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# UNIT 12 CASE STUDIES ON HACCP

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## 12.0 OBJECTIVES

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After reading this unit, we shall be able to:

- design the HACCP worksheet;
- determine the critical points using decision tree;

- establish critical limits and monitoring controls;
- formulate the verification and validation studies; and
- learn the record keeping procedures.

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## 12.1 INTRODUCTION

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To facilitate our discussion of HACCP. Let us review a Guava Juice Company say Guavapure Juice Company. With this fictitious company as a base, evolution of a HACCP plan for Guava juice shall be illustrated. Do please keep in mind that the HACCP plan developed for Guavapure Juice Company is intended to demonstrate the procedures used in plan development. Since HACCP plans are very much product, process and plant specific, Guavapure Juice Company's plan might not be suitable for other companies.

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## 12.2 GUAVA JUICE PRODUCTION PLANT

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### Refrigerated Pasteurized Guava Juice Processing Narrative

Company: Guavapure Juice Company

Final Product: Refrigerated pasteurized Guava juice

Procedures/Steps:

#### 12.2.1 Incoming Materials

- Locally grown fresh Guavas are purchased directly from farms. Guava are received in bulk in wooden boxes containing approximately 20 kg and upon receipt are visually examined for gross filth. Following acceptance, the guavas are assigned a lot number, and placed in refrigerated storage. Furthermore, a supplier agreement specifying that the guavas are tree-picked is in effect for each incoming shipment of guavas.
- 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.

#### 12.2.2 Processing

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

(**Note:** Defective guavas are diverted, not to be used for human consumption.)

- Accepted guava continue on to a wet scrubber where they are brushed and sprayed with treated water. Then, the guava pass across a rubberized roller where they are partially dried.
- Guavas are elevated, rinsed in potable water, drained, and dropped into a 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.

### 12.2.3 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 checked 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.

### 12.2.4 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.

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## 12.3 HAZARD ANALYSIS WORKSHEET

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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

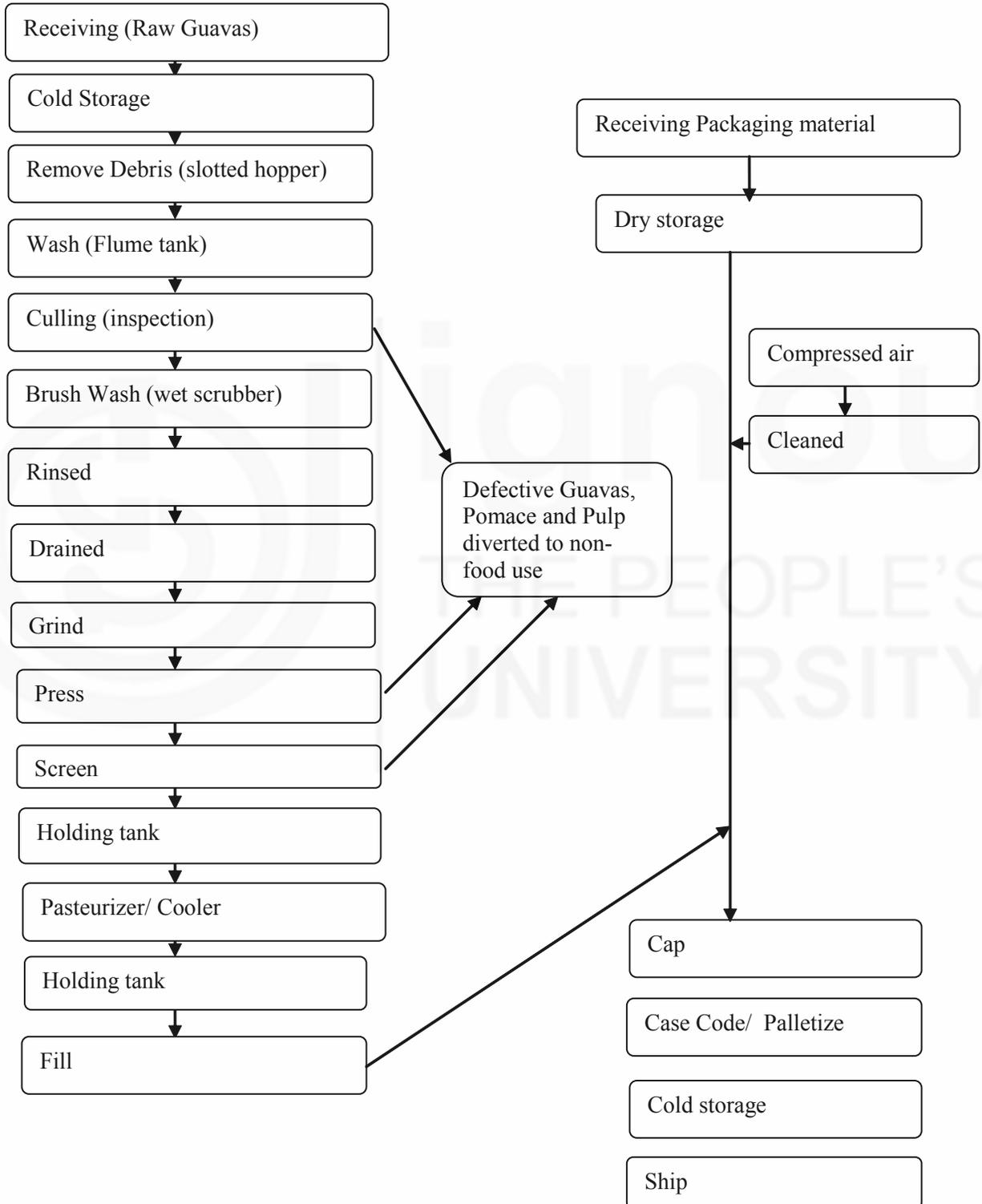
food safety hazards. In the pasteurized refrigerated guava juice the arrangement is as follows:

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.



**Fig. 12.1: Process Flow Diagram for Guavapure Juice Company**

Column 5. List potential control measures available for controlling hazards that are likely to occur.

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

On the hazard analysis worksheet for pasteurized refrigerated guava juice, at the receiving step potential hazards identified include biological hazards such as vegetative pathogens and *Cryptosporidium* and chemical hazards including aflatoxin and pesticides. No physical hazards were identified. Based on the identified 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 guava juice and were determined to be a significant hazard. During the hazard evaluation it was determined that *Cryptosporidium* could occur even though Guavapure Juice Company only uses potable water and monitors the water it uses under its Sanitation Standard Operating Procedure (SSOP) program. This program reduces the likelihood of occurrence of the hazard, but is not considered sufficient to eliminate the possible hazard. The Guavapure Juice Company HACCP team determined that aflatoxin was a significant hazard in the incoming guavas and that aflatoxin levels could increase further during cold storage of the guavas. Pesticide residues may be found on incoming guavas. 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 not to be reasonably likely to occur.

### 12.3.2 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 Guavapure Juice Company continued its hazard analysis, it noted that the supplier agreement specifying the use of tree-picked and undamaged guavas along with the subsequent culling and washing steps, would not be adequate measures to control incidence of *Cryptosporidium* contamination. Since levels of aflatoxin could increase during cold storage of guavas, a control measure for aflatoxin only at receipt would not be totally adequate. A more effective control measure would be after the cold storage step in the process. Guavapure Juice Company chose to control for aflatoxin at the culling step.

**Note:** Published information relevant to control strategies for aflatoxin 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 guavas), or
- A culling step after the cold storage and brush/wash/scrub steps (the control measure would be the culling of visually damaged guavas), 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 guava used. For instance, some varieties may

be susceptible to aflatoxin whose 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 guavas are received, because there is no CCP requiring that only tree-picked guavas be accepted. In some cases, it may be necessary to employ both steps as CCPs. The Guavapure Juice Company determined that metal fragments were reasonably likely to be introduced into the juice from the hammer mill 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 Guavapure Juice Company 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 pasteurisation temperature and time to ensure the destruction of pathogenic microorganisms.

(1) Ingredient/ Processing Step	(2) Identify Potential Hazards introduced, controlled or enhanced in 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?
Receiving (Raw guavas)	Biological (B) 1) Vegetative pathogens 2) Protozoan Pathogens  Chemical (C) 1) Pesticides  2) Aflatoxin  Physical (P) - None	B  1) Yes 2) Yes  C 1) No  2) Yes	B. History of outbreaks   In India, unapproved pesticide levels rarely occur in guavas and health impact is not severe.  Causes illness or injury. May exceed regulatory specifications if not controlled	B. Pasteurisation Step   C 1) Not applicable  2) Culling
Receiving (Packaging)	B – None C – None P – None			
Dry storage (Packaging)	B – None C – None P - None			
Cold Storage	B – None C – Aflatoxin P - None	C- Yes	Aflatoxin levels may increase during cold storage due to fungus	C- Culling
Remove debris (Slotted Hopper)	B – None C – None P – None			
Wash (Flume Tank)	B – None C – None P – None			

Culling	B – None C – Aflatoxin P – None	C - Yes	Aflatoxin levels decrease when spoilt guavas are culled	Cull defective guavas
Brush/ wash	B – None C – None P – None			
Partially Dried	B – None C – None P – None			
Grind	B – None C – None P – Metal Pieces	P- Yes	P- Metal may be introduced from grinder blades	Metal shall not pass through the intact screens. Visually check integrity of screen regularly
Holding Tank	B – None C – None P – None			
Pasteurizer/ Cooler	B 1. Vegetative Pathogens 2. Protozoan pathogens C – None P – None	B Yes	Microbial contamination on incoming guavas	B- Pasteurisation
Holding Tank	B – None C – None P – None			
Fill	B – None C – None P – None			
Cap	B – None C – None P – None			
Case/ Code/ Palletize	B – None C – None P – None			
Cold Storage	B – None C – None P – None			
Ship	B – None C – None P – None			

## 12.4 CCP DECISION TREE

Principle 1 addresses whether the hazards enter a process; may be enhanced during the process; or both. 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 (Fig. 12.2). 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.

**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 rise 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 guava juice, three significant hazards were identified for the refrigerated pasteurized guava juice namely, vegetative and protozoan pathogens, specifically *E. coli* O157:H7 and *Cryptosporidium parvum*, aflatoxin, and metal pieces. Table 12.1 is an illustration of how the CCP decision tree is applied to consider these hazards.

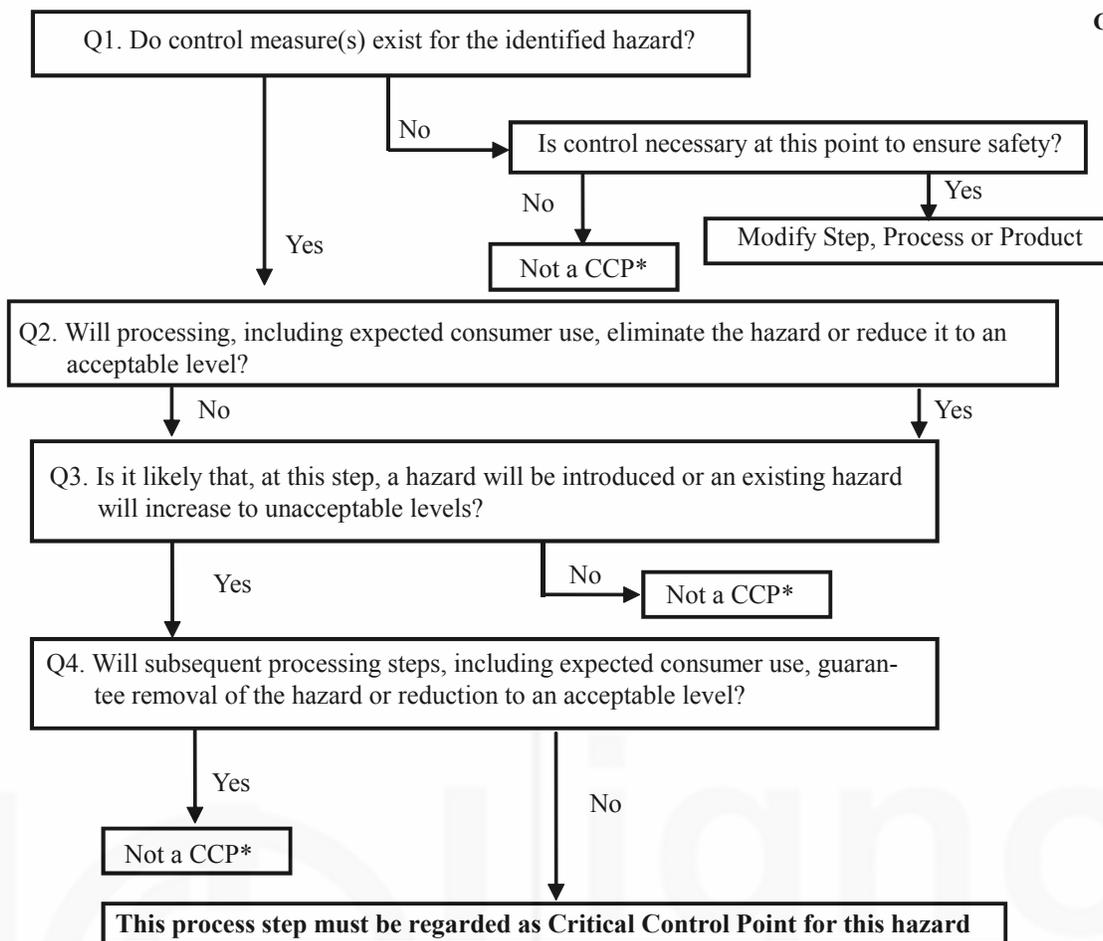


Fig. 12.2: CCP Decision Tree

Table 12.1: Summary for Decision Tree

Step	Hazard	Q1	Q2	Q3	Q4	CCP
Receiving	B- Vegetative and Protozoan Pathogens	Yes	No	Yes	Yes	No
	C- Aflatoxin Presence	Yes	No	Yes	Yes	No
Cold Storage	C- Increase in Aflatoxin	Yes	No	Yes	Yes	No
Cull	C- Aflatoxin reduction	Yes	Yes	-	-	CCP 1
Grind	P- Metal contamination	Yes	No	Yes	Yes	No
Screen	P- Metal removal	Yes	Yes	-	-	CCP 2
Pasteurizer	B- Pathogen Destruction	Yes	Yes	-	-	CCP 3

## 12.5 DETERMINATION OF CRITICAL LIMITS

### 12.5.1 Critical Limits

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. 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 12.2).

## 12.5.2 Information on Critical Limits

The critical limits may be identified with help from literature, research, experts and consultants, or even regulatory bodies. 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 suggest control options and critical limits that could be applied at the pasteurisation step to control vegetative and protozoan pathogens in pasteurized guava juice.

**Table 12.2: Sources of Information on Critical Limits**

General Source	Examples
Scientific publications	Journal articles, Food science texts, Microbiological texts.
Regulatory Guidelines	State and local guidelines; FDA guidelines, tolerance and acceptable levels.
Experts	Consultants, Food scientists, microbiologists, equipment manufacturers, University extensions, Trade associations.
Experimental studies	In-house experiments; Contract labs.

It must be noted that 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. In this example, sampling and microbiological tests of the pasteurized juice are unlikely to be sensitive enough or practical.

### 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

### Good Choice of Critical Limit

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

Hazard - presence of pathogens (biological)

CCP - pasteurisation

Critical limit - minimum process temperature of 72°C 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.

## 12.5.3 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. 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 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 2°C variability should be set at least 2°C above the critical limit to avoid violating it).

Fig. 12.2 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 pasteurisation process, an operating limit is established at 74°C and a critical limit at 72°C.

Somewhere in the 2°C range between these two points, prudent processors will make a process adjustment to bring the pasteurisation temperature back above 72°C. Because an adjustment is made before the temperature drops below the critical limit of 72°C, 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 Fig. 12.2, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file. 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 change.

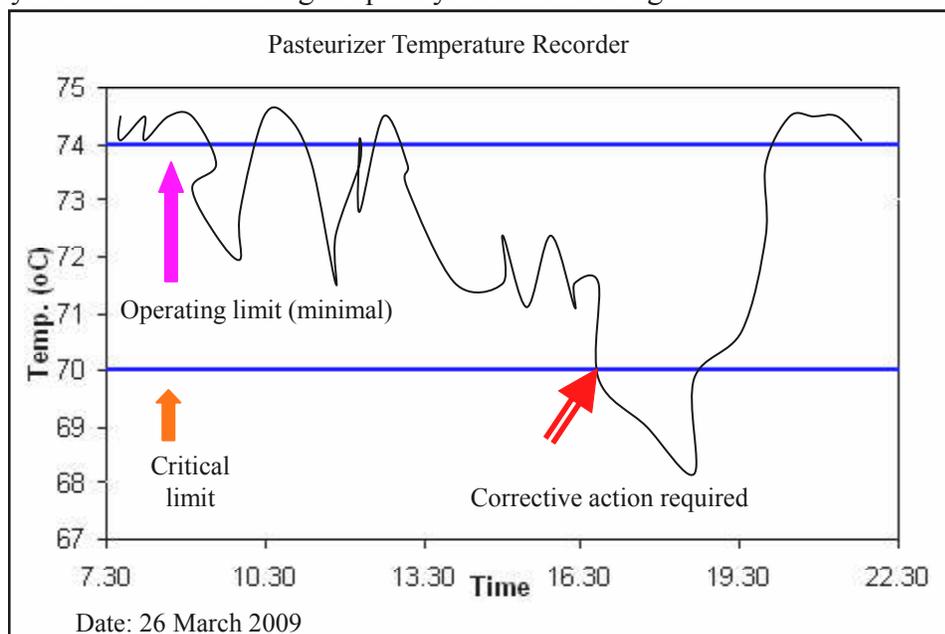


Fig. 12.3: Example of Operating and Critical Limits

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 guava juice identifies three CCPs: culling, screen and pasteurizer. In Table 12.3 there are examples of critical limits for these CCPs.

**Table 12.3: Establishment of Critical Limits**

Critical Control Point (CCP)	Hazard (s)	Critical Limits
CCP 1 Culling	Aflatoxin	Not more than 1% visually spoilt guavas after culling
CCP 2 Screen	Metal contamination	Intact screen
CCP 3 Pasteurizer	<i>E coli</i> and Protozoan pathogens	> 72°C for > 6 s

**Example of HACCP Plan Worksheet**

Critical Control Point (CCP)	Hazard (s)	Critical limits	Monitoring				Corrective action	Verification	Validation
			What	How	Freq- uency	Who			

## 12.6 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); and
- provide written documentation of the process control system.

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.

### 12.6.1 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)

\*usually a measurement or observation to assess if the CCP is operating within the critical limit.

**How the critical limits and control measures will be monitored? (Column 5)**

\*usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits; Needs to be real-time and accurate).

**How frequently monitoring will be performed? (Column 6)**

\*continuous or periodic (non-continuous).

**Who will perform the monitoring? (Column 7)**

\*responsible individual trained to perform the specific monitoring activity or evaluate monitoring records.

**What will be Monitored**

Monitoring could be for:

- Time
- Temperature
- pH
- Flow rate
- Screen

Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit. Examples include: Measurement of cold-storage compartment temperature when critical for temperature-sensitive ingredients (like chocolates, butter or cheese); Measurement of the pH of an acidifying ingredient when critical for the production of an acidified food (like tomato sauce, cold drinks); and Measurement of pasteurisation temperature (many products like milk, juice).

**How Critical Limits and Control Measures will be Monitored**

Monitoring can be done using equipment like timer, thermometer, pH meter, scales, water activity meter, or chemical analysis. 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 guava juice example. Examples of physical- and chemical measurement monitoring at a CCP are as follows:

**Time and temperature:** Growth of pathogenic micro-organisms is usually checked by using an appropriate time-temperature combination. For example, pasteurized guava juice should be heated to  $>72^{\circ}\text{C}$  for  $> 6$  s. This can be monitored at the end of the pasteurisation process. In addition, pathogens can be controlled by minimizing exposure of a food to the critical pathogen growth temperatures between  $4^{\circ}\text{C}$  and  $45^{\circ}\text{C}$ . This can be achieved through rapid heating and/or cooling of the product through these critical temperatures and maintaining temperatures below  $4^{\circ}\text{C}$  (or above  $45^{\circ}\text{C}$ ) during storage. The selection of the monitoring

equipment is a major consideration during development of a HACCP plan. 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 63°C is necessary to kill pathogens in a product and the thermometer has an accuracy of  $\pm 0.5^\circ\text{C}$ , then the operating limit should be set no lower than 64°C. Periodic calibration or standardisation is necessary to ensure accuracy.

### 12.6.2 Monitoring Frequency

Monitoring can be continuous or periodic. The length of the period will affect the amount of product affected by a critical limit deviation so 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).

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 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 previous 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 guavas to ensure the efficacy of culling; and Periodic monitoring of metal detector operation using standards.

### 12.6.3 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 a person who has clearly defined responsibilities; trained; follows clearly delineated procedures; has initial responsibility for corrective actions; and is responsible for documentation. These could 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, and
- 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.

Critical Control Point (CCP)	Hazard (s)	Critical limits	Monitoring				Corrective action	Verification	Validation
			What	How	Frequency	Who			
CCP 1 Culling	Aflatoxin	Not more than 1% visually spoiled guavas after culling	Rot in 5 kg sample	Cut rot and weigh rot	Twice per production run	QC staff			
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Daily	Pre-operation and Post operation	Production employee			
CCP 3 Pasteurizer	<i>E coli</i> and Protozoan pathogens	> 72°C for > 6 s	Temp. of juice	Temp. recorder	Continuous recording with hourly check up of record	Pasteurizer operator			
			Set up pump speed for holding time > 6s	Visual inspection of pump speed	Daily at beginning of operation	Pasteurizer operator			

## 12.7 CORRECTIVE ACTIONS

**Corrective actions** are procedures to be followed when a deviation occurs. When critical limits are violated at a CCP, the pre-determined, documented corrective

actions should be followed. These corrective actions should specify 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.

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 non-compliance to assure that the CCP is brought back under control,
- Segregate, assess and determine the disposition of the non-compliant product, and
- Prevent deviated product that is injurious to health from being supplied.

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.

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

- To correct and eliminate the cause of the deviation and restore process control.
- To identify the product which 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 non-conforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan as follows:

- 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. For example:

**Table 12.4: Corrective Action Format**

If	Temperature of the juice falls below the critical limit and the diversion valve does not function correctly.
Then	<p>The untreated juice will be segregated and held for further disposition (diverted to non-food use or destroyed).</p> <p>Check the operation of the pump, heating/ cooling units, flow diversion valve to determine the reason for temperature deviation.</p> <p>Repair/ correct, Re-establish control and resume production.</p>

It is tempting to classify automatic flow diversion in a properly operating continuous flow pasteurisation 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.

### **12.7.2 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.
- e) Results of the evaluation when necessary.

HACCP plan records should contain a separate file in which all deviations corresponding corrective actions are maintained in an organised fashion. Corrective actions are recorded in column 8 of the HACCP plan form. The following are the corrective actions for the Guavapure Juice Company

**Table 12.5: Corrective Action Records**

If	There is no supplier agreement that the guavas are tree-picked
Then	Reject lot and Discontinue with the supplier until agreement is set up and fulfilled.

## 12.8 VERIFICATION PROCEDURES

### *Verification*

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.

### 12.8.1 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
- HACCP system verification:
  - Observations and reviews
  - Microbiological end-product testing
  - Regulatory inspections/audits

### 12.8.2 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. 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 control 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.

**By Whom:** 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.

### ***Examples of Validation Activities***

- 1) In our example, pasteurisation at  $>72^{\circ}\text{C}$  and  $> 6$  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.

### **12.8.3 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. 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.

#### **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 aflatoxin control in guava 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 on every 5 working days.

### **12.8.4 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 (outside expert/ consultant) to conduct the system-wide verification activities

#### **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.

#### **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 discussed earlier, 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 micro-organisms 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 millilitre (mL) sample (consisting of two 10 mL sub-samples) 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.

### 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.

**Table 12.6: Company-Established HACCP Verification Schedule**

Activity	Frequency
Initial validation of HACCP Plan	Prior to and during implementation of the plan
Subsequent validation of the HACCP plan	When critical limits change, significant changes in the process occur, equipment failure, system failure, or what other factors warrant
Verification of CCP monitoring as per HACCP plan	According to HACCP plan
Validation of HACCP plan	Annually

**Guavapure Juice Company  
HACCP plan worksheet**

Critical Control Point (CCP)	Hazard (s)	Critical Limits	Monitoring				Corrective action	Verification	Validation
			What	How	Frequency	Who			
CCP 1 Culling	Aflatoxin	Not more than 1% visually spoilt guavas after culling	Rot in 5 kg sample	Cut rot and weigh rot	Twice per production run	QC staff	Segregate and hold product for evaluation or destroy or divert for non-food use. Slow the production process; Re-train the linemen.	Review all records within one week of preparation.  Sample for presence of aflatoxin quarterly.	
CCP 2 Screen	Metal inclusion	Screen is intact	Integrity of screen	Daily	Pre-operation and Post operation	Production employee	Segregate product and re-process to eliminate metal pieces, pass through metal detector, or divert to non-food use or destroy.  Replace screen.	Review all records within one week of preparation	
CCP 3 Pasteurizer	<i>E. coli</i> and Protozoan pathogens	> 72°C for > 6 s	Temp. of juice  Set up pump speed for holding time > 6s	Temp. recorder  Visual inspection of pump speed	Continuous recording with hourly check up of record  Daily at beginning of operation	Pasteurizer operator  Pasteurizer operator	Segregate product and re-pasteurize or divert to non-food use.  Adjust temperature to > 72°C.  and /or adjust the pump for holding time of > 6 s  and/ or Clean and sanitize all equipment post-pasteurisation.	Documentation of process establishment  Check the accuracy of temperature recording device using approved thermometer daily.  Calibrate the approved thermometer annually.  Confirm the flow rate from the pump using salt water test.  Review all records within one week of preparation.	

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## 12.9 RECORD KEEPING PROCEDURES

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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.

### 12.9.1 Required Records

- Records of Sanitation Standard Operating Procedures (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 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.

### 12.9.2 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. 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)
- 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***

**4) *Verification Records***

**12.9.3 Verification Records**

Verification records 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: 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 are an option to record keeping. When using computerized records, include controls to ensure that records are authentic, accurate and protected from unauthorized changes.

**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 Guavapure Juice Company. The names of these forms should be entered in Column 10 of the HACCP plan form. These records include: Cull report: This form is used to record that the inspectors at the cull step are culling visually defective guavas; Screen integrity report: This form is used to record the integrity of the press screen.

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**Check Your Progress Exercise 1**



**Note:** a) Use the space below for your answers.

b) Compare your answers with those given at the end of the unit.

1) What is hazard analysis worksheet?

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2) What were biological and chemical hazard identified during the pasteurisation of refrigerated guava juice at the receiving steps?

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3) What do you understand by control measures?

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4) What are critical limits?

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5) What is the purpose of monitoring?

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6) What are elements of verification?

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7) What is the role of regulatory agencies in HACCP Plan verification?

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## 12.10 LET US SUM UP

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Through the example of Guavapure Juice Company, we learnt the application of the seven principles of HACCP. We learnt that it is very important to properly draw the systematic flowchart for the entire operation with all the inputs in the process affecting the final product. In addition to this exercise, it is very important to comply with the prerequisite norms with respect to plot location and layout, water quality, Sanitation, General Cleanliness, Personnel health and hygiene etc. as discussed in Unit 10. If a company adheres to both the prerequisite norms and HACCP properly, most hazards will be averted. It should be kept in mind that the HACCP worksheet should be reviewed as per development in view of the latest scientific research, disease outbreak, adulteration or legislations. The students should please note that the above example is purely for demonstration purposes, and the same might not be applicable to specific juice processing plants depending on their operations, raw materials and nature of hazards, equipment and packaging material.

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## 12.11 KEY WORDS

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**Hazard Analysis Worksheet** : It is the record of the deliberations of HACCP team during hazard analysis.

**Corrective Actions** : Corrective actions are the procedures to be followed when a deviation occurs and critical limits are violated at a CCP. The options include isolation and holding product for safety evaluation, diverting the product to another line where deviation would not be considered critical, reprocessing or destroying the product.

- Validation** : The purpose of validation is to provide objective evidence that all essential elements have a scientific basis and represent a process approach to control Food Safety hazards associated with a specific product is process.
- Calibration** : Verification activities at CCPs include calibration of monitoring devices to assure the accuracy of the measurement taken. Calibration is conducted to verify that monitoring results are accurate.

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## 12.12 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

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Your answer should include the following points.

### Check Your Progress Exercise 1

- 1) Hazard analysis worksheet is the documented record of decisions during hazard analysis. It includes processing/ingredients steps identification of potential hazards, evaluation of the significance of hazard, a justification for the decision and proposed control measures.
- 2) Vegetative pathogens and cryptosporidium, are biological and aflatoxin and pesticide residues are chemical hazards.
- 3) Actions and activities that can be used to prevent or eliminate a food hazard.
- 4) Boundaries that are used to ensure that an operation produces safe products. For each CCP there are one or two CL for each hazards.
- 5)
  - Track the operation of process and enable the identification of trends towards is CL that may trigger process adjustment.
  - Identify the loss of control.
  - Provide written documentation of the process control system.
- 6)
  - Calibration of monitoring devices
  - Review of calibration records
  - CCP record review
  - Monitoring records
  - Corrective action records
  - HACCP system verification
  - Observations and review
  - Microbiological and product testing
  - Regulatory inspections/audit
- 7) Verification of effectiveness of HACCP Plans.

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## 12.13 SUGGESTED READING

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Juice HACCP Training Curriculum, First edition (August 2002) *Juice HACCP Alliance, Food and Drug Administration.*

Kader, A.A. and Rolle, R.S. (2004). *The Role of Post-Harvest Management in Assuring the Quality and Safety of Horticultural Produce.* Food and Agriculture Organisation of the United Nations, Rome.

Naqvi, S.A.M.H. and Misra, A.K. (2004). *Guava Diseases — their Symptoms, Causes and Management Diseases of Fruits and Vegetables,* Springer, Netherlands.

