Prevent Cross-Contamination:</b> a. Production supervisors have received basic food sanitation training (when hired). b. Employees trained in proper handwashing and sanitation (when hired). c. Foreman maintains handwash stations. d. Foreman maintains separate utensil wash stations.			<b>Name(s)</b>
<b>5. Adulteration:</b> a. Invoices for food-grade chemicals checked before chemicals are stored (when received). b. MSDS for all compounds and agents stored in plant (when received).			
<b>6. Toxic Compounds:</b> a. Labels or documents for toxic compounds checked before compounds stored (when received).			
<b>7. Employee Health Conditions:</b> a. Employees trained to report illness (when hired)			<b>Name(s)</b>
<b>8. Exclusion of Pests:</b> a. MSDSs for all pesticides are on file (when first introduced). b. Certified sanitarian consulted if modifications made to physical facility (as needed).			
<b>Comments and Corrections:</b>			
<b>Report by:</b>		S = Satisfactory / U = Unsatisfactory	

## CHAPTER 5: PRINCIPLE 1. HAZARD ANALYSIS

Overhead 45

### Objectives

In this module you will learn:

- What hazard analysis is
- How to conduct a hazard analysis
- How to identify significant hazards
- What control measures are
- How to identify control measures

The hazard analysis step is fundamental to the HACCP system. To establish a plan that effectively prevents food safety hazards, it is crucial that all significant food safety hazards and the measures to control them be identified.

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### HACCP Principle #1

Conduct a hazard analysis

Notes :

Explanatory Note:  
HACCP traditionally deals only with food safety hazards. Participants may realize that some issues such as sanitation, economic fraud and wholesomeness, are important and must be properly handled by the processor. However, unless these issues specifically address food safety or reduce the likelihood of occurrence of a hazard, they should not be part of a company's HACCP plan.

Notes :

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## Definition

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

As previously stated, a hazard is a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The term hazard, when used in the context of HACCP, is limited to safety.

### *Considerations for the HACCP Team*

During the hazard analysis, the potential significance of each hazard should be assessed by considering the likelihood of occurrence and severity. This is usually based upon a combination of experience, epidemiological data and information in the technical literature.

During the hazard analysis, factors that may be beyond the immediate control of the processor must be considered. For example, product distribution may be beyond the direct control of your firm, but information on how the food will be distributed could influence how the food will be processed and/or packaged. For some processors, the expertise necessary to properly assess the likelihood of occurrence and severity of the various hazards is available within the company. However, others may need to seek outside assistance to address this issue adequately.

The HACCP team has the initial responsibility to decide which hazards are significant and must be addressed by the HACCP plan. Keep in mind that there may be differences of opinion, even among experts, as to the significance of the hazard. The HACCP team may rely on available guidance materials and the opinions of experts who assist in the development of HACCP plans. During the hazard analysis, safety concerns must be differentiated from quality concerns.

## Hazard Analysis

- Hazard identification
- Hazard evaluation

### *Hazard Analysis*

One approach to hazard analysis divides it into two activities—hazard identification and hazard evaluation. Hazard identification should result in a list of potential hazards at each operation's step (use a flow diagram) in the process from the receipt of raw materials to the release of the finished product. During hazard identification, the team need not be confined by the hazard's likelihood of occurrence or its potential for causing disease.

All potentially significant hazards must be considered. To assist in this, the following list of hazards will be valuable.

## Hazard Identification

- Biological hazards:
  - Pathogenic microorganisms (e.g., bacteria, protozoa, viruses)

### Notes :

Explanatory Note:  
First-time HACCP plan writers often identify too many hazards! This is a problem because the potential exists to dilute a processor's ability to focus efforts and control the truly significant hazards. The dilemma is deciding what hazards are likely to cause illness or injury in absence of control.

Explanatory Note:  
The list of hazards in FDA's Juice Products Hazards and Controls Guide can be very useful, especially for firms that do not have strong technical expertise. These firms may also need to seek outside technical assistance in developing their HACCP programs.

## Notes :

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## Hazard Identification (cont'd)

- Chemical hazards:
  - Natural toxins
  - Chemicals
  - Allergens
    - Undeclared ingredients/cross-contaminants
  - Unlawful pesticide residues
  - Unapproved food and color additives
- Physical hazards:
  - Metal, glass, etc

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## Hazard Evaluation

1. Assess severity if not controlled.
2. Determine likelihood of occurrence.
3. Determine if hazard should be addressed in HACCP plan.

After hazard identification, the team conducts a hazard evaluation. This is a three-step process in which the list of potential hazards developed during the hazard identification is narrowed to those hazards that are significant to the product and process in question. The steps in hazard evaluation are:

1. Assess severity of health consequences if potential hazard is not properly controlled,
2. Determine likelihood of occurrence of potential hazard if not properly controlled, and
3. Determine, using information from steps 1 and 2, if the potential hazard should be addressed in the HACCP plan.

HACCP focuses solely on hazards that are likely to occur and likely to result in illness or injury to consumers if not controlled. Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

## Hazard Analysis

A hazard must be controlled if it is:

- Likely to occur, and
- Likely to result in illness or injury to consumers

A hazard must be controlled if it is: (1) likely to occur, and (2) if not properly controlled, is likely to result in illness or injury to consumers. In the case of hazards for which regulatory action levels have been established for safety concerns (e.g., mycotoxins), the mere presence of the substance in the product does not constitute a hazard. It is when the regulatory action level is exceeded that there may be an unacceptable health risk to consumers. If violation of an action level in a particular food is reasonably likely to occur, then the processor's hazard analysis should identify that hazard as one to be controlled through its HACCP system.

### ***Hazard Analysis Worksheet***

Deliberations of the HACCP team during the hazard analysis must be documented. A useful way for documenting decisions during the hazard analysis is to use a hazard analysis worksheet.

There are several formats available for a hazard analysis worksheet. Essentially all of them include processing/ingredient steps, identification of potential hazards, evaluation of the significance of the hazard, a justification for the decision, and proposed control measures.

A hazard analysis worksheet can be used to organize and document the considerations in identifying food safety hazards. In the pasteurized refrigerated apple juice example the arrangement is as follows:

- Column 1. List each ingredient or processing step obtained from process flow diagrams.
- Column 2. Record potential hazards.
- Column 3. Record results of the hazard evaluation.
- Column 4. Justify the decision.
- Column 5. List potential control measures available for controlling hazards that are likely to occur.

### ***Hazard Identification and Evaluation, and Justification for Decisions***

On the hazard analysis worksheet in the example for pasteurized refrigerated apple juice, at the receiving step potential hazards identified include biological hazards such as vegetative pathogens and *Cryptosporidium* and chemical hazards including patulin and pesticides. No physical hazards were identified. Based on the identified

### **Notes :**

#### **Explanatory Note:**

A hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the food hazard will occur in the particular type of product being processed. Severity is the seriousness of a hazard.

#### **Explanatory Note:**

The juice HACCP regulation requires a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control these hazards.

#### **Explanatory Note:**

In some hazard analysis worksheets there may be a final column to indicate whether or not a particular point or processing step may be considered a CCP at this time. There is much debate on whether or not this pre-empts or short-cuts a thorough, comprehensive and complete determination of CCPs using available tools, such as the CCP decision tree. An alternative to inclusion of such an "early call" on "CCP determination" on the hazard analysis worksheet is to carry-over and continue a full and systematic CCP determination at those points or processing steps where the hazard evaluation on the hazard analysis worksheet has determined that the identified food safety hazards may be significant. These steps would then be assessed on a separate CCP determination worksheet.

**Notes :**

potential hazards the following evaluations were made:

- Vegetative and protozoan pathogens (e.g., *E. coli* O157:H7 and *Cryptosporidium parvum*) have been associated with illness outbreaks from apple juice and were determined to be a significant hazard.
- During the hazard evaluation it was determined that *Cryptosporidium* could occur even though XYZ Apple Juice Co. only uses potable water and monitors the water it uses under its SSOP program. This program reduces the likelihood of occurrence of the hazard, but is not considered sufficient to eliminate the possible hazard.
- The XYZ Apple Juice Co. HACCP team determined that patulin was a significant hazard in the incoming apples and that patulin levels could increase further during cold storage of the apples.
- Pesticide residues may be found on incoming apples. However, government monitoring data demonstrate that in the U.S., the occurrence of unapproved pesticide residues in the food is likely to be infrequent and is unlikely to have a severe public health impact. Therefore, any hazard associated with pesticide residues was deemed to be not reasonably likely to occur.

**Control Measures**

Control measures are actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. In practice, control measures encompass a wide array of activities. FDA's Juice HACCP Hazards and Controls Guide lists appropriate control measures for several hazards.

As XYZ Apple Juice Co. continued its hazard analysis, it noted that the supplier agreement specifying the use of tree-picked and undamaged apples along with the subsequent culling and washing steps, would not be adequate measures to control incidence of *Cryptosporidium* contamination. It did not identify any control measures that are taken at the receiving step for bacterial pathogens or patulin on product received directly. Since levels of patulin could increase during cold storage of apples, a control measure for patulin only at receipt would not be totally adequate. A more effective control measure would be after the cold storage step in the process. XYZ Apple Juice Co. chose to control for patulin at the culling step.

Note: Published information relevant to control strategies for patulin is minimal at this time. The most common approaches are likely to involve establishing CCPs at:

- The receiving step (the control measure would be a supplier agreement specifying the use of tree-picked and undamaged apples), or
- A culling step after the cold storage and brush/wash/scrub steps (the control measure would be the culling of visually damaged apples), or
- Both of the above steps.

Which of these approaches will be successful in a given situation may depend upon factors such as the variety of apples used. For instance, some varieties may be susceptible to patulin level increases during cold storage, while others may not. In the former case, a culling step may be a necessary CCP, while in the later case, a CCP only at the receiving step may suffice. If the culling step is the only CCP, the processor should establish that culling will be effective even if dropped apples are received, because there is no CCP requiring that only tree-picked apples be accepted. In some cases, it may be necessary to employ both steps as CCPs.

Explanatory Note:  
Control measures for each significant hazard should be recorded in Column 5 of the hazard analysis worksheet. Further discussion is available in the Hazards and Controls Guide.

The XYZ Apple Juice Co. determined that metal fragments were reasonably likely to be introduced into the juice from the hammermill at the grinding step. This hazard could be controlled at the screening step following the pressing operation. The screen is sized to exclude metal fragments that may be injurious to health.

The XYZ Apple Juice Co. also noted a significant hazard, the presence of vegetative and protozoan pathogens, could be controlled at the pasteurizing step by heating the juice at an adequate pasteurization temperature and time to ensure the destruction of pathogenic microorganisms.

### ***Examples of Control Measures***

The following examples are control measures that could be used in the food industry to control the three types of hazards.

## **A. Biological Hazards**

### ***Bacteria***

1. Time/temperature control (e.g., proper control of refrigeration and storage time minimizes the growth of pathogens).
2. Thermal treatment (e.g., pasteurization).
3. Cooling and freezing (e.g., cooling and freezing retard the growth of pathogenic bacteria).
4. Fermentation and/or pH control (e.g., fermentation of apple cider by yeast produces ethanol which is inhibitory to pathogenic bacteria).
5. Addition of salt or other preservatives (e.g., salt and other preservatives inhibit growth of some pathogenic bacteria).
6. Drying or concentration (reduction of water activity,  $a_w$ ) may remove enough water from the food to prevent pathogens from growing.
7. Source control (e.g., the presence or amount of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources).

### ***Viruses***

1. Thermal process (e.g., adequate heating will destroy viruses).
2. Personal hygiene (especially handwashing) limits the spread of viruses. This is usually addressed in the SSOP program.

### ***Parasites***

1. Source control (e.g., preventing the parasite from having access to fruit by using GAPs).
2. Inactivation/removal (e.g., some parasites, such as *Cryptosporidium*, are resistant to chemical disinfection but can be inactivated by heating, drying or freezing).

**Notes :**

Notes :

### **B. Chemical Hazards**

1. Source control (e.g., vendor certification and raw material testing).
2. Production control (e.g., proper use and application of food additives).
3. Process control (e.g., proper application of the process such as washing, scrubbing and culling to control patulin).
4. Labeling control (e.g., finished product properly labeled with ingredients and known allergens).
5. Production scheduling (e.g. running products containing allergens last in the production run).

### **C. Physical Hazards**

1. Source control (e.g., vendor certification and raw material testing).
2. Production control (e.g., use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers and x-ray equipment).

The steps, potential hazards, significance justification and potential control measures should be recorded in columns 1, 2, 3, 4 and 5 respectively. The CCP determination will be addressed in the next chapter.

The XYZ Apple Juice Co. will serve as our model juice processing firm. Following the discussion of each HACCP principle, that principle will be applied to the XYZ Apple Juice Co. Please become familiar with the process flow diagram and process narrative associated with the model, found in Chapter 4.

## Hazard Analysis Worksheet - Hazard Identification and Evaluation

(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 measure(s) can be applied to control the significant hazards?
--	---	---	---	---

Add the steps, potential hazards and their significance, justification, and potential control measures in columns 1-5, respectively

**XYZ Apple Juice Co.  
Refrigerated Pasteurized Apple Juice**

<b>(1) Ingredient/ processing step</b>	<b>(2) Identify potential hazards introduced, controlled or en- hanced at this step</b>	<b>(3) Are any poten- tial food safety hazards signifi- cant? (Yes/No)</b>	<b>(4) Justify your decision for Column 3</b>	<b>(5) What measure(s) can be applied to control the significant hazards?</b>
<b>Receiving (raw apples)</b>	<p><b>Biological (B) -</b> 1. Vegetative pathogens  2. protozoan pathogens</p> <p><b>Chemical (C) -</b> 1. Pesticides  2. Patulin</p>	<p><b>B -</b> 1. Yes  2. Yes</p> <p><b>C -</b> 1. No  2. Yes</p>	<p><b>B -</b> History of outbreaks.</p> <p><b>C -</b> 1. In the U.S. unapproved pesticide residues occur infrequently and public health impact is typically not severe.  2. Causes illness or injury. Patulin is reasonably likely to exceed regulatory action levels if not controlled.</p>	<p><b>B -</b> Pasteurization step</p> <p><b>C -</b> 1. Not applicable  2. Culling</p>
<b>Receiving (packaging)</b>	<p><b>Physical (P) - None</b>  <b>B - None</b> <b>C - None</b> <b>P - None</b></p>			

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 5.1. Hazard Analysis Worksheet—Hazard Identification and Evaluation (cont'd)\*

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or en- hanced at this step	(3) Are any poten- tial food safety hazards signifi- cant? (Yes/No)	(4) Justify your decision for Column 3	(5) What measure(s) can be applied to control the significant hazards?
<b>Dry Storage (packaging)</b>	B - None C - None P - None			
<b>Cold Storage</b>	B - None C - Patulin P - None	C - Yes	C - Patulin levels may in- crease in storage due to mold growth	C - Culling
<b>Remove Debris (slotted hopper)</b>	B - None C - None P - None			
<b>Wash (flume tank)</b>	B - None C - None P - None			
<b>Culling</b>	B - None C - Patulin P - None	C - Yes	C - Patulin levels are re- duced by culling visually defective apples	C - Cull defective apples
<b>Brush/Wash</b>	B - None C - None P - None			

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 5.1. Hazard Analysis Worksheet—Hazard Identification and Evaluation (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?
<b>Partially Dried</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None			
<b>Grind</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - Metal pieces	<b>P</b> - Yes	<b>P</b> - Metal fatigue, worn and damaged blades can cause contamination of slurry	<b>P</b> - Controlled at screen step
<b>Press</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None			
<b>Screen</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - Metal pieces	<b>P</b> - Yes	<b>P</b> - Metal introduced from grinder blades	<b>P</b> - Intact screen filters out the metal pieces; visual examination of screen for integrity
<b>Holding Tank</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None			

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 5.1. Hazard Analysis Worksheet—Hazard Identification and Evaluation (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?
<b>Pasteurizer/ Cooler</b>	<b>B -</b> 1. Vegetative pathogens (E. coli O157:H7)  2. Protozoan pathogens (Cryptosporidium parvum) <b>C - None</b> <b>P - None</b>	<b>B - Yes</b>	<b>B -</b> Microbial contamination on incoming apples.	<b>B -</b> Pasteurization
<b>Holding Tank</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>			
<b>Fill</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>			
<b>Cap</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>			
<b>Case/Code/ Palletize</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>			

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 5.1. Hazard Analysis Worksheet—Hazard Identification and Evaluation (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?
<b>Cold Storage</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None			
<b>Ship</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None			

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

## **CHAPTER 6: PRINCIPLE 2. DETERMINE THE CRITICAL CONTROL POINTS**

Notes :

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### **Objectives**

In this module you will learn:

- The definition of a critical control point (CCP)
- The relationship between a hazard reasonably likely to cause illness or injury in absence of control and a CCP
- A CCP may change with product formulations and processing lines
- The use of a decision tree to determine a CCP
- Examples of CCPs

For every significant hazard identified during the hazard analysis (Principle 1), there must be one or more CCPs where the hazard is controlled. The CCPs are the points in the process where the HACCP control activities will occur.

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### **HACCP Principle #2**

Determine critical control points (CCPs)

Notes:

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## Definition

**Critical control point:** a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

A CCP should be a specific point in the process flow where application of a control measure effectively prevents, eliminates or reduces the hazard to an acceptable level.

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## Hazard Prevention

- Points may be identified as CCPs when hazards can be prevented:
  - For some products and processes the following may be true:
    - Introduction of hazard can be prevented by control at receiving step (e.g., supplier declaration)
    - A chemical hazard can be prevented by control at ingredient addition or blending step

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### Hazard Prevention (cont'd)

- Points may be identified as CCPs when hazards can be prevented:
  - Pathogen growth in the finished product can be prevented by control at formulation or ingredient addition step (e.g., pH adjustment or addition of preservatives)
  - Pathogen growth can be controlled by refrigerated storage or chilling

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### Hazard Elimination

- Points may be identified as CCPs when hazards can be eliminated:
  - For some products and processes the following may be true:
    - Pathogens and parasites can be killed during heat treatment or UV light treatment
    - Metal fragments can be detected by a metal detector and eliminated by removing the contaminated product

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### Hazard Reduction

- Points may be identified as CCPs when hazards are reduced to acceptable levels:
  - For some products and processes the following may be true:
    - Occurrence of foreign objects can be minimized by manual sorting and automatic collectors
    - Some chemical hazards such as patulin can be reduced by processes such as culling, brushing and washing

Notes :

**Notes:**

It may not be possible to fully eliminate or prevent a hazard. In some processes and with some hazards, minimization may be the only reasonable goal of the HACCP plan. For example, patulin in apple juice is not destroyed at pasteurization temperatures and other processing steps may not completely eliminate patulin from apple juice. Processing steps such as receiving only tree-picked apples, culling, brushing and washing can reduce patulin to acceptable levels that will not pose a hazard to consumers.

Although hazard minimization is acceptable in some instances, it is important that all food safety hazards be addressed and that any limitations of the HACCP plan to control those hazards be understood.

Many points in the flow diagram not identified as CCPs may address control of quality factors such as color or flavor or non-HACCP regulatory requirements such as standards of fill. A HACCP plan may lose focus if these points are unnecessarily identified as CCPs.

Only points at which food safety hazards can be controlled are considered to be CCPs. A tendency exists to control too much and to designate too many CCPs. A CCP should be limited to that point or those points at which control of the hazards can best be achieved. For example, a metal hazard can be controlled by ingredient sourcing, magnets, screens and a metal detector, all in one line. However, sourcing, magnets and screens would not be considered CCPs if the metal hazard is best controlled by use of metal detection and product rejection.

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## **Multiple CCPs and Hazards**

- Single hazard controlled by multiple CCPs
- Multiple hazards controlled by single CCP

### ***Multiple CCPs and Hazards***

A CCP can be used to control multiple hazards. For example, thermal processing might be a CCP to control vegetative pathogens and parasites in juice. Likewise, more than one CCP may be needed to control a single hazard such as both brush washing and sanitization steps for treating the surface of citrus fruit to reduce pathogen levels in fresh juice.

## CCPs are Product- and Process-Specific

- CCPs may change with differences in:
  - Plant layout
  - Formulation
  - Process flow
  - Equipment
  - Ingredient selection
  - Sanitation and support programs

### *CCPs are Product- and Process-Specific*

CCPs identified for a product on one processing line may be different for the same product on another line. This is because the hazards and the best points for controlling them may change with differences in:

- Plant layout,
- Formulation,
- Process flow,
- Equipment,
- Ingredient selection, and
- Sanitation and support programs.

In some cases, products can be grouped into a single HACCP plan as long as the products have similar hazards and CCPs (critical limits can differ). An example of this is a facility that produces pasteurized orange juice and grape juice from concentrate. Processors can have one plan to cover these different juices even though the process time/temperature parameters (critical limits) may differ for these juices.

Although HACCP models and generic HACCP plans can be useful in considering CCPs, the HACCP requirements of each formulation and processing line must be considered separately.

### *CCP Decision Tree*

Principle 1 addresses where hazards enter a process, may be enhanced during the processor both. Often the best place to control a hazard is at the point of entry. But this is not always the case. The CCP can be several process steps away from the point where the significant hazard is introduced. A series of questions can help to identify CCPs for a process (Figure 6.1). The questions are referred to as a “CCP Decision Tree” and are asked at each process step identified in Principle 1 with a significant hazard. Properly used, a CCP decision tree can be a helpful tool in identifying CCPs, but it is not a perfect tool. Although application of a CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. The CCP decision tree is not a substitute for expert knowledge, since complete reliance on the decision tree can lead to false conclusions.

**Notes:**

## Explanatory Note:

In the XYZ Apple Juice Co. hazard analysis, it was previously noted that microbial hazards can be controlled at a step subsequent to receiving even though the hazard was identified at the receiving step. Thus the answer to Question 1 on the decision tree is yes.

## Explanatory Note:

In the XYZ Apple Juice Co. refrigerated pasteurized apple juice example, vegetative and protozoan pathogens were identified as a significant hazard at the receiving-fresh apples step. In some instances, supplier guarantees or raw material handling can minimize pathogen levels at a receiving step. However, such measures are not likely to reduce the hazard of pathogens, such as *E. coli* O157:H7, to acceptable levels in the finished product. Therefore, the receiving step should not be used in this plant to prevent, eliminate or reduce the hazard to an acceptable level. The answer to Question 2 is no.

## Explanatory Note:

In the refrigerated pasteurized apple juice example, vegetative and protozoan pathogens can be introduced at the receiving-fresh apples step in excess of acceptable levels. The answer to Question 3 is yes.

## Explanatory Note:

In the refrigerated pasteurized apple juice example, the pasteurization step will reduce pathogens to an acceptable level and will be the best point to control the hazard. At the receiving step, the answer to Question 4 is yes, meaning that there is a subsequent step that will eliminate the hazard or reduce its likely occurrence to an acceptable level. Hence, this step is not considered a CCP for vegetative and protozoan pathogens.

The CCP decision tree in figure 6.1 is but one example of numerous other decision trees that have been developed to assist in the appropriate determination of CCPs.

**Question 1.** Does a control measure(s) exist at this step or subsequent steps in the process flow for the identified hazard?

If the answer is **yes**, ask Question 2.

If you cannot identify a control measure in the process for the hazard, answer no. If the answer is **no**, then ask: Is control at this step necessary for safety? If the answer is again no, the step is not a CCP for that hazard. Move to the next hazard at that step or to the next step with a food safety hazard. If the answer is **yes**, then a significant hazard is not being controlled. In this case, the step, process or product must be redesigned to include a control measure.

**Question 2.** Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?

To answer this question, consider if this is the **best** step at which to control the hazard. If the answer is **yes**, then the step is a CCP; move to the next food safety hazard.

If the answer is **no**, ask Question 3.

**Question 3.** Could contamination with identified hazards occur in excess of acceptable levels or could these increase to unacceptable levels?

The question refers to contamination that exists, occurs or increases at this step. If the answer is **no**, then the step is not a CCP for that hazard. Move to the next hazard at that step or the next step with a food safety hazard.

If the answer is **yes**, then ask question 4.

**Question 4.** Will a subsequent step eliminate identified hazards or reduce the likely occurrence to an acceptable level?

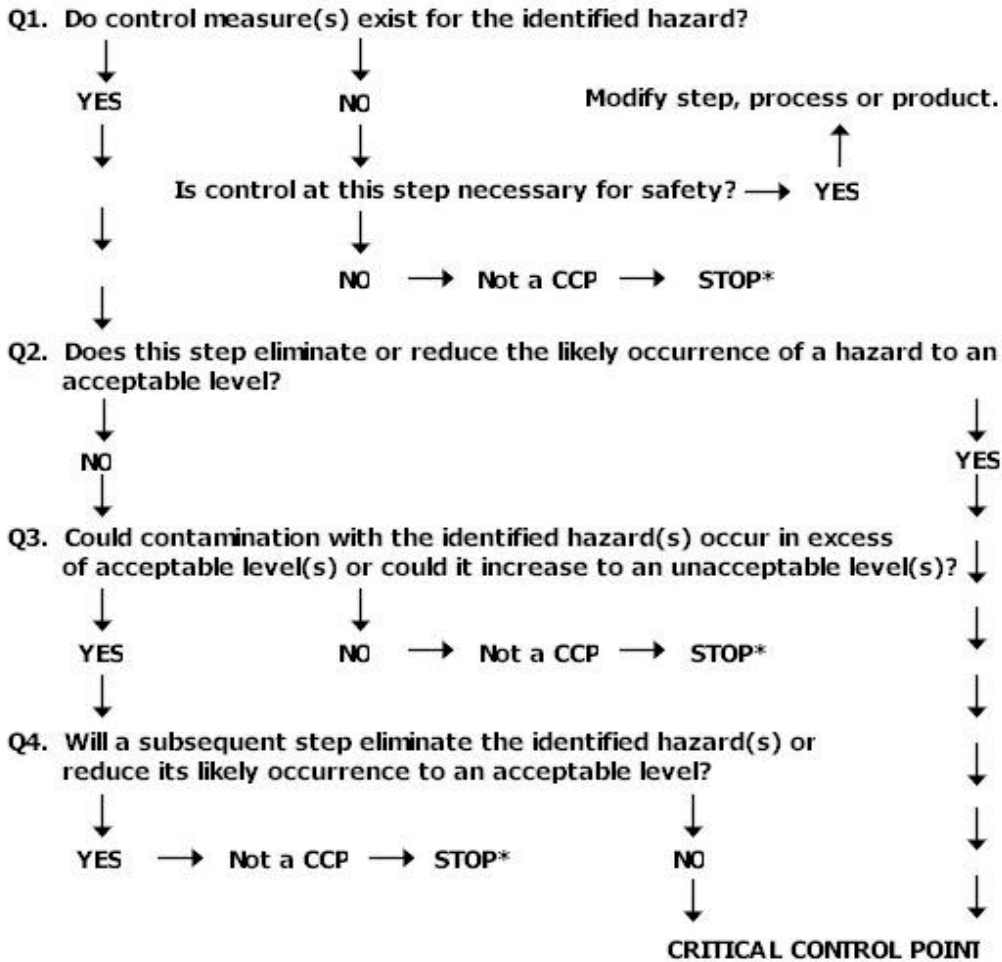
If the answer is **no**, then this step is a CCP. If the answer is **yes**, then this step is not a CCP for this hazard. In this case, be sure the hazard is controlled by a subsequent processing step.

In Chapter 5, three significant hazards were identified for the refrigerated pasteurized apple juice namely, vegetative and protozoan pathogens, specifically *E. coli* O157:H7 and *Cryptosporidium parvum*, patulin, and metal pieces. Table 6.1 is an illustration of how the CCP decision tree is applied to consider these hazards.

Figure 6.1. NACMCF CCP Decision Tree

Important considerations when using the decision tree:

- The decision tree is used after the hazard analysis.
- The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.
- A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.
- More than one step in a process may be involved in controlling a hazard.
- More than one hazard may be controlled by a specific control measure.



\*Proceed to next step in the described process

Notes:

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### Decision Tree Summary for XYZ Apple Juice Co.

Step	Hazard	Q1	Q2	Q3	Q4	CCP?
Receiving	B. Vegetative and protozoan pathogens	Y	N	Y	Y	N
	C. Patulin presence	Y	N	Y	Y	N
Cold storage	C. Increase in patulin	Y	N	Y	Y	N
Cull	C. Patulin reduction	Y	Y	-	-	<b>CCP#1</b>
Grind	P. Metal contamination	Y	N	Y	Y	N
Screen	P. Metal removal	Y	Y	-	-	<b>CCP#2</b>
Pasteurizer	B. Pathogen destruction	Y	Y	-	-	<b>CCP#3</b>

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### Hazard Analysis Worksheet – CCP Determination

(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 measure(s) can be applied to control the significant hazards?	(6) Is this step a Critical Control Point? (Yes/No)
Add CCPs in column 6					

Table 6.1. Hazard Analysis Worksheet—CCP Determination\*

**XYZ Apple Juice Co.  
Refrigerated Pasteurized Apple Juice**

<b>(1) Ingredient/ processing step</b>	<b>(2) Identify potential hazards intro- duced, controlled or enhanced at this/ards signifi- cant?</b>	<b>(3) Are any po- tential food safety haz- ards signifi- cant? (Yes/No)</b>	<b>(4) Justify your decision for Column 3</b>	<b>(5) What measure(s) can be applied to control the sig- nificant hazards?</b>	<b>(6) Is this step a Critical Con- trol Point? (Yes/No)</b>
<b>Receiving (raw apples)</b>	<p><b>Biological (B) -</b> 1. Vegetative pathogens 2. protozoan pathogens</p> <p><b>Chemical (C) -</b> 1. Pesticides</p> <p>2. Patulin</p>	<p><b>B -</b> 1. Yes 2. Yes</p> <p><b>C -</b> 1. No 2. Yes</p>	<p><b>B -</b> History of out-breaks.</p> <p><b>C -</b> 1. In the U.S. unap- proved pesticide resi- dues occur infre- quently and public health impact is typi- cally not severe.</p> <p>2. Causes illness or injury. Patulin is reasonably likely to exceed regulatory action levels if not controlled.</p>	<p><b>B -</b> Pasteurization step.</p> <p><b>C -</b> 1. Not applicable 2. Culling</p>	<p><b>B -</b> No</p> <p><b>C -</b> 1. No 2. No</p>
<b>Receiving (packaging)</b>	<p><b>Physical (P) -</b> None</p> <p><b>B -</b> None <b>C -</b> None <b>P -</b> None</p>				

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 6.1. Hazard Analysis Worksheet—CCP Determination (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?	(6) Is this step a Critical Control Point? (Yes/No)
Dry Storage (packaging)	B - None C - None P - None				
Cold Storage	B - None C - Patulin P - None	C - Yes	C - Patulin levels may increase in storage due to mold growth.	C - Culling	C - No
Remove Debris (slotted hopper)	B - None C - None P - None				
Wash (flume tank)	B - None C - None P - None				
Culling	B - None C - Patulin P - None	C - Yes	C - Patulin levels are reduced by culling visually defective apples.	C - Cull defective apples.	C - Yes
Brush/Wash	B - None C - None P - None				

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Chapter 6. Principle 2. Determine the Critical Control Points

Table 6.1. Hazard Analysis Worksheet—CCP Determination (cont'd)\*

(1) Ingredient/ processing step	(2) Identify potential hazards intro- duced, controlled or enhanced at this step	(3) Are any poten- tial food safety hazards significant? (Yes/No)	(4) Justify your decision for Column 3	(5) What measure(s) can be ap- plied to control the signifi- cant hazards?	(6) Is this step a Critical Con- trol Point? (Yes/No)
<b>Partially Dried</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None				
<b>Grind</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - Metal pieces	<b>P</b> - Yes	<b>P</b> - Metal fatigue, worn and damaged blades can cause contamina- tion of slurry.	<b>P</b> - Controlled at screen step.	<b>P</b> - No
<b>Press</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None				
<b>Screen</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - Metal pieces	<b>P</b> - Yes	<b>P</b> - Metal introduced from grinder blades.	<b>P</b> - Intact screen filters out the metal pieces; visual examination of screen for integrity.	<b>P</b> - Yes
<b>Holding Tank</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None				

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 6.1. Hazard Analysis Worksheet—CCP Determination (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?	(6) Is this step a Critical Control Point? (Yes/No)
<b>Pasteurizer/ Cooler</b>	<b>B –</b> 1. Vegetative E. coli O157:H7  2. Protozoan pathogens Cryptosporidium parvum  <b>C - None</b> <b>P - None</b>	<b>B - Yes</b>	<b>B -</b> Microbial contamination on incoming apples.	<b>B -</b> Pasteurization	<b>B -</b> Yes
<b>Holding Tank</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>				
<b>Fill</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>				
<b>Cap</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>				
<b>Case/Code/ Palletize</b>	<b>B - None</b> <b>C - None</b> <b>P - None</b>				

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

Table 6.1. Hazard Analysis Worksheet—CCP Determination (cont'd)\*

(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 measure(s) can be applied to control the significant hazards?	(6) Is this step a Critical Control Point? (Yes/No)
<b>Cold Storage</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None				
<b>Ship</b>	<b>B</b> - None <b>C</b> - None <b>P</b> - None				

\* For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide

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## **CHAPTER 7: PRINCIPLE 3. ESTABLISH CRITICAL LIMITS**

Notes:

Overhead 65

### **Objectives**

In this module you will learn:

- How to identify critical limits
- How to set critical limits for the CCP
- How to find sources of critical limit information
- How to determine the relationship between critical limits and operating limits

Critical limits must be established for each CCP identified in the hazard analysis.

Overhead 66

## **HACCP Principle #3**

Establish critical limits

## Notes:

## Overhead 67

## Definition

**Critical limit:** a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each identified hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety. Examples of critical limits are listed in Table 7.1.

Table 7.1. Examples of Critical Limits

Hazard	CCP	Critical Limit
Bacterial pathogens (biological)	HTST pasteurization	Time/temperature $\geq 161^{\circ}\text{F}$ for $\geq 15$ seconds for elimination of pathogens from milk
Bacterial pathogens (biological)	oven drying	Drying schedule - oven temperature: $\geq 200^{\circ}\text{F}$ , drying time: $> 120$ min, air flow rate: $\geq 2$ cu ft/min, product thickness: $< 0.5$ in (to achieve $a_w \leq 0.85$ to control pathogens in dried foods)
Bacterial pathogens (biological)	acidification	Batch schedule - product weight: $< 100$ lb, soak time: $\geq 8$ h, acetic acid concentration: $\geq 3.5$ percent, volume $\leq 50$ gal (to lower the pH to 4.6 or below to control <i>Clostridium botulinum</i> spores in pickled foods)

**Explanatory Note:**

These critical limits are for illustrative purposes only. They do not relate to any specific product but demonstrate how critical limits could apply at CCPs utilizing different control parameters for bacterial pathogens. In actual practice, critical limits must be scientifically based.

## Chapter 7: Principle 3. Establish Critical Limits

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from sources such as scientific publications, regulatory guidelines, experts or experimental studies (Table 7.2).

**Notes:**

Table 7.2. Sources of Information on Critical Limits

General Source	Examples
Scientific publications	Journal articles, food science texts, microbiology texts
Regulatory guidelines	State and local guidelines, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances, and action levels
Experts	NACMCF; thermal process authorities; consultants, food scientists/microbiologists; equipment manufacturers; sanitarians; university extension; trade associations
Experimental studies	In-house experiments; contract labs

If the information needed to define the critical limit is limited, a conservative value should be selected. The rationale and reference material used to establish a critical limit should become part of the support documentation for the HACCP plan.

Often a variety of options exist for controlling a particular hazard. The selection of the best control option and the best critical limit is often driven by practicality and experience. The following examples (overheads 68 and 69) suggest control options and critical limits that could be applied at the pasteurization step to control vegetative and protozoan pathogens in pasteurized apple juice.

Overhead 68

### Poor Choice of Critical Limit

Monitoring for presence of pathogens in finished product:

- Hazard - presence of pathogens (biological)
- CCP - storage
- Critical limit - no pathogens detected

**Notes:**

Setting a microbial limit as a critical limit for an in-process CCP is rarely practical. Microbiological limits are difficult to monitor, and testing to determine critical limit deviations may require several days. Therefore, microbial limits cannot be monitored on a timely basis. Microbial contamination is often sporadic, and samples may need to be large to be meaningful. In this example, sampling and microbiological tests of the pasteurized juice are unlikely to be sensitive enough or practical.

Overhead 69

## Good Choice of Critical Limit

Processing at a certain temperature for a specific time (flow rate):

- Hazard - presence of pathogens (biological)
- CCP - pasteurization
- Critical limit - minimum process temperature of 160°F for at least six seconds

Setting a microbial limit is not necessary in this example as long as an appropriate critical limit can be set that is based on the conditions needed to inactivate the microorganisms of concern. Pathogens of concern in this juice are destroyed by heating the juice to a minimum temperature of 160°F for at least six seconds. In this option, the product temperature at the end of the holding tube and the flow rate of the product are used as critical limits. This option is typically more practical and sensitive than finished-product pathogen testing.

The process should be capable of operating within the bounds set by the critical limit. The critical limits should not be confused with the operating parameters of the equipment.

## Definition

**Operating limit:** a criterion that is more stringent than a critical limit and that is used by an operator to reduce the risk of deviation

### *Establishing Operating Limits*

Operators should take action to bring the CCP under control before the critical limit is exceeded. The point where operators take such an action is called the operating limit. Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated.

## Definition

**Process adjustment:** an action taken by an operator to bring the process back within operating limits

**Notes:**

The process should be adjusted when the operating limit is reached to avoid violating critical limits. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product rework, or worse yet, product destruction. Corrective action is only required when the critical limit is not met.

Operating limits may be selected for various reasons:

- For quality (e.g., higher processing temperatures for flavor development or to control organisms that can cause spoilage).
- To avoid exceeding a critical limit (e.g., a processing temperature higher than the critical limit could be used as an alarm point to warn the operator that the temperature is approaching the critical limit and needs adjusting).
- To account for normal variability (e.g., a pasteurizer with a 5°F variability should be set at least 5°F above the critical limit to avoid violating it).

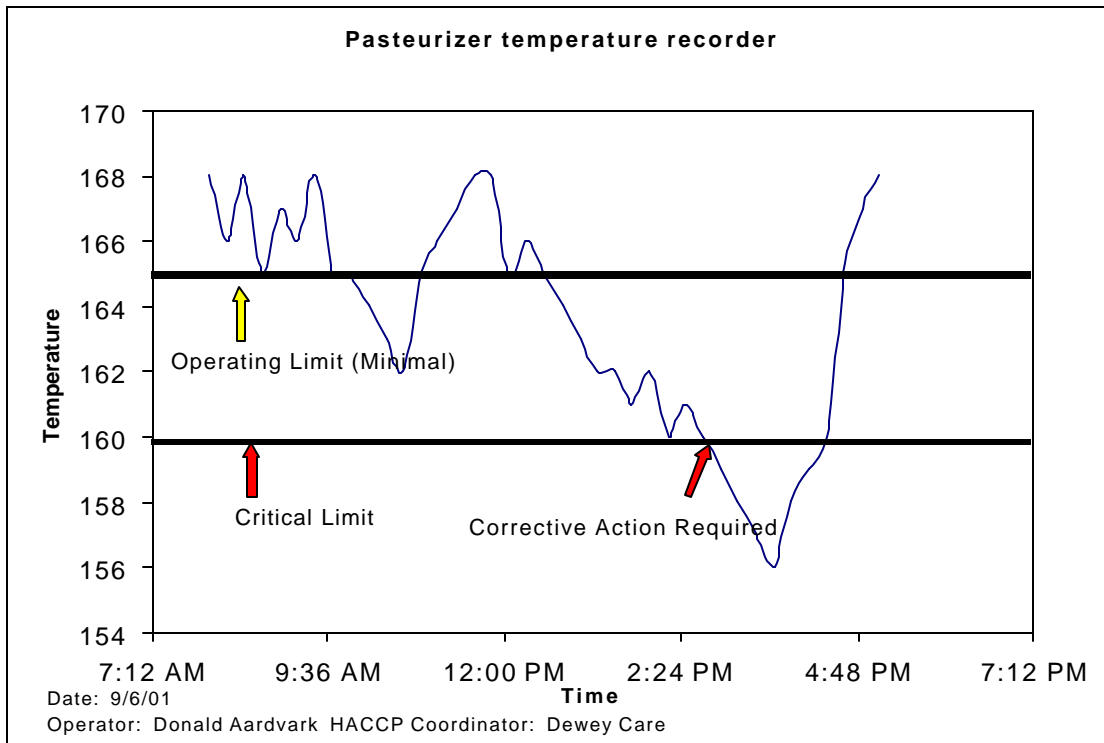
Figure 7.1 illustrates several important points:

1) operating limits and process adjustments, 2) critical limits and corrective actions, and 3) implications of lot size. In this example of a generalized juice pasteurization process, an operating limit is established at 165°F and a critical limit at 160°F. Somewhere in the 5°F range between these two points, prudent processors will make a process adjustment to bring the pasteurization temperature back above 165°F. Because an adjustment is made before the temperature drops below the critical limit of 160°F, no corrective action record is required. However, if an adjustment is not taken until after the temperature drops below the critical limit, as shown in Figure 7.1, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file (corrective actions and records will be discussed in chapters 9 and 11, respectively).

When a corrective action is necessary, processors must be able to identify and segregate the affected lots. If lot sizes are big, large quantities of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Coding production into smaller lots means far less product may be involved when violation of a critical limit occurs. Therefore, prudent processors should change codes often during the production day and match monitoring frequency with code changes.

Chapter 7: Principle 3. Establish Critical Limits

Figure 7.1. Example of Operating and Critical Limits



Notes:

Overhead 72

# HACCP Plan Form

1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions	9. Verification	10. Record- keeping
			4. What	5. How	6. Frequency	7. Who			

### *Critical Limits for XYZ Juice Co.*

The CCP, hazards and critical limits should be recorded in columns 1, 2 and 3 on the HACCP plan form. The hazard analysis worksheet for refrigerated pasteurized apple juice identifies three CCPs: culling, screen and pasteurizer. In Table 7.2 there are examples of critical limits for these CCPs.

Table 7.2. Establishment of Critical Limits

Critical Control Point (CCP)	Hazard(s)	Critical Limits
CCP 1 Culling	Patulin	No more than 1% by weight visually damaged fruit after culling
CCP 2 Screen	Metal inclusion	Screen is intact
CCP 3 Pasteurizer	<i>E. coli</i> O157:H7 and <i>Cryptosporidium parvum</i>	$\geq 160^{\circ}\text{F}$ and $\geq 6\text{ s}$

## HACCP Plan Form – Critical Limits

1. CCP	2. Hazards	3. Critical limits

The CCP, hazards and critical limits should be recorded in columns 1,2 and 3 on the HACCP plan form

Table 7.3. HACCP Plan – Critical Limits\*

**XYZ Apple Juice Co.  
Refrigerated Pasteurized Apple Juice**

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring			Corrective Action	Verification	Record keeping
			What	How	Frequency			
CCP 1 Culling	Patulin	No more than 1% by weight rot after culling						
CCP 2 Screen	Metal inclusion	Screen is intact						
CCP 3 Pasteurizer	E. coli O157:H7 and <i>Cryptosporidium parvum</i>	≥ 160°F and ≥ 6 s						

\*For illustrative purposes only. Models may not be fully consistent with FDA’s Juice HACCP Hazards and Controls Guide.

## **CHAPTER 8: PRINCIPLE 4. CRITICAL CONTROL POINT MONITORING**

Notes:

Overhead 74

### **Objectives**

In this module you will learn:

- How monitoring is defined
- Why monitoring is needed
- How to design a monitoring system
- What methods and equipment are used for monitoring critical limits
- How often monitoring should be performed
- Who should monitor

Monitoring is important to ensure that the critical limits are consistently met.

Overhead 75

### **HACCP Principle #4**

Monitor each CCP

Notes:

Overhead 76

## Definition

**Monitor:** 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

Overhead 77

## Monitoring

The purpose of monitoring is to:

- Track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments
- Identify when there is a loss of control (a deviation at a CCP)
- Provide written documentation of the process control system

### *Purpose of Monitoring*

Monitoring is the process that the operator relies upon to maintain control at a CCP. Accurate monitoring indicates when there is a loss of control at a CCP and a deviation from a critical limit. When a critical limit is compromised, a corrective action is required. The extent of the problem needing correction can be determined by reviewing the monitoring records and finding the last recorded value that meets the critical limit.

Monitoring also provides a record that products were produced in compliance with the HACCP plan. This information is useful in the verification of the HACCP plan as discussed in Principle 6.

**Design of a Monitoring System**

The control measures discussed in Principle 1 and the critical limits discussed in Principle 3 are intended to control the hazards at each CCP. Monitoring procedures are used to determine if the control measures are being taken and the critical limits are being met. Monitoring procedures must identify:

- What will be monitored (Column 4).
- How the critical limits and control measures will be monitored (Column 5).
- How frequently monitoring will be performed (Column 6).
- Who will perform the monitoring (Column 7).

Overhead 78

HACCP Plan Form - Monitoring						
1. CCP	2. Hazards	3. Critical limits	Monitoring			
			4. What	5. How	6. Frequency	7. Who
Specify the monitoring procedures for each CCP						

Overhead 79

## Monitoring

- What: usually a measurement or observation to assess if the CCP is operating within the critical limit
- How: usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits)
  - Needs to be real-time and accurate

**Notes:**

Notes:

Overhead 80

## Monitoring (cont'd)

- Frequency: continuous or periodic (non-continuous)
- Who: responsible individual trained to perform the specific monitoring activity or evaluate monitoring records

Overhead 81

## What Will Be Monitored?

- Time
- Temperature
- pH
- Flow rate
- Screen

### *What Will Be Monitored*

- Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit. [Monitoring may also involve observing if a control measure at a CCP is being performed.]

Examples include:

- Measurement of cold-storage compartment temperature when critical for temperature-sensitive ingredients,
- Measurement of the pH of an acidifying ingredient when critical for the production of an acidified food, and
- Measurement of pasteurization temperature.

What will be monitored is listed in Column 4 of the HACCP plan form (overhead 78).

## How Critical Limits and Control Measures Will Be Monitored:

- Timer
- Thermometer
- pH meter
- Scales
- Water activity meter
- Chemical analytical equipment

### *How Critical Limits and Control Measures Will Be Monitored*

Monitoring must be designed to provide rapid (real-time) results. There is no time for lengthy analytical testing because critical limit deviations must be detected quickly and an appropriate corrective action instituted before distribution.

Microbiological testing is seldom effective for monitoring CCPs. Very often the analytical methods are lengthy. Additionally, to do a statistically adequate job of finding pathogenic organisms at levels that may cause illness, large sample sizes are usually needed.

Physical and chemical measurements are preferred monitoring methods because testing can be done rapidly. Physical and chemical measurements (e.g., pH, time, temperature) can often be related to the microbiological control as illustrated by the apple juice example in Principle 3. Examples of physical- and chemical-measurement monitoring at a CCP follow:

- Time and temperature. This combination of measurements is often used to monitor the effectiveness for destroying or controlling the growth of pathogenic bacteria. By processing a food at a set temperature for a set time, pathogenic bacteria can be destroyed. For example, pasteurized apple juice should be heated to  $\geq 160^{\circ}\text{F}$  for  $\geq 6$  s. This can be monitored at the end of the pasteurization process depending upon the type of pasteurizer used. In addition, pathogens can be controlled by minimizing exposure of a food to the critical pathogen growth temperatures between  $40^{\circ}\text{F}$  and  $140^{\circ}\text{F}$ . This can be achieved through rapid heating and/or cooling of the product through these critical temperatures and maintaining temperatures below  $40^{\circ}\text{F}$  (or above  $140^{\circ}\text{F}$ ) during storage.
- Water activity ( $a_w$ ). Pathogen growth can be controlled by limiting water activity — the amount of water available for microbial growth. For example, drying products to a  $a_w$  below 0.85 stops pathogen growth. In this case, samples may be collected during the drying process and tested for water activity. The process is completed when  $a_w$  falls below 0.85. Processors may monitor temperature, time and flow if the rate of drying under these conditions is known to achieve an  $a_w$  of 0.85 at the end of the process. Another way to lower  $a_w$  is by adjustment of concentration of solutes, such as by the addition of sugars or salts.

**Notes:**

- Acidity (pH). Pathogen growth can be controlled by limiting the pH of the product to a level that does not allow growth. For instance, the growth of *Clostridium botulinum*, which leads to botulism, is controlled in acidified products by adding acid to lower the pH to 4.6 or below. In this case, the pH of an acidifying agent may be monitored before it is added to a batch.

The selection of the monitoring equipment is a major consideration during development of a HACCP plan. Equipment used for monitoring CCPs varies with the attribute being monitored. Examples of monitoring equipment include:

- Timers,
- Thermometers,
- pH meters,
- Scales,
- Water activity meters and
- Chemical analytical equipment.

The equipment chosen for monitoring at the CCP must be accurate to ensure control of the hazard. The variability of the monitoring equipment should be considered when setting the operating limit. For example, if a minimum internal temperature of 145°F is necessary to kill pathogens in a product and the thermometer has an accuracy of  $\pm 2^\circ\text{F}$ , then the operating limit should be set no lower than 147°F. Periodic calibration or standardization is necessary to ensure accuracy. This is further discussed in Chapter 11.

How monitoring will be performed is recorded in column 5 of the HACCP plan form.

Overhead 83

## Monitoring Frequency

- Continuous
- Periodic (non-continuous)

Note: The length of the period will affect the amount of product affected by a critical limit deviation

### ***Monitoring Frequency***

Monitoring can be continuous or periodic. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters. Examples of continuous monitoring include:

- The pasteurizing temperature, and
- Meter-based timing system (flow rate).

Explanatory Note:  
The length of time between monitoring checks will directly affect the amount of rework or product loss when a critical limit deviation is found.

## Chapter 8: Principle 4. Critical Control Point Monitoring

A monitoring instrument that produces a continuous record of the measured value will not control the hazard on its own. The continuous record needs to be observed periodically and action taken when needed. This too is a component of monitoring. The length of time between checks will directly affect the amount of rework or product loss when a critical-limit deviation is found. In all cases, the checks must be performed in time to ensure that irregular product is isolated before shipment.

When it is not possible to monitor a CCP on a continuous basis, it is necessary for the monitoring interval to be short enough to detect possible deviations from critical limits or operating limits.

The frequency of non-continuous monitoring should be partially determined from historical knowledge of the product and process. Questions that will help determine the correct frequency include:

- How much does the process normally vary (i.e., how consistent are the data)? If the data vary considerably, the time between monitoring checks should be short.
- How close are the normal values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much product is the processor prepared to risk if the critical limit is exceeded?

Examples of potential non-continuous monitoring include:

- Examination of the screen at specified time intervals for integrity,
- Temperature checks of the core temperature of a hot filled product at specified time intervals,
- Periodic checks on the amount of decay in apples to ensure the efficacy of culling, and
- Periodic monitoring of metal detector operation using standards.

Overhead 84

### **Who Will Monitor?**

A person who:

- Has clearly defined responsibilities
- Has been trained
- Follows clearly delineated procedures
- Has initial responsibility for corrective actions
- Is responsible for documentation

**Notes:**

**Notes:**

***Who will Monitor?***

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan.

Individuals assigned to CCP monitoring can be:

- Line personnel,
- Equipment operators,
- Supervisors,
- Maintenance personnel, or
- Quality assurance personnel.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously viewing the product and/or equipment and can readily observe changes from the norm. Also, including line personnel in HACCP activities has the advantage of building a broad base of understanding and commitment to the HACCP program.

Those responsible for monitoring a CCP should:

- Be trained in the CCP monitoring techniques,
- Fully understand the importance of CCP monitoring,
- Have ready access to the monitoring activity,
- Accurately report each monitoring activity,
- Immediately report critical-limit deviations so that immediate corrective actions (Principle 5) can be taken.

The monitor's duties should require that all unusual occurrences and deviations from critical limits be reported immediately to ensure adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

The monitoring procedures for each of the critical limits identified in Principle 3 for the refrigerated pasteurized juice are contained in the attached HACCP plan. The individual who performs the monitoring will be recorded in column 7 of the HACCP plan form.

Overhead 85

## **Definition**

**Deviation:** Failure to meet a critical limit

XYZ Apple Juice Co.  
Refrigerated Pasteurized Apple  
Juice

Table 8.1. HACCP Plan—Monitoring\*

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			
CCP 1 Culling	Patulin	No more than 1% by weight by rot after culling	Rot in 5000 g sample	Cut rot and weigh rot	Twice per production run	QC staff			
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Visual	Daily Pre-op and post-op	Production employee			
CCP 3 Pasteurizer	E. coli O157:H7 and Cryptosporidium parvum	≥160°F for ≥ 6 s	1. Temp. of juice  2. Set pump speed to 5 to deliver ≥ 6 s	Temp. recorder  Visual check of positive displacement pump at set speed	Continuous recording with hourly visual check of record.  Visual daily check of MIG thermometer  Daily at beginning of production	Pasteurizer operator  Pasteurizer operator			

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Control Guide.

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## **CHAPTER 9: PRINCIPLE 5. CORRECTIVE ACTIONS**

Overhead 86

### **Objectives**

In this module you will learn:

- The definition of corrective actions
- Procedures for corrective actions
- Record-keeping requirements for corrective actions

**Notes:**

Explanatory Note:  
Corrective actions are implemented when monitoring results indicate a deviation from critical limits. Effective corrective actions depend heavily on an adequate monitoring program.

Overhead 87

### **HACCP Principle #5**

Establish corrective actions

Corrective actions must be taken when critical limits at a CCP have been violated. Although not an absolute requirement, corrective actions should be predetermined as the HACCP plan is developed.

## Notes:

Overhead 88

## Definition

**Corrective action:** procedures to be followed when a deviation occurs

When critical limits are violated at a CCP, the predetermined, documented corrective actions should be instituted. These corrective actions should state procedures to restore process control and determine the safe disposition of the affected product. It may be possible, and is always desirable, to correct the problem on the spot.

Corrective action options include:

- Isolating and holding product for safety evaluation,
- Diverting the affected product or ingredients to another line where deviation would not be considered critical,
- Reprocessing, or
- Destroying product.

The primary objective is to establish a HACCP program that permits rapid identification of deviations from a critical limit. The sooner the deviation is identified, the more rapidly corrective actions can be taken and the greater the potential for minimizing the amount of noncompliant product. An individual who has a thorough understanding of the process, product and HACCP plan and who has the authority to make decisions needs to be assigned the responsibility of making corrective actions.

Effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control,
- Segregate, assess and determine the disposition of the noncompliant product, and
- Prevent deviated product that is injurious to health from entering commerce.

All corrective actions taken must be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

### ***Components of Corrective Actions***

There are two components of corrective actions: 1) to correct and eliminate the cause of the deviation and restore process control and 2) to identify the product that was produced during the process deviation and determine its disposition.

Overhead 89

## **Corrective Action Components**

- To correct and eliminate the cause of the deviation and restore process control
- To identify the product that was produced during the process deviation and determine its disposition

### **Correct and Eliminate the Cause of the Deviation and Restore Process Control**

Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to re-establish control so that the process can be restarted as soon as possible without further process deviation.

It may be necessary to determine the root cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or one that reoccurs should result in an adjustment to the product or process or a re-evaluation of the HACCP plan.

One outcome of the re-evaluation may be a decision to modify the HACCP plan. A permanent solution to eliminating or minimizing the initial cause or causes for the process deviation should be implemented if necessary. Specific instructions for corrective actions must be available to plant workers and should be part of the documented HACCP plan.

### **Identify the Product that was Produced During the Process Deviation and Determine the Disposition**

When a deviation occurs, identify nonconforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan as follows:

### **Notes:**

#### **Explanatory Note:**

If a product is to be tested and released, the sampling method is highly important. The use of a faulty sampling protocol can result in accepting, rather than rejecting, an undesirable product. The limits of sampling plans must be understood. It may be prudent to consult an expert.

#### **Explanatory Note:**

It is important to ensure that any reworking does not result in the creation of a new hazard. Of primary concern are toxic materials, including heat-stable biological toxins. It must be realized that reworked product is still subject to regulatory scrutiny and that reworking must result in a safe product.

**Notes:**

1. Determine if the product presents a safety hazard, based on:
  - a. Expert evaluation
  - b. Biological, chemical, or physical testing
2. If no hazard exists, the product may be released
3. If a potential hazard exists, determine if the product can be:
  - a. Reworked/reprocessed
  - b. Diverted for an alternate use
4. If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed

Overhead 90

**In Summary:**

1. Determine if the product presents a safety hazard, based on:
  - a. Expert evaluation
  - b. Biological, chemical, or physical testing
2. If no hazard exists, the product may be released
3. If a potential hazard exists, determine if the product can be:
  - a. Reworked/reprocessed
  - b. Diverted for an alternate use
4. If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed

***Corrective Action Format Examples***

Corrective actions are usually written in an "if/then" format. The "if" part of the corrective action describes the condition and the "then" part describes the action taken. For example:

IF deviation:	Temperature of juice at the end of the holding period drops below the critical limit and the divert valve does not function correctly.
THEN corrective action:	The untreated juice will be segregated and held for further disposition, diverted to non-food use, or destroyed. Check the operation of the heating/cooling units and flow diversion valve to determine the reason for the temperature deviation and improper operation of the flow diversion valve. Repair if necessary, re-establish control and resume production.

Chapter 9: Principle 5. Corrective Actions

It is tempting to classify automatic flow diversion in a properly operating continuous flow pasteurization system as a critical limit deviation. However, the critical limit should be the application of the process. If flow diversion is a deviation, a deviation would occur every time the system was started before the system went into forward overflow.

IF deviation:	Product (e.g., hot-filled juice) does not reach required internal temperature for the required time.
THEN corrective action:	Isolate affected product AND Reprocess or destroy product AND Determine the reason for the deviation and make necessary adjustment(s)

**Corrective Action Records**

In the following example, predetermined corrective actions are written into the HACCP plan. When critical limits are exceeded and a corrective action occurs, it is recorded. The corrective action can be recorded directly on the monitoring record but a separate corrective action report form should also be completed.

Any corrective action report should contain the following:

- a. Product identification (e.g., product description, amount of product on hold),
- b. Description of the deviation,
- c. Corrective action taken including final disposition of the affected product,
- d. Name of the individual responsible for taking the corrective action, and
- e. Results of the evaluation when necessary.

IF deviation:	There is no supplier agreement that apples were tree picked
THEN corrective action:	Reject apples AND Discontinue use of supplier until agreement is in place and fulfilled.

HACCP plan records should contain a separate file in which all deviations and corresponding corrective actions are maintained in an organized fashion. Corrective actions are recorded in column 8 of the HACCP plan form. The following are the corrective actions for the XYZ Apple Juice Co.

**Notes:**

Explanatory Note:  
During the process, it is possible to extend the cook time until the desired internal temperature is reached for the required time. However, this would be a "process adjustment" rather than a corrective action.

Notes:

Overhead 91

## HACCP Plan Form – Corrective Actions

1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions
			4. What	5. How	6. Frequency	7. Who	

Specify the corrective action procedures for each CCP

Table 9.1. HACCP Plan—Corrective Action\*

**XYZ Apple Juice Co.**  
**Refrigerated Pasteurized Apple Juice**

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			
CCP 1 Culling	Patulin	No more than 1% by weight rot after culling	Rot in 5000 g sample	Cut rot and weigh rot	Twice per production run	QC staff	Segregate and hold product for evaluation or destroy or divert to nonfood use and/or Move people and/or Slow the line and/or Retrain production employees (cullers) on inspection procedures		
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Visual	Daily  Pre-op and post-op	Production employee	Segregate product and rework to eliminate metal pieces, or run product through metal detector, or divert to nonfood use, or destroy  Replace screen		

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Control Guide.

Table 9.1. HACCP Plan—Corrective Action (cont'd)

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring			Corrective Action	Verification	Record keeping	
			What	How	Frequency				Who
CCP 3 Pasteurizer	E. coli O157:H7 and Cryptosporidium parvum	≥160°F for ≥ 6 s	1. Temp. of juice  2. Set pump speed to 5 to deliver ≥ 6 s	Temp. recorder  Visual check of positive displacement pump at set speed	Continuous recording with hourly visual check of record.  Visual daily check of MIG thermometer  Daily at beginning of production	Pasteurizer operator  Pasteurizer operator	Segregate and hold product for repasteurization or divert to nonfood use  Adjust pasteurizer temperature to achieve ≥ 161°F  and/or  Adjust pump to deliver ≥ 6 s  and/or  Clean and sanitize all equipment post-pasteurization		

## **CHAPTER 10: PRINCIPLE 6. VERIFICATION PROCEDURES**

Overhead 92

### **Objectives**

In this module you will learn:

- How to define verification
- What functions are part of the HACCP system verification
- What functions are part of HACCP plan validation

Overhead 93

### **HACCP Principle #6**

Establish verification procedures

Notes:

Explanatory Note:  
Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities. This could be a point of confusion, and the instructor should keep this in mind while addressing this chapter.

## Notes:

## Overhead 94

## Definition

**Verification:** those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

### *Verification*

One of the more complex HACCP principles is verification. Although it is complex, the proper development and implementation of the verification principle is fundamental to the successful execution of the HACCP plan. HACCP has spawned the use of a new adage — "trust what you verify," which speaks to the heart of the verification principle.

## Overhead 95

- **Verification asks whether the HACCP system is being implemented according to the plan**
  - "do what you say"
  
- **Validation asks whether the hazard analysis was complete and if the control measures are effective**
  - "are you doing the right thing"

Perhaps one of the reasons verification has been difficult to understand is because there are several elements associated with this principle, including validation and reviews. Confusion also arises because the HACCP plan must include verification procedures for individual CCPs and for the overall plan. To facilitate understanding, each of these elements will be discussed.

## Elements of Verification

CCP verification activities:

- Calibration of monitoring devices
- Review of calibration records
- Targeted sampling and testing
- CCP record review
  - Monitoring records
  - Corrective action records

## Elements of Verification (cont'd)

- HACCP system verification:
  - Observations and reviews
  - Microbiological end-product testing
- Regulatory inspections/audits

## Definition

**Validation:** the element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the identified food hazards.

**Notes:****Validation**

Validation is an essential component of verification and requires substantiation that the HACCP plan, if implemented effectively, is sufficient to control the food safety hazards that are likely to occur. Initial validation occurs before implementation of the plan. Revalidation occurs when there are significant changes to the plan. The purpose of validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a proven approach to controlling the food safety hazards associated with the specific product and process. There are several approaches to validating the HACCP plan, among them are: incorporation of fundamental scientific principles; use of scientific data; reliance on expert opinion; or conducting in-plant observations or tests.

Overhead 99

**What does validation involve?**

- Scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy

**Validation of the HACCP plan; who does it?**

- HACCP team
- Individual qualified by training or experience

Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation activities may be similar in scope and time commitment to the original HACCP plan development. An in-plant validation should be performed initially before actual reliance on the HACCP plan and when factors warrant. These factors could include: changes to the raw materials, product or process; adverse review findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

## Validation Frequency

- Initially
  - When factors warrant, e.g.,:
    - Changes in raw material
    - Changes in product
    - Changes in processing methods
    - Adverse review findings
    - Recurring deviations
    - New information on hazards or control measures
    - On-line observations
    - New distribution or consumer handling
- Annually

### *Examples of Validation Activities:*

1. In our example, pasteurization at  $\geq 160^{\circ}\text{F}$  and  $\geq 6$  seconds has been recommended as a minimum criterion to achieve a 5-log reduction of vegetative and protozoan pathogens in juice. Proper process validation activities (i.e. commissioning equipment) must occur to ensure this recommended process is delivered.
2. When a processor uses a handheld computer and software system to record the monitoring activities, the system should be validated according to 21 CFR 11 to meet the processor's and the computer manufacturer's requirements.
3. It has been shown that a screen with a pore size of 2.0 mm eliminates foreign objects and restricts the particle size going into the pasteurizer.

## CCP Verification Activities

- Calibration of monitoring devices
- Review of calibration records
- Targeted sampling and testing
- CCP record review
  - Monitoring records
  - Corrective action records

**Notes:*****Verification of CCPs***

Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating and calibrated within appropriate ranges for food safety control. Additionally, CCP verification includes supervisory review of CCP calibration, monitoring and corrective action records to confirm compliance with the HACCP plan. CCP verification may also include targeted sampling and testing.

***Calibration***

Verification activities at CCPs include calibration of monitoring devices to assure the accuracy of the measurements taken. Calibration is conducted to verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implementation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable. If this happens, the process monitoring data should be evaluated to see if there are any possible deviations since the last documented acceptable calibration. This situation should be given ample consideration when establishing the frequency of calibration. Frequency of calibration should also be influenced by equipment sensitivity.

Overhead 102

### **Calibrations Are Performed**

- On equipment and instruments used in monitoring or verification
- At a frequency to ensure accuracy of measurements
- By checking accuracy against a recognized standard at or near the condition that the instrument or equipment will be used

Examples of calibration activities:

1. A mercury-in-glass (MIG) thermometer or alternate temperature measuring device used to monitor temperature at a pasteurization CCP may be checked for accuracy by comparing it against a certified thermometer.
2. The continuous temperature chart recorder on a pasteurizer may be compared during each production run against a calibrated thermometer.
3. A pH meter is calibrated against pH buffer standards of 7.0 and 4.0 when it is used to test products with a final pH of 4.2.

***Review of Calibration Records***

Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results (e.g., equipment passing or failing). Calibration records are kept and reviewed.

Example of calibration record review:

A review of the MIG thermometer records indicates that the thermometer was checked for accuracy against a certified thermometer at a frequency specified in the HACCP plan. The records also indicate that the thermometer performed within established limits and did not need adjustment. This review disclosed no problems in the MIG calibrations.

### ***Targeted Sampling and Testing***

Verification may also include targeted sampling and testing. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied on as critical limits. Typically, when a monitoring procedure is not as stringent as desired, it should be coupled with a strong verification strategy.

Examples of targeted sampling and testing:

1. Periodic samples could be collected to verify that the culling step is achieving patulin control in apple juice.
2. Fresh citrus juice processors that rely on surface treatments to achieve a 5-log reduction must analyze the finished juice for biotype I *E. coli* for each 1,000 gallons of juice produced per day or once every 5 working days.

### ***CCP Record Review***

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them to ascertain that the HACCP plan is being followed.

### ***HACCP System Verification***

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system-wide verification should be annually (at a minimum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. The HACCP team may contract an independent third party to conduct the system-wide verification activities.

**Notes:**

**Notes:****Explanatory Note:**

The frequency of verification activities will likely change over time. A history of review findings that indicate that the processes are consistently in control may justify safely reducing the frequency. On the other hand, adverse findings, such as inconsistent monitoring activities, inconsistent record keeping and improper corrective actions, warrant correcting the problems and more frequent verification reviews. Adverse findings may indicate a need for subsequent validation of the HACCP plan. FDA's juice HACCP regulation requires validation of the hazard analysis and the HACCP plan on an annual basis. This is a process that includes a technical review of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from the operation of the plan. The purpose of the validation is to ensure that the hazard analysis and the HACCP plan accurately identify and control relevant hazards.

## Overhead 103

## HACCP System Verification Frequency:

- Annually
- Occurrence of a system failure or significant change in product or process

***System Verification Activities***

Common system verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities.

System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

## Overhead 104

## Verification Activities of the HACCP System

- Accuracy of the product description and flow chart
- CCPs are monitored as required by the HACCP plan
- Processes are operating within established critical limits
- Records are completed accurately, at the time intervals required and reviewed appropriately
- Processor review of consumer complaints

## Record Review:

- Monitoring activities have been performed at the locations specified in the HACCP plan.
- Monitoring activities have been performed at the frequencies specified in the HACCP plan.
- Corrective actions have been performed whenever monitoring indicated deviation from critical limits.
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

### ***End-Product Microbiological Testing in HACCP Verification***

As explained in Chapter 2, microbiological testing is ineffective for routine monitoring but can be used as a verification tool. Microbiological testing can be used to determine (i.e., during verification audits) that the overall operation is under control.

Example of microbiological testing:

FDA's juice HACCP regulations require for fresh squeezed citrus juices that achieve a 5-log reduction of a pertinent microorganism by means of surface treatment the processor must analyze for biotype I *E. coli* in finished product. Samples shall be analyzed by the method entitled "Analysis for *Escherichia coli* in Citrus Juices – Modification of AOAC Official Method 992.30" or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *E. coli*. One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced per day. If less than 1,000 gallons produced per day, samples must be taken for each 1,000 gallons produced but not less than once every 5 working days.

**Notes:*****Company Verification Schedule***

Table 10.1. Company-Established HACCP Verification Schedule.

<b>Activity</b>	<b>Frequency</b>
Initial validation of HACCP plan	Prior to and during initial implementation of plan
Subsequent validation of HACCP plan	When critical limits change, significant changes in process occur, equipment failure, system failure, or when other factors warrant
Verification of CCP monitoring as described in the plan (e.g., monitoring of juice pasteurization time and temperature)	According to HACCP plan (e.g., daily record review)
Validation of the HACCP plan	Annually

***The Role of Regulatory Agencies in HACCP Plan Verification***

The major role of regulatory agencies in a HACCP system is to verify that HACCP plans are effective and are being followed. Verification normally will occur at the inspected facility; however, some aspects of verification may be conducted at other appropriate locations.

HACCP plans are unique documents prepared by a processor to ensure the control of a specific process or procedure. The plans may contain proprietary information and must be appropriately protected by the regulatory agency. Agency personnel must have access to records that pertain to CCPs, deviations, corrective actions and other information pertinent to the HACCP plan that may be required for verification.

**Verification Procedures by a Regulatory Agency**

- These may include
  - Review of the hazard analysis, the HACCP plan and any modification
  - Review of CCP monitoring records
  - Review of corrective action records
  - Review of the verification records
  - Visual inspection of operations to determine if the HACCP plan is followed and records are properly maintained
  - Random sample collection and analysis

**HACCP Plan Form - Verification**

1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions	9. Verification
			4. What	5. How	6. Frequency	7. Who		

Establish verification activities and frequencies

XYZ Apple Juice Co.  
Refrigerated Pasteurized Apple Juice

Table 10.2. HACCP Plan—Verification\*

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			
CCP 1 Culling	Patulin	No more than 1% by weight rot after culling	Rot in 5000 g sample	Cut rot and weigh rot	Twice per production run	QC staff	Review all records within one week of preparation  Sample for presence of patulin quarterly		
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Visual	Daily  Pre-op and post-op	Production employee	Segregate product and rework to eliminate metal pieces, or run product through metal detector, or divert to nonfood use, or destroy  Replace screen	Review all records within one week of preparation	

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide.

Table 10.2. HACCP Plan— Verification (cont'd)\*

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			
CCP 3 Pasteurizer	E. coli O157:H7 and Cryptosporidium parvum	≥160°F for ≥ 6 s	1. Temp. of juice recorder	Temp. recorder	Continuous recording with hourly visual check of record.  Visual daily check of MIG thermometer	Pasteurizer operator	Documentation of process establishment  Check the accuracy of the temperature recording device against the MIG thermometer daily  Calibrate the MIG and certified thermometer annually  Confirm that pump setting delivers correct flow rate by performing the salt test  Review all records within one week of preparation		
			2. Set pump speed to deliver ≥ 6 s	Visual check of positive displacement pump at set speed	Daily at beginning of production	Pasteurizer Operator	Segregate and hold product for repasteurization or divert to nonfood use  Adjust pasteurizer temperature to achieve ≥ 161°F and/or  Adjust pump to deliver ≥ 6s and/or  Clean and sanitize all equipment post-pasteurization		

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide.

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## **CHAPTER 11: PRINCIPLE 7. RECORD-KEEPING PROCEDURES**

Notes:

Overhead 108

### **Objectives**

In this module you will learn:

- What kinds of records are needed in a HACCP system
- When to record monitoring information
- How to conduct a record review

Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

Overhead 109

### **HACCP Principle #7**

Establish record-keeping and documentation procedures

**Notes:**

Explanatory Note:  
Written hazard analysis is required in the juice HACCP regulation. Some of the HACCP plan support documents described in this chapter may be part of the written hazard analysis.

**Types of Records Needed**

Overhead 110

## Required Records

- Records of SSOPs (8 key sanitation operations)
- Hazard analysis/HACCP plan and supporting documentation used in developing the plan
- Records of CCP monitoring
- Records of corrective action
- Records of verification activities

**1. Hazard Analysis/HACCP Plan Support Documents**

HACCP support documents include the information and data used to develop the HACCP plan. These include the written hazard analysis (Chapter 5) and records of any information used in performing the hazard analysis and establishing the critical limits.

Support documents may include sufficient data to establish the adequacy of any measures to control bacterial growth, to establish the safe shelf life of the product (if age of the product can affect safety), and to establish the adequacy of a process in destroying pathogens. In addition to data, support documents may also include correspondence with consultants or other experts.

Support documents should also include:

- A list of the HACCP team and their responsibilities,
- A summary of the preliminary steps taken in the development of the HACCP plan, and
- Prerequisite programs.

**2. Monitoring Records**

HACCP monitoring records are primarily kept to demonstrate control at CCPs. HACCP records provide a useful way to determine if critical limits have been violated. Timely record review by a management representative ensures that the CCPs are being controlled in accordance with the HACCP plan. This was discussed in Chapter 10. Monitoring records also provide a means by which regulators can determine whether a firm is in compliance with its HACCP plan.

By tracking the values recorded on monitoring records, an operator or manager can determine if a process is approaching its critical limit. Trends can be identified through record review to make necessary process adjustments. If timely adjustments are made before the critical limit is violated, processors can reduce or eliminate the labor and material costs associated with corrective actions.

**All HACCP monitoring records shall be on forms that contain the following information:**

- Form title
- Firm name and location
- Time and date
- Product identification (including product type, package size, processing line and product code, where applicable)

**All HACCP monitoring records shall be on forms that contain the following information (cont'd):**

- Actual observation or measurement
- Critical limits
- Operator's signature or initials
- Date of review

Examples of CCP monitoring records may include:

- Storage temperature records for temperature-sensitive ingredients, in-process materials and finished products where temperature control is necessary to ensure product safety,
- Container-seal examination records when the hermetic seal affects product safety, or
- Sanitizer concentration records for surface treatment of citrus fruits where levels of sanitizer concentrations are necessary to ensure product safety.

**3. Corrective Action Records**

Corrective action records were discussed in Chapter 9.

**Notes:****4. Verification Records**

Verification records (Chapter 10) should include:

- Validation of the hazard analysis/HACCP plan,
- Modifications to the HACCP plan (e.g., changes in ingredients, formulations, processing, packaging and distribution),
- Processor audit records verifying supplier compliance with guarantees or certifications,
- Verification of the accuracy and calibration of all monitoring equipment,
- Results of microbiological challenge tests, environmental microbiological tests, and periodic in-line and finished-product microbiological, chemical and physical tests if applicable,
- Results of in-house, on-site inspections, and
- Results of equipment evaluation tests.

Examples of verification records include:

- Letter from a process authority establishing a scheduled process.
- Metal detector calibration log.

**Record-Monitoring Information**

Monitoring information should be recorded at the time the observation is made. False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system.

**Computerized Records**

Computerized records are an option to record keeping. When using computerized records, include controls to ensure that records are authentic, accurate and protected from unauthorized changes. Additional information can be found in 21 CFR 11.

**Record Review**

Monitoring records for CCPs and critical limit deviations must be reviewed within seven days by a HACCP-trained individual. All records should be signed or initialed and dated by the reviewer.

Sample records are included for each of the monitoring activities identified in columns 4 to 7 of the HACCP plan for XYZ Apple Juice Co. The names of these forms should be entered in column 10 of the HACCP plan form. These records include:

**Figure 11.1. Cull report**

This form is used to record that the inspectors at the cull step are culling visually defective apples.

**Figure 11.2. Screen integrity report**

This form is used to record the integrity of the press screen.

Chapter 11: Principle 7. Record-keeping Procedures

Figure 11.3. Pasteurization log

This form is used to record temperature and pump setting of the pasteurization process.

Figure 11.4. Temperature recording chart

This chart records the temperature during pasteurization.

**Additional Records**

Figure 11.5. Patulin test report

This document indicates the results of a laboratory analysis for patulin, which is used as a quarterly verification of the supplier's certification.

Figure 11.6. Pasteurization validation letter

The pasteurization temperature and time document should be established by a process authority.

Figure 11.7. Equipment calibration log

This form records the results of the annual calibration of the thermometers used on the pasteurizers.

Figure 11.8. Corrective action report

This record relates to the pasteurization process records that have been previously discussed. This form is used to document the action taken when a critical limit is exceeded.

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Notes:

HACCP Plan Form – Record Keeping									
1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions	9. Verification	10. Record keeping
			4. What	5. How	6. Frequency	7. Who			
Specify the record keeping procedures for each CCP									

Figure 11.1. Cull Report - Refrigerated Pasteurized Apple Juice

Apple Juice - Cull Report  
XYZ Juice Co., Wheaton, IL

Date: 9/3/01 Critical Limits: < 1% Visually Defective  
 Line: Number 8 Product: Refrigerated Pasteurized Apple Juice  
 Inspector: Graham R. Smith

Time	Weight of Apples (grams)	Weight of Rot (gram)	% of Rot	Met Critical Limits		Signature/ Initials
				Yes	No	
6:00 a.m.	5,000	50	1.0	✓		G. R. Smith
7:01 a.m.	4,800	47	0.98	✓		G. R. Smith
8:05 a.m.	5,010	48	0.96	✓		G. R. Smith
9:02 a.m.	4,950	45	0.91	✓		G. R. Smith
10:03 a.m.	5,000	49	0.98	✓		G. R. Smith

Review: Seymour Samples Date: 9/7/01

*If critical limits are not met, notify the shift supervisor, and separate and identify the batch involved.*

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Figure 11.2. Screen Integrity Report - Refrigerated Pasteurized Apple Juice

Apple Juice - Daily Screen Integrity Report YZ Juice Co., Wheaton, IL			
Date:	<u>9/7/01</u>	Critical Limits:	<u>No Visible Holes or Tears</u>
Line:	<u>Number 8</u>	Product:	<u>Refrigerated Pasteurized Apple Juice</u>
Inspector:	<u>Inge Pressum</u>		
Date	Met Critical Limits		Signature/Initials
	Pre-Ops Yes/No (Time)	Post-Ops Yes/No (Time)	
9/3/01.	Yes (5:55 a.m.)	Yes (2:20 p.m.)	I. Pressum
9/4/01	Yes (5:50 a.m.)	Yes (2:45 p.m.)	I. Pressum
9/4/01.	Yes (5:45 a.m.)	Yes (3:00 p.m.)	I. Pressum
9/5/01	Yes (5:50 a.m.)	Yes (2:40 p.m.)	I. Pressum
9/6/01	Yes (5:35 a.m.)	Yes (2:25 p.m.)	I. Pressum
9/7/01	Yes (5:40 a.m.)	Yes (2:10 p.m.)	I. Pressum
Review:	<u>Seymour Samples</u>		Date: <u>9/10/01</u>
<p><i>If critical limits are not met, notify the shift supervisor, and separate and identify the batch involved.</i></p>			

Figure 11.3. Pasteurization Log - Refrigerated Pasteurized Apple Juice

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Apple Juice Pasteurization Log  
XYZ Juice Co., Wheaton, IL

Date:	3/4/2001	Critical Limits:	Pump Setting 3
Line:	Number 8	Product:	Apple juice
Operator:	Good M. Practice		

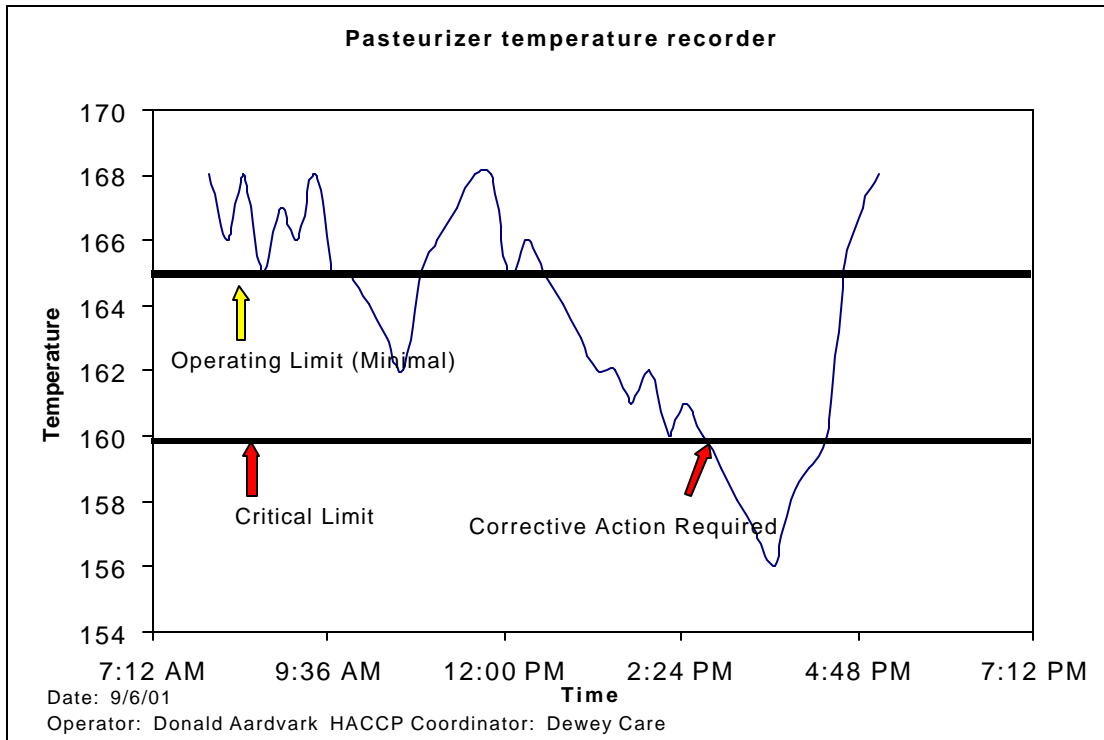
  

Line No.	Lot No.	Time of Day	Temp. MIG (°F)	Temp. from Recorder (°F)	Pump Setting	Critical Limits Met	Comments
8	124	1:00 p.m.		160	N/A	Yes	
8	134	2:02 p.m.		161	N/A	Yes	
8	144	3:05 p.m.		157	N/A	No	<i>See corrective actions</i>
8	154	4:00 p.m.		161	N/A	Yes	
8	164	4:59 p.m.	160*	160	3*	Yes	*Daily Monitoring

*If critical limits are not met, notify the shift supervisor, and separate and identify the batch involved.*

Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Figure 11.4. Temperature Recording Chart



**Notes:**

Explanatory Note:  
 Figure 11.5. Finished product analyses may often be included as part of a firm's periodic verification efforts. Firms should establish specifications for the patulin tests that are performed as part of verification.

Figure 11.5. Patulin Test Report

<b>A-One Laboratory Report for:</b>	
<b>XYZ JUICE CO., WHEATON, IL</b>	
Ref: Lot# 123	
Remarks: <i>The above sample was analyzed for the presence of patulin using official AOAC recognized methods.</i>	
Irene Wright Laboratory Director A-One Laboratories Jonestown, PA 25418	

Date:	10/28/01	Sample Number:	XYZ Juice lot# 123
Vendor:	Apple Pickers Coop.	Patulin:	Negative
Examined by:	Sheila Good		

Figure 11.6. Pasteurization Validation Letter

Juice Processing Research and Extension Unit  
Your State University

January 5, 2001

XYZ Apple Juice Co.  
P.O. Box 5678  
Wheaton, IL 60187

Dear Mr. Juicer:

A thorough review of the published literature discovered that for juices with a pH of less than 4.0 a time-temperature combination of 160°F for 3 seconds is sufficient to destroy all vegetative bacterial pathogens by at least 5-log reductions. However, for parasites literature indicates that a slightly longer processing time is needed to deliver a 5-log reduction of *Cryptosporidium parvum*. Thus, for your apple juice, a thermal process of 160°F for 6 seconds should be sufficient to meet the microbial reduction requirements of 21 CFR 120.

This recommendation is with the understanding that the thermal processing equipment you use is constructed and operated correctly so that all portions of the food product are given the recommended thermal treatment, and that there is no post process contamination before filling.

Sincerely,  
I.M. Helpful  
Juice Processing Research and Extension Unit  
Your State University

Notes:

Some may question why a validation letter is not needed by XYZ Juice Co. for the plate heat exchanger. The reason is that the process treatment is what requires validation. This includes establishment of the correct processing of the critical limit (supplied by I. M. Helpful of Your State University) and the correct application of the treatment by the heat exchanger. Often the producer, using specific equipment, will validate the application of treatment by ensuring proper flow rate and temperature control. The producer would also need to validate the function of the flow diversion device if installed.

**Notes:**

Explanatory Note:  
Figure 11.7. Emphasize that all monitoring equipment such as thermometers and scales should be checked against a standard. In some cases, this standard may be a boiling-water bath, an ice slush or a known weight, depending upon the instrument and the accuracy requirements for the critical limit being monitored. Note that on the 6/12/00 calibration, the thermometer was 1°F above the standard. This could have an impact on the previously produced product and could have resulted in critical limit deviations. Product should be evaluated, and appropriate corrective action should be taken and recorded.

Figure 11.7. Equipment Calibration Log - Temperature Measurement

XYZ JUICE CO., WHEATON, IL				
Instrument/Equipment:		Mercury-in-glass (MIG) thermometer		
Location in Plant:		Juice Pasteurizer Number Eight		
Serial Number:		B546		
Model Number:		Always Right 140°F to 260°F		
Date received in Plant:		3/2/99		
Date Calibrated	Calibration Results	Method of Calibration	Employee	Reviewer Date
3/27/00	Thermometer was in calibration.	Tested in steam flow 215°F using certified thermometer S.N. 07569	Sam Smith	Becky Allen 3/28/00
6/12/00	Thermometer scale adjusted 1°F down to match standard thermometer.	Tested in steam flow 215°F using certified thermometer S.N. 07569	Stan Jones	Becky Allen 6/19/00
9/11/00	Thermometer was in calibration.	Tested in steam flow 215°F using certified thermometer S.N. 56432	Sam Smith	Becky Allen 9/13/00
12/4/00	Thermometer was reading 5°F below the standard thermometer scale. Adjusted	Tested in steam flow 215°F using certified thermometer S.N. 56432	Stan Jones	Becky Allen 12/8/00
2/28/01	Thermometer was in calibration	Tested in steam flow 215°F using certified thermometer S.N. 56432	Stan Jones	Becky Allen 3/4/01

Chapter 11: Principle 7. Record-keeping Procedures

Figure 11.8. Corrective Action Report

XYZ Apple Juice Co., Wheaton, IL			
Date:	3/4/01	Lot I.D.:	153
<b>Description of Problem:</b>			
At 3:05 p.m., the temperature dropped to 157°F for 30 seconds according to the recorder.			
<b>Action Taken:</b>			
Temperature drop was noted immediately. The product exiting the pasteurizer for the next five minutes was destroyed since the system does not have a Flow Diversion Device.			
The system shut down and switched to water.			
The system was cleaned and sanitized.			
System was restarted; temperature and monitoring were reestablished.			
<b>Date Problem Solved:</b>	3/4/01		
<b>Current Status:</b>			
Remainder of lot is acceptable.			
Supervisor:	Ollie K. Fellows		
Reviewer:	Seymour Samples	Date:	3/4/01

**Notes:**

Explanatory Note:  
 Figure 11.8. The critical limit failure in the corrective action report would not likely have been noted without the continuous monitoring provided by the recording thermometer. In a continuous pasteurizer, when a temperature drop occurs, the product in the pasteurizer at the time of the deviation must be held and evaluated, re-pasteurized, destroyed or shifted to some other acceptable use.

Table 11.1. HACCP Plan - Record Keeping\*

XYZ Apple Juice Co.  
Pasteurized Refrigerated Apple Juice

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record Keeping
			What	How	Frequency	Who			
CCP 1 Culling	Patulin	No more than 1% by weight rot after culling	Rot in 5000 g sample	Cut rot and weigh rot	Twice per production run	QC staff	Segregate and hold product for evaluation or destroy or divert to nonfood use and/or Move people and/or Slow the line and/or Retrain production employees (cullers) on inspection procedures	Review all records within one week of preparation  Sample for presence of patulin quarterly	Cull report  Patulin Lab Report
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Visual	Daily  pre-op and post-op	Production employee	Segregate product and rework to eliminate metal pieces, or run product through metal detector, or divert to nonfood use, or destroy  Replace screen	Review all records within one week of preparation	Screen integrity log

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide.

Table 11.1. HACCP Plan - Record Keeping (cont'd)\*

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record keeping
			What	How	Frequency	Who			
CCP 3 Pasteurizer	E. coli O157:H7 and <i>Cryptosporidium parvum</i>	≥160°F for ≥ 6 s	1. Temp. of juice	Temp. recorder	Continuous recording with hourly visual check of record.	Pasteurizer operator	Documentation of process establishment  Check the accuracy of the temperature recording device against the mercury in glass thermometer daily  Calibrate the mercury and certified thermometer annually	Pasteurization log  Thermometer chart recorder  Calibration log	
			2. Set pump speed to deliver ≥ 6 s	Visual check of positive displacement pump at set speed	Daily at beginning of production	Pasteurizer operator	Adjust pump to deliver ≥ 6 s and/or  Adjust pump to deliver ≥ 6 s and/or  Clean and sanitize all equipment post-pasteurization	Confirm that pump setting delivers correct flow rate by performing the salt test  Review all records within one week of preparation	

\*For illustrative purposes only. Models may not be fully consistent with FDA's Juice HACCP Hazards and Controls Guide.

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## CHAPTER 12: THE JUICE HACCP REGULATION

Notes:

Overhead 114

### Objectives

In this module you will learn:

- What are the requirements of the juice HACCP regulation
- How to reference the specific requirements

On January 19, 2001, FDA published a juice safety regulation based on the seven principles of HACCP called "Procedures for the Safe and Sanitary Processing and Importing of Juice." This regulation has become known as "the juice HACCP regulation." It will be referred to in this chapter as "the regulation." A copy of the regulation is provided in Appendix I.

Overhead 115

### Regulation Format

- Subpart A – General Provisions
  - 120.1 Applicability
  - 120.3 Definitions
  - 120.5 current Good Manufacturing Practices
  - 120.6 Sanitation standard operating procedures
  - 120.7 Hazard analysis
  - 120.8 HACCP plan

#### ***Regulation Format***

The regulation is part of Title 21 of the Code of Federal Regulations (CFR), Part 120, and is subdivided into two subparts and 15 sections.

Notes:

Overhead 116

**Regulation Format  
(cont'd)**

- Subpart A – General Provisions (cont)
  - 120.9 Legal basis
  - 120.10 Corrective actions
  - 120.11 Verification and validation
  - 120.12 Records
  - 120.13 Training
  - 120.14 Application of requirements to imported products

Overhead 117

**Regulation Format (cont'd)**

- Subpart B – Pathogen Reduction
  - 120.20 General
  - 120.24 Process controls
  - 120.25 Process verification for certain processors

Overhead 118

**Definitions 120.1, 120.3, 120.24  
and the Juice HACCP Hazards and  
Controls Guide (HG)**

- |                          |                          |
|--------------------------|--------------------------|
| • Cleaned                | • Fallen fruit (HG)      |
| • Control                | • Food hazard            |
| • Control measure        | • Hazard analysis (HG)   |
| • Critical control point | • Importer               |
| • Critical limit         | • Juice concentrate (HG) |
| • Culled                 |                          |

### Definitions 120.1, 120.3 and the Juice HACCP Hazards and Controls Guide (cont'd)

- Juice
- Monitor
- Pertinent microorganism
- Processing
- Processor
- Retail establishment
- Shall
- Shelf-stable product
- Should
- Validation
- Verification

#### *Definitions 120.3*

Twenty-one important terms are used throughout the regulation and FDA's Hazards and Controls Guide (HG). Of the terms listed above, some are focused specifically on the application of HACCP principles to juice processing, and a few definitions need to be emphasized.

**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.

**Cleaned** means washed with water of adequate sanitary quality.

**Culled** means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with 21 CFR Part 120.24, culled means the separation of damaged fruit from undamaged, tree-picked fruit.

**Fallen fruit** (HG) 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, drops.

**Hazard analysis** (HG) means the process of collecting and evaluating information on hazards associated with the food under consideration to decide what hazards are significant and must be addressed in the HACCP plan.

**Juice concentrate** (HG) 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.

**Retail establishment** means an operation that provides juice directly to 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.

**Notes:**

Explanatory Note:

The terms importer, processor and processing together define who is subject to this regulation.

Explanatory Note:

The ownership of an imported product can change many times in a short period of time after entry into the United States. However, the person who is the owner or consignee at the time that the product is offered for entry is identified as the importer because: 1) that person has the ability to decide whether to offer the product for entry, and 2) that person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this to FDA.

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

Overhead 120

## Who Must Comply?

- Importer
- Processor – domestic and foreign

**Pertinent Microorganism** The most resistant microorganism of public health significance that is likely to occur in the juice.

**Processor** means any person engaged in commercial, custom or institutional processing of juice or juice products either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

**Processing** means activities that are directly related to the production of juice products. For purposes of this part, processing does not include: harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and the operation of a retail establishment.

Overhead 121

## Operations Exempt from Regulation

- The regulation does not apply to:
  - The harvest, picking or transport of raw agricultural ingredients of juice products, if the person is not otherwise engaged in processing
  - The operation of a retail establishment

**Shall** is used to state mandatory requirements.

**Should** is used to state recommended or advisory procedures or to identify recommended equipment.

Overhead 122

## Effective Dates

- January 22, 2002 for all businesses not defined as small businesses or very small businesses in 120.1(b)
- January 21, 2003 for small businesses as defined in 120.1 (b)(1)
- January 20, 2004 for very small businesses as defined in 120.1(b)(2)

**Small businesses** are those operations employing fewer than 500 persons.

**Very small businesses** are those operations that have either 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.

Overhead 123

## Products Exempt from or Not Subject to the Regulation

- Juice produced as part of the operation of a retail establishment
- Beverage with a juice ingredient (but the juice ingredient is subject to the regulation)
- Non-beverage food with juice ingredient (e.g., fruit-flavored candy)
- Ingredients from fruit other than juice (e.g., citrus oil)

### Notes:

#### Explanatory Note:

The use of the term "should" in the FDA regulation may differ from its use in Chapters 5 through 11 of this manual. Chapters 5 through 11 are designed to teach the principles of HACCP, including certain activities that need to be carried out to properly implement HACCP plans. Identifying these activities as those that "should" be enacted means they are important for the HACCP program to be effective. Many of these activities may be mandatory elements of the regulation.

**Notes:**

Some juice products are exempt from the regulation. Juice produced at a retail establishment is exempt. A “retail establishment” includes establishments in which juice is produced and sold directly to consumers, e.g., in stores, from roadside stands, at farmers markets, and in food service operations, such as juice bars.

Overhead 124

## **HACCP versus Warning Label**

- Juice processors subject to the regulation must use a HACCP system on the applicable effective date of the regulation
- Retail establishments must continue to use warning labels on containers of juice that has not been treated to achieve the 5-log pathogen reduction

On July 8, 1998, FDA published a regulation requiring warning labels on packaged juice products that were not processed to achieve a 5-log pathogen reduction. FDA published additional guidance on the 5-log pathogen reduction regulation, December 21, 2001. This document is attached in Appendix III. For most untreated juice products, the warning label was an interim measure until HACCP regulations could be finalized. Juice processors subject to the juice HACCP regulation must use a HACCP system on the applicable effective date of the regulation. The warning label will no longer be an option. However, retail establishments are not subject to the HACCP regulation, and the warning label requirement remains in effect for untreated juice produced in a retail establishment. Retailers must continue to use warning labels on packaged juice products, that have not been treated for the 5-log pathogen reduction.

Overhead 125

## **Intrastate and Interstate Juice Subject to Regulation**

- 120.1(a) - The regulation is applicable to “any juice, regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce.”

Both products that move in interstate commerce and products made and sold within a state (intrastate products) are subject to the regulation.

Overhead 126

## **Raw Agricultural Ingredients of Juice, e.g., Fruits, Vegetables**

- Not subject to the regulation
- Growers should follow the FDA's GAPs, (i.e., "Guide to Minimize Food Safety Hazards for Fruits and Vegetables")

Hazards on incoming fruit must be identified in the processor's hazard analysis and controlled under the processor's HACCP plan. A juice processor should know as much as possible about the source of the fruits and vegetables he/she uses to establish that these foods have been grown, harvested and handled in a manner consistent with the GAPs. Following the GAPs minimizes the likelihood that the produce will contain pathogenic microorganisms.

Overhead 127

## **120.5 - Current Good Manufacturing Practices (cGMPs)**

- Regulations found in Title 21, part 110, of the Code of Federal Regulations
- General requirements for proper practices for the safe and sanitary handling of all human foods, including juice

**Notes:**

**Notes:*****Current Good Manufacturing Practices (cGMPs) 120.5***

The Food Drug and Cosmetic Act deems food to be adulterated if prepared, packed or held under insanitary conditions that may cause the food to become injurious to health or to become contaminated with filth. The cGMPs in Title 21, Part 110 of the CFR describe the criteria and definitions that are generally applicable to determining whether a food is being processed under such insanitary conditions. Part 110 applies to the processing of all FDA-regulated food products including juice products. The juice HACCP regulation sets forth additional, more specific requirements that apply to the processing of juice.

***Sanitation 120.6***

Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. The regulation requires that processors have and implement a sanitation standard operating procedure (SSOP) to address the sanitation conditions and practices before, during and after processing.

SSOPs are required even if a processor determines there is no need for a HACCP plan. The sanitation requirements of the regulation may be made part of the processor's HACCP plan or may be managed separately. Some processors may choose to use a combination of these approaches.

The SSOPs shall address eight key areas.

Overhead 128

**SSOPs Shall Address Eight Key Areas**

1. Safety of water that contacts food and food contact surfaces.
2. Condition and cleanliness of food-contact surfaces.
3. Prevention of cross-contamination between insanitary objects and food, packaging materials, etc.
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities.

## **SSOPs Shall Address Eight Key Areas (cont'd)**

5. Protection of food, packaging materials, etc. from adulterants.
6. Labeling, storage and use of toxic compounds.
7. Control of employee health conditions that could cause contamination of food, food packaging materials, etc.
8. Exclusion of pests from food plant.

## **SSOP Requirements**

- Mandatory sanitation monitoring of eight key areas with record keeping
- Mandatory corrections with record keeping

Processors shall monitor sanitation conditions and practices with sufficient frequency to ensure that they meet the requirements of the cGMP regulations in Part 110. Conditions and practices that are not met must be corrected in a timely manner. Processors shall maintain SSOP records that document monitoring and corrections.

**Notes:**

Explanatory note:  
 FDA has established an action level 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 (if the food is an apple juice concentrate). See FDA's Compliance Policy Guide (CPG) guidance for patulin at [www.cfsan.fda.gov](http://www.cfsan.fda.gov) under "Pesticides and Chemical Contaminants," in the subsection on "Natural Toxins".

## Overhead 131

## 120.7(a) – Hazard Analysis

- Each processor shall develop or have developed for it a written hazard analysis

### *Hazard Analysis 120.7(a)*

The regulation requires that every processor develop or have developed for it a written hazard analysis. It gives two major purposes for the hazard analysis:

- Determine whether there are hazards that are reasonably likely to occur, for each type of juice produced, and
- Identify control measures the processor can apply to control the identified hazards.

## Overhead 132

## Food Hazards That Are "Reasonably Likely to Occur"

- Those "for which a prudent processor would establish controls"

This means a prudent processor would establish controls because there is a reasonable possibility that a hazard will occur in the absence of control. To make this decision, examine:

- Experience,
- Illness data,
- Scientific reports, and
- Other information (e.g., FDA's Juice HACCP Hazards and Control Guide).

The criteria for including a food hazard in a processor's HACCP plan should be the likelihood that the hazard will occur or develop in that product without proper controls (e.g., based on the processing procedures, product ingredients, packaging, storage, and intended use).

An example of a hazard that may be considered to be reasonably likely to occur in apple juice is the mycotoxin patulin. Patulin is a mycotoxin that can occur on rotten, moldy or damaged apples, and may occur at hazardous levels if such apples are used to make juice. Chronic exposure (exposure over time) to high levels of patulin may pose a health hazard.

The hazard analysis also identifies control measures to control the identified hazards. Control measures such as a supplier agreement, specifying that only tree-picked apples will be supplied, or culling (removal of damaged fruit) may effectively control patulin.

The hazard analysis must be documented in writing for regulatory review. A written hazard analysis will help the processor remember the thought process used to identify the hazards and develop the HACCP plan. This will be useful when periodic plan reassessments are conducted and when the plan is reviewed by regulators.

Overhead 133

### **120.8(a) The HACCP Plan**

- Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing as described in 120.7(a)

**Notes:**

**Notes:**

## Explanatory Note:

HACCP plans will not be preapproved by FDA before they are implemented by the processor. They should not be submitted to the agency for review. FDA reached this decision because:

- HACCP plans should be evaluated on-site, a process best accomplished during inspections of processing facilities.
- FDA does not have sufficient resources to review HACCP plans from all domestic and foreign juice processors in advance of HACCP implementation by processors.

## Overhead 134

## The HACCP Plan

- A HACCP plan shall be specific to:
  - Each processing location
  - Type of juice

***HACCP Plan 120.8(a)***

When HACCP plan components are essentially identical, some types of juice may be grouped under a single HACCP plan.

## Overhead 135

## The HACCP Plan

- The HACCP plan shall:
  - List the food hazards that are reasonably likely to occur
  - List the CCPs
  - List the critical limits
  - List the monitoring procedures
  - List predetermined corrective action plans\*
  - List the verification measures
  - Provide for a system of monitoring records

\*Processors are not required to have written corrective action plans

***HACCP Plan Contents 120.8(b)***

Food hazards can include: microbiological hazards such as bacteria or parasites; chemical hazards such as, harmful pesticide residues, natural toxins, presence of undeclared ingredients that may be allergens, presence of residues of other foods that may be allergens resulting from cross contact with inadequately cleaned shared processing equipment; and physical hazards, such as metal or glass fragments.

They can be hazards that are introduced inside the processing plant or hazards that occur apart from the plant before, during or after harvest.

The frequencies of the monitoring and verification procedures must be included in the HACCP plan. Monitoring records must provide the actual values or observations noted during monitoring.

***Signing and Dating the HACCP Plan 120.12(c)***

Overhead 136

Notes:

## The HACCP Plan

- The HACCP plan shall be signed and dated by:
  - The individual most responsible at the processing facility or a higher level official of the processor
  - This signature shall signify that the HACCP plan has been accepted for implementation by the firm

Overhead 137

## The HACCP Plan

- The HACCP plan shall be signed and dated:
  - Upon initial acceptance
  - Upon any modification\*
  - Upon verification and validation of the plan (at least annually)\*

\*This is a plan validation requirement

***Legal Basis 120.9(g)***

FDA's application of HACCP is based upon the Federal Food Drug and Cosmetic Act (FFDCA) and the Public Health Service (PHS) Act. The FFDCA makes it unlawful to process food under insanitary conditions that may render it injurious to health. Any juice processed or imported in violation of this regulation is legally adulterated and subject to regulatory action. The PHS Act enables FDA to enact regulations to control the spread of communicable disease.

Notes:

Overhead 138

## 120.10 – Corrective Action

- Whenever a deviation from a critical limit occurs, a processor shall take corrective action

### *Corrective Actions 120.10*

The regulation requires that a corrective action take place whenever a critical limit is not met at a CCP.

Overhead 139

## Corrective Actions

- Two options are available:
  - Predetermined
  - Alternate procedure:
    - Segregate and hold product
    - Determine product acceptability
    - Apply corrective action to product and process
    - Reassess the HACCP plan

Processors have a choice of developing a predetermined corrective-action plan in advance as part of their HACCP plans or of following the alternate procedure for corrective actions provided in the regulation. When a processor develops a plan in advance, he/she follows the plan that is appropriate when the deviation occurs. These corrective-action plans become part of their HACCP plans as previously described in section 120.8(b).

A predetermined corrective-action plan provides a processor with benefits such as faster action when a deviation occurs and less need to justify to management the appropriateness of the corrective action after it has been taken. But unusual situations may arise that may not be addressed in predetermined corrective-action plans. Processors may choose not to predetermine their corrective actions. In these cases, the alternate corrective-action procedure must be followed.

A proper corrective-action plan describes the steps that are to be taken and assigns responsibility for taking those steps. It is designed to ensure that:

- No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and
- The cause of the deviation is corrected.

The alternate corrective-action procedure involves:

- Segregating and holding the affected product until the next two requirements are met,
- Perform or obtain a review to determine whether the product is safe for distribution. This review must be performed by someone who has adequate training or experience to understand the public health consequences of the deviation,
- Take corrective action, as necessary, to ensure no injurious or otherwise adulterated product affected by the deviation enters commerce,
- Take corrective action, as necessary, to fix the problem that caused the deviation, and
- Perform or obtain a timely verification of the HACCP plan in accordance with 120.11 to determine whether the HACCP plan needs to be modified to reduce the risk that the deviation will happen again and modify the HACCP plan as necessary. This determination must be made by someone who has met the training requirements covered in section 120.13.

All corrective actions must be fully documented in records.

Overhead 140

## **Verification and Validation**

- Every processor shall:
  - Validate that the HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur
  - Verify that the HACCP system is being implemented effectively

**Notes:**

**Notes:*****Verification 120.11***

The HACCP plan must be validated within 12 months of implementation, and at least annually thereafter, or whenever any changes occur that could affect the hazard analysis or the HACCP plan in any way. This could include changes in:

- Raw materials or source of raw materials,
- Product formulation,
- Processing methods or systems,
- Packaging,
- Finished product distribution systems, or
- The intended use or consumers of the finished product.

The purpose of the validation is to ensure that the HACCP plan is adequate to control the food safety hazards which are reasonably likely to occur. It must be performed by an individual who meets the training requirements described in section 120.13. If a processor has no HACCP plan because no significant hazards were identified, then the hazard analysis must be reassessed whenever any changes occur that could affect the hazard analysis.

The regulation requires ongoing verification activities in addition to periodic plan re-validation. These ongoing activities are in keeping with the HACCP principle that verification must ensure that the HACCP plan is being implemented on a day-to-day basis. These ongoing verification procedures must be listed in the HACCP plan.

Overhead 141

### **Verification Shall Include**

- Consumer complaint review
- Calibration of process-monitoring equipment
- Periodic end-product and in-process testing (processor's option unless required for a citrus juice under 120.25)
- Additional process verification for a citrus juice under 120.25

Records must be kept of the calibration procedures and end-product or in-process testing that is performed as part of a processor's HACCP activities.

Consumer complaints must be reviewed by the processor to determine whether they relate to the performance of the HACCP plan or reveal previously identified CCPs. The regulation does not give regulators access to consumer complaints but does give them access to corrective action records that relate to problems identified by consumer complaints.

## Verification Shall Include

- Review of monitoring records for CCPs
- Review of corrective action records and procedures
- Review of calibration records for process monitoring instruments used at CCPs
- Review of in process and end product testing records

The regulation requires that processors review certain records as part of verification. The purpose of these reviews is to ensure that the records are complete and that the activities occurred in accordance with the processor's written procedures. The records must be reviewed by someone who meets the training requirements described in section 120.13.

Monitoring and corrective-action records must be reviewed within one week of when the record was made. Calibration and in-process or end-product testing records must be generated within a reasonable time after the records are made.

Sometimes the review of a consumer complaint or the performance of a verification procedure will indicate the need to take a corrective action. When this happens, the processor must follow the corrective-action procedures described in section 120.10.

## Required Records

- SSOP implementation
- Written hazard analysis
- Written HACCP plan
- Ongoing implementation e.g., monitoring, corrective action
- Verification and validation

### Notes:

Explanatory Note:  
For 21 CFR Parts 113 and 114  
regulated product records must be  
retained for three years.

**Notes:**

Explanatory Note:  
Records, of course, should contain details of observations and/or real values of measurements made at each CCP.

**Records 120.12**

The records required by the regulation must contain certain information. They must:

- Bear the name and location of the processor or importer.
- Be completed at the time of the activity. In most cases, indicate date/time of the reflected activity.
- Be signed or initialed by the operator or creator.
- Where appropriate, identify the product and production code.
- Be retained for specified periods of time at the processing facility or at the importers place of business (some provisions for offsite storage exist).
- Be available for review and copying by regulatory authorities.

Overhead 144

## Records Requirements

- The following information is required on each record:
  - Name and location of the processor or importer
  - Date and time of the activity being recorded (in most cases)
  - Signature or initials of the operator or the person making the record
  - Identity of the product and the production code where appropriate

Overhead 145

## Record Retention

- Records must be retained as follows:
  - One year for perishable or refrigerated juices
  - Two years for preserved, frozen, or shelf-stable products, or to shelf life, whichever is greater

Records required under the HACCP regulation, must in most cases, be maintained at the processing facility or the importer's place of business in the U.S. There are some provisions for off-site storage of records, e.g., when a processing facility closes between seasonal packs. The provisions state procedures and timeframes for retrieving the records if official review is requested.

A key feature of the HACCP regulation is official review by government inspectors of the records required by the HACCP regulation. Examination of HACCP records enables an inspector to see how the processing facility operates over time rather than just on the day of the inspection. Additionally, it enables the inspector to review the adequacy of the processor's HACCP system.

FDA has existing regulations that preclude disclosure of trade secrets and confidential commercial information. HACCP records that contain such information will not be disclosed to the public under the Freedom of Information Act.

***Training 120.13***

The regulation requires that certain activities and functions be performed by an individual trained in the application of HACCP principles to juice processing.

Overhead 146

**Activities That Require  
HACCP Training**

- Individuals performing the following require HACCP training:
  - Developing the hazard analysis
  - Developing the HACCP plan
  - Verifying, validating, and modifying the HACCP plan and hazard analysis as required
  - Reviewing required HACCP records

Processors can use a trained employee or a trained third party to perform these activities. The jobs may be done by one person or by several as long as they have been properly trained. The regulation defines a "HACCP trained individual" as one "who has successfully completed training in the application of HACCP principles to juice processing that is at least equivalent to that received under a standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify if it has provided knowledge at least equivalent to that provided through the standardized curriculum." This course material, developed by the National Juice HACCP Alliance, is the standardized curriculum recognized by FDA.

***Imported Products 120.14***

It has always been the importer's responsibility to offer for entry into the U.S. products that are not adulterated under U.S. law. FDA's surveillance system for imports has traditionally consisted of:

- Reviews of customs entry forms for juice being offered for entry into the United States,
- Random sample collections for laboratory analysis of products awaiting entry, and
- Automatic detention of products with a history of problems.

**Notes:**

**Notes:**

As with traditional processing-plant inspections, this method is a "snapshot" approach that is not preventive.

Under the juice HACCP regulation, imported juice must also be processed under a HACCP system in accordance with the requirements of the regulation. Additional requirements also pertain to importers.

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## **Importer Responsibilities**

- Importers are required to:
  - Import from countries with memorandum of understanding (MOU), that meets certain requirements

**or**

- Implement written procedures to ensure that juice is processed in compliance with the regulation

Importers may meet their obligation in one of two ways. They may import juice that is covered by memoranda of understanding between the United States and a foreign country that, among other things, covers food and documents the equivalency or compliance of the foreign country's inspection system with the U.S. system, and is functioning and enforceable in its entirety. In this case, they do not need to take any other action to meet the requirements of the regulation.

Otherwise, the importer must have and implement written procedures for ensuring that the juice offered for import into the United States was processed in accordance with the requirements of the regulation. The written procedures shall provide at a minimum, certain product specifications and affirmative steps.

## Importer Written Procedures

- Product specifications, and
- Affirmative steps

Product specifications should cover those characteristics of the product that would be useful in providing assurance that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or may have been processed under insanitary conditions. For example, such a specification could address a contaminant that may render the food injurious to health. It may be appropriate for a specification for apple juice to include a maximum limit for patulin of 50 ppb.

The affirmative steps are to ensure that the juice being imported was processed under controls that meet the requirements of the juice HACCP regulation.

## Importer Written Procedures

- Affirmative steps may be any of the following:
  - For each lot being entered, obtain foreign processor's HACCP plan and SSOP monitoring and correction records
  - Obtain continuing lot-by-lot certificate from foreign government or competent third party that the juice has been processed in accordance with the juice HACCP regulation

Notes:

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## **Importer Written Procedures (cont'd)**

- Affirmative steps may be any of the following:
  - Regularly inspect foreign processor
  - Maintain foreign processor's HACCP plan on file and written guarantee that the juice is processed in accordance with the requirements of the juice HACCP regulation

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## **Importer Written Procedures (cont'd)**

- Periodically test the imported product and maintain on file written guarantee that the juice is processed in accordance with the requirements of the juice HACCP regulation
- Perform other verification procedures that provide equivalent level of assurance
- Importer must maintain records in English that document the performance and results of the affirmative steps

An importer may hire a competent third party to perform the verification activities specified within the affirmative steps. However, the importer remains responsible for demonstrating to FDA that the requirements have been met.

The importer must maintain records in English that document that the affirmative steps have been performed. The records must describe the results of the steps. These records are subject to the records requirements described in section 120.12.

## Process Controls

- All juice processors must include control measures in their HACCP plans to achieve a 5-log reduction in the pertinent microorganism, except:
  - Juice processors subject to Part 113 or Part 114 (acidified juices and low acid canned juices)
  - Juice processors who use a single thermal processing step to achieve a shelf-stable juice or juice concentrate if they include a copy of their thermal process in the hazard analysis

## Process Controls (cont'd)

- The 5-log process must be applied directly to the juice with the exception of citrus juice processors who may use surface treatments of the citrus fruit to achieve the 5-log reduction after culling and cleaning of the fruit
- All juice processors must perform the 5-log reduction process and perform the final product packaging within a single production facility operating under cGMPs

### ***Pathogen Reduction 120.20 and 120.24.***

Processors of juice products must include in their HACCP plans control measures that will consistently produce, at a minimum, a 5-log (or 100,000 fold) reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. The pertinent microorganism is the most resistant microorganism of public health significance that is likely to occur in the juice.

The regulation exempts processors of thermally processed shelf-stable juice and thermally prepared juice concentrates from having to include control measures for pathogen reduction in their HACCP plans. However these processors must include a copy of the thermal process used to achieve shelf-stability or concentration in their written hazard analysis.

**Notes:**

Processors of acidified and low-acid canned juices continue to be subject to Parts 113 or 114. These processors are also exempted from having to include control measures for pathogen reduction in their HACCP plans. Hazards associated with pathogens in these juices, e.g., *C. botulinum* are controlled through compliance with Parts 113 and 114.

All juice processors must achieve the 5-log reduction process by direct treatment of the juice with the exception of citrus juice processors who may utilize treatments to the fruit surfaces provided that the treatment process begins after culling and cleaning of the fruit. Cleaning is defined as washing with water of adequate sanitary quality and culling means the separation of damaged fruit from tree-picked, undamaged fruit.

For all juices, the 5-log reduction must be accomplished within a single production facility where the juice will also be packaged into its final form. This facility must be operating under cGMPs. Processors of thermally processed shelf stable juice and thermally processed juice concentrate processors subject to parts 113 and 114 must also process and perform final product packaging within a single production facility that is operating under cGMPs.

***Process Verification for Certain Citrus Juices 120.25***

Each juice processor that relies 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 *E. coli* (Figure 12.1). One 20 ml sample consisting of two, 10 ml subsamples for each 1,000 gallons of juice produced must be sampled on each production day.

If less than 1,000 gallons of juice is produced each day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days. Each subsample shall be a randomly selected package of juice for consumption by the consumer.

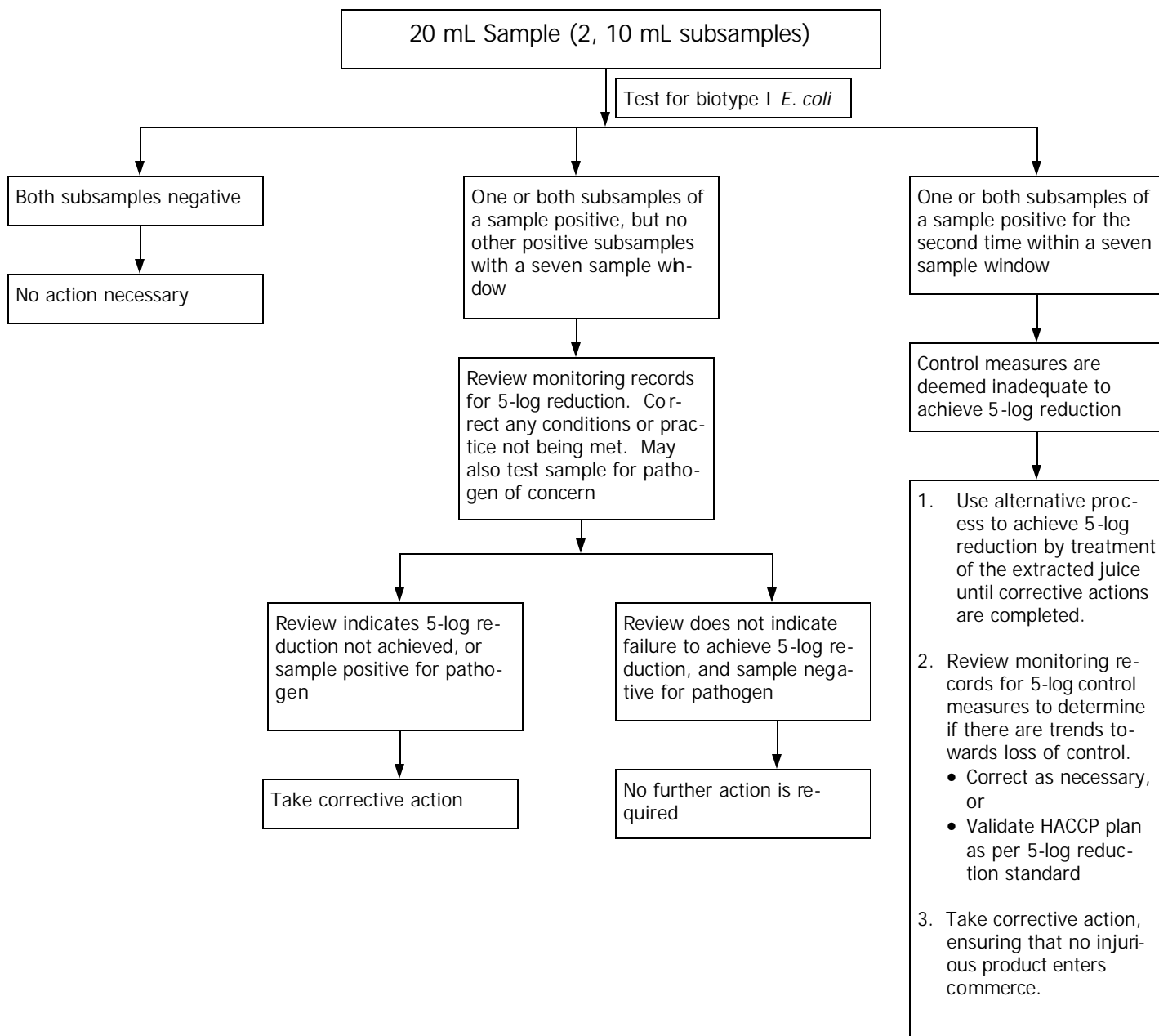
If either 10 ml subsample is positive, the 20 ml sample is recorded as positive and the processor shall review the monitoring records for the control measures to attain the 5-log reduction standard. The processor may also test the sample for the presence of pathogens of concern. If the record review or test results indicate that the 5-log reduction standard was not achieved, corrective actions (120.10) must be undertaken.

If two samples in a series of seven tests are positive, the control measures used to attain the 5-log reduction are deemed inadequate and until corrective actions are completed the processor must include the use of an alternate process to achieve the 5-log reduction on the extracted juice.

The processor must perform a review of monitoring records for the control measures to attain the 5-log reduction standard to determine that there are no trends toward loss of control, and either correct conditions and practices that are not being met, or if no such corrections are indicated, validate the HACCP plan in relation to the 5-log reduction standard.

The processor must also take corrective action as set forth in 120.10 to include that no product enters commerce that is injurious to health.

Figure 12.1. Verification for Certain Citrus Juices



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## CHAPTER 13: SOURCES OF INFORMATION ON PREPARING HACCP PLANS

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### Objectives

- In this module you will learn:
  - What sources of information exist to help identify juice safety hazards and establish effective control measures
  - How to use the “Juice Hazards and Controls Guide” to identify hazards and establish control measures

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### Sources of Information

- Juice processors
- Federal, state, and local government inspectors
- Trade associations
- Suppliers and buyers
- Cooperative extension service
- Universities
- Publications

#### Sources of Information on Juice Hazards and Control Measures

- *The Juice Processor*

You and your employees know your operation better than anyone. Experience is an excellent source of information. You may already have knowledge about hazards that can affect your product, and you may have already implemented suitable controls.

- *Government Inspectors*

Federal, state and local inspectors that visit your plant can be a good source of information. Inspectors may point out potential hazards, but it will usually be your responsibility to implement effective control measures.

Notes:

Explanatory Note:  
Although not required by the juice HACCP regulation, it is advisable to maintain HACCP plan supporting documentation described in this chapter.

## Notes:

- ***Trade Associations***

Trade associations can also provide useful information. Trade journals often provide general information on potential hazards and controls. Articles on specific processes or products also can be useful. Some trade organizations provide services such as consulting, educational programs and publications that can help identify hazards and control measures.

- ***Suppliers and Buyers***

Suppliers of cleaning materials, processing equipment and packaging materials can provide information on potential hazards and control measures. A buyer's specification may point to a hazard in one of your products. For example, a buyer may require a *Salmonella*-free product. It is important to note, however, that not all buyer's specifications relate to safety.

- ***Cooperative Extension Programs/Universities***

Many universities have Cooperative Extension programs. These programs provide continuing education and technical assistance to industry. Extension specialists and agents can assist in identifying potential hazards and control measures.

- ***Publications***

Textbooks, government publications and scientific literature provide general and specific HACCP information. These publications usually include a list of references that can be used to get further information.

Scientific journals are available in most libraries, especially university libraries. Summaries of information from scientific journals are also available in FDA and other publications. Following is a listing of organizations that produce publications that may be helpful.

- ***U.S. FDA Juice HACCP Hazards and Controls Guide***

The *Juice HACCP Hazards and Controls Guide* includes information on key aspects of the juice HACCP regulation, identifies hazards that are common in juice, and provides information on how to control these hazards. The Guide can be used as a resource in conducting your hazard analysis and developing your HACCP plans. However, you need to perform a hazard analysis to determine whether the hazards identified in the Guide or other hazards are reasonably likely to occur in your product(s). Also, to devise effective controls for these hazards, you need to evaluate your operations. To do this, gather information from a variety of sources and choose the information that best applies to your situation. Some of the most useful sources are described in this chapter.

- ***FDA Compliance Policy Guides (CPGs) and Import Alert***

The FDA CPGs provide information on FDA compliance policy. The FDA Import Alerts are notices from FDA headquarters to district offices concerning new or unusual problems affecting import products. The CPGs and import alerts can be obtained by contacting: FDA, Office of Regulatory Affairs (HFC), 5600 Fishers Lane, Rockville, MD 20857. Alternately, you may purchase the Import Alerts Manual and the Compliance Policy Guides Manual from: U.S. Department of Commerce, Technology Administration, National Technical Service (NTIS), Sales Desk, 5285 Port Royal Road, Springfield, VA 22161 (Phone: 703/487-4650). In addition, the import alerts can be obtained at [http://www.fda.gov/ora/fiars/ora\\_import\\_alerts.html](http://www.fda.gov/ora/fiars/ora_import_alerts.html).

- ***U.S. Department of Agriculture (USDA) Model HACCP Plans***

The USDA Food Safety and Inspection Service conducted a 1990 study to determine how to implement the HACCP system in meat and poultry inspection operations. The project resulted in the development of model HACCP plans. Two generic HACCP models deal with refrigerated foods and cooked sausage. They are available from: USDA, Food Safety and Inspection Service, Washington, DC 20250. [www.usda.gov/](http://www.usda.gov/)

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

NACMCF provides advice and recommendations to the secretaries of the Department of Agriculture and the Department of Health and Human Services concerning the development of microbiological criteria used to evaluate the safety and wholesomeness of food, including criteria for microorganisms that indicate whether food has been processed using GMPs.

Web address: <http://www.usda.gov/fsis/ophs/nacmcf.htm>

- ***National Academy of Sciences (NAS)***

The NAS received its congressional charter in 1863, which established it as a private, nonprofit organization designated as an official advisor to the federal government on science and technology matters. Its members include experts from many disciplines, including scientists, engineers, doctors, lawyers and corporate executives.

- ***Centers for Disease Control and Prevention (CDC)***

The CDC is responsible for characterizing risk factors and prevention strategies for diseases that impact on public health. In addition, the CDC assists local health agencies in epidemiological investigations of foodborne illness outbreaks. Certain diseases are reported to the CDC by state epidemiologists. The *Morbidity and Mortality Weekly Report* contains summaries of this information. It can be obtained by contacting CDC at: *Morbidity and Mortality Weekly Report*, Mailstop C-08, CDC, 1600 Clifton Road N.E., Atlanta, GA 30333 (Phone: 404/332-4555). Web address: <http://www2.cdc.gov/mmwr/>.

- ***Codex Alimentarius (CODEX)***

The *Codex Alimentarius* Commission is sponsored by the Food and Agriculture Organization and the World Health Organization of the United Nations. Its purpose is to facilitate international trade by establishing uniform food standards. The commission has developed many standards and guidelines, including a HACCP guideline document. Information may be obtained from the U.S. Coordinator for Codex Alimentarius, USDA, Food Safety and Inspection Service, Washington, D.C. 20250.

- ***Canadian Food Inspection Agency (CFIA) Food Safety Enhancement Program (FSEP)***

The Canadian Food Inspection Agency (CFIA) Agriculture Canada has developed FSEP, a HACCP-based program for food manufacturing operations. Guidance manuals for the FSEP, including *Guidelines and Principles for the Development of HACCP Generic Models*, are available from CFIA, 59 Camelot Dr., Nepean, Ontario, Canada K18 0Y9.

Web address: <http://www.inspection.gc.ca/ppc/psps/haccp/haccpe.html>

Notes:

## Notes:

**Computer-Accessible Information Sources**

- ***FDA's Home Page***

The FDA home page Internet address is: <http://www.fda.gov>. From there, you can easily locate consumer education materials, industry guidance, bulletins for health professionals and other documents and data from FDA's centers and offices. The World Wide Web enables you to download and print the documents you want. In addition, FDA's Office of Plant and Dairy Foods and Beverages maintains a question-and-answer document regarding HACCP issues. Web address: <http://vm.cfsan.fda.gov/~dms/qa2haccp.html>

FDA juice information is located on the Center for Food Safety and Applied Nutrition (CFSAN) home page. Use the search option found on the FDA home page to find CFSAN.

In addition, the FDA maintains a HACCP web site on its home page at <http://www.fda.gov>. Useful information relative to HACCP and juice issues may also be found there as well as information related to scientific issues regarding the safe processing of juice and juice products.

- ***USDA***

USDA Food and Nutrition Information Center has a database on training programs and resource materials. Web address: <http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml>

- ***Selected Additional References***

FDA/DHHS. 1998. "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice," Proposed Rule, 21 CFR Part 120, 63 FR20450-20486, April 24, 1998.

NACMCF. 1999 public meeting. "National Advisory Committee on Microbiological Criteria for Foods, Meeting on Fresh Citrus Juice; Transcript of Proceedings,"

NACMCF. 1997. "National Advisory Committee on Microbiological Criteria for Foods, Recommendations on Fresh Juice

FDA. 2001. Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products; Guidance for FDA Components and Industry: Apple Juice, Apple Juice Concentrates, and Apple Juice Products-Adulteration with Patulin. Web address: <http://vm.cfsan.fda.gov/~dms/patubckg.html>.

FDA. 2000. "Guidance for FDA Components and Industry; Apple Juice, Apple Juice Concentrates and Apple Juice Products-Adulteration with Patulin; Draft Compliance Policy Guide," (also 65 FR 37791-37792, June 16, 2000). Web address: <http://vm.cfsan.fda.gov/~dms/patuguid.html>.

## Chapter 13: Sources of Information on Preparing HACCP Plans

NACMCF. 1998. National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System Adopted August 14, 1997. *Journal of Food Protection*, 61(6):762-775.

Schmidt, R.H., C.A. Sims, M.E. Parish, S. Pao, and M.A. Ismail. 1997. A model HACCP Plan for Small-Scale, Fresh Squeezed (Not Pasteurized) Citrus Juice Operations. Publication CIR 1179, Food Science and Nutrition Department, Florida Co-operative Extension Service, Institute of Food and Agricultural Sciences, University of Florida.

Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, NAS. 1985. "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," National Academy Press.

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### **Preliminary Steps**

1. Assemble HACCP team.
2. Describe food and its distribution.
3. Identify intended use and consumers of food.
4. Develop process flow diagram.
5. Verify flow diagram.

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### **Hazard Analysis Worksheet**

- Set up the hazard analysis worksheet
- Identify the potential hazards
- Complete the hazards analysis worksheet
- Understand the potential hazard
- Determine if the potential hazard is significant
- Identify the CCPs

**Notes:**

## Notes:

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## Complete the HACCP Plan Form

- Establish critical limits
- Monitor each CCP:
  - What?
  - How?
  - Frequency?
  - Who?
- Establish corrective actions
- Establish verification procedures
- Establish record-keeping and documentation procedures

### *How to Use the Juice HACCP Hazards and Controls Guide*

The guide is designed so that a processor or regulator can identify potential food hazards. It contains the same hazard analysis worksheet and HACCP plan form that has been used throughout this course. In this way, the user is lead through a series of decisions such as: whether a potential hazard is a significant hazard; what is the proper CCP; what critical-limit monitoring programs, corrective-action procedures and verification procedures are appropriate; and what records are necessary.

The recommendations included in the guide are not, for the most part, binding FDA requirements. Use of the guide in developing HACCP plans is not mandatory. The guide provides useful guidance, but juice processors and importers are free to choose other control measures as long as they meet the requirements of the juice HACCP regulation. There may also be circumstances where a hazard identified in the guide may not apply to a product because of conditions specific to the processor.

Food hazards can be introduced to a product because of the nature of the product (e.g., the type of fruit) or because of the way it is processed. Processors must control both types of hazards.

The guide provides information to help processors and regulators decide if these potential hazards are reasonably likely to occur in any given circumstance. It further provides information and possible examples about how the hazard might be controlled. These control options are not intended to be all-inclusive. Rather they represent the mechanisms that FDA is aware of that should prove effective in eliminating or minimizing the risk of a hazard developing in a product. In particular, the guide provides information about critical limits that may be appropriate in certain circumstances. In some cases, the suggested critical limits are derived from existing tolerances or action levels. In other cases, they are derived from a review by FDA of the scientific and technical literature, conducted for the specific purpose of assisting in the development and review of HACCP plans.

You have been provided a copy of the latest edition of the guide along with your other training materials. You should use it as a reference tool during the practical exercise on the last day of the course.