Indira Gandhi
National Open University
School of Agriculture

MVP-003
Principles of Food Safety and Quality Management

Block

3

HACCP

Programme and Course Design Committee

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Director General, FICCI

Sh. S. Dave
Director, APEDA

Dr. A.K. Sharma
Head, Food Technology
BARC, Mumbai

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Dr. J.S. Sindhu, Senior Consultant, SOA

Dr. P. Vijayakumar, Lecturer, SOA

Dr. Mita Sinhamahapatra, Lecturer, SOA

Dr. Lalita Kumar, SOS

Programme Coordinators: Sh. S. Dave, Dr. B.S. Hansra, Dr. M.K.Salooja and Dr. S.K. Yadav

Block Preparation Team

Block Author
Dr. Shalini Gaur, Assistant Director
(Agri-business), NPC, New Delhi
(Unit-9,10,11,12)

Editors
Mr. T. Appa Ji Rao, Consultant
The Quality Catalyst
Mrs. Amita Verma, SOA, IGNOU
Dr. M.K. Salooja, SOA, IGNOU
Dr. J.S. Sindhu, SOA, IGNOU

Course Coordinators: Dr. B.S. Hansra, Dr. M.K. Salooja, Mrs. Amita Verma and Dr. Shalini G. Rudra.

Material Production

Sh. Rajiv Girdhar	Miss. Rajshree Saini	Mrs. Geeta Negi, Mr. Bhim
Section Officer (P)	Proof Reader	Mr. Chandra Prakash
SOA, IGNOU	SOA, IGNOU	Word Processing

August, 2009

ISBN:978-81-266-3960-1

Further information on the Indira Gandhi National Open University courses may be obtained from the University's office at Maidan Garhi, New Delhi - 110 068 or the official website of IGNOU at www.ignou.ac.in.

Printed and published on behalf of Indira Gandhi National Open University by the Director, School of Agriculture.

Laser Composed by: Tessa Media & Computers, C-206, A.F.E.-II, Okhla, New Delhi-110025

Printed:

BLOCK 3 HACCP

Food is subjected to deterioration/contamination during production, processing, transport and storage. The physical, chemical and microbiological agents which may result in deterioration of food quality are identified as hazards in a process. The process is then monitored and designed in such way that the identified hazards are prevented from occurring. This preventive approach is called as Hazard Analysis and Critical Control Point (HACCP) and has been universally accepted as a management tool to safeguard food quality. In this block, we shall acquaint with the history, structure, principles and application of HACCP through case study. We shall work through various steps to form a complete HACCP plan.

Unit 9 History, Background and Structure of HACCP outlines the historical advent of HACCP and its development, needs and advantages. Thereafter its structure and the seven principles are outlined in this unit.

Unit 10 HACCP Prerequisites and Good Hygienic Practices provides an insight into the basic facilities, infrastructure and systems needed in a food processing establishment before HACCP is operationalized. These also comprise of generally accepted Good Hygienic Practices as recommended in most of the food quality systems.

Unit 11 Principles and Implementation of HACCP explain the detailed description of each principle and numerous ways to apply these principles in practice.

Unit 12 Case Studies on HACCP enumerates a case study, and chart the development of HACCP plan through each stage of processing. This however serves only as an example, the actual situations may vary from each plant and its process.

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UNIT 9 HISTORY, BACKGROUND AND STRUCTURE OF HACCP

Structure

9.0 OBJECTIVES

This unit contains the information necessary for you or a team to:

- have a basic understanding of the principal HACCP activities and terminology;
- adopt a common approach for the identification of hazards, critical control points and critical limits; and
- understand and be aware of food safety practices.

9.1 INTRODUCTION

Hazard Analysis and Critical Control Point (HACCP) is a process control system designed to identify and prevent microbial and other hazards in food production. It includes steps designed to prevent problems before they occur and to correct deviations as soon as they are detected. Such preventive control system with documentation and verification are widely recognised by scientific authorities and international organisations as the most effective approach available for producing safe food.

- 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 micro-organisms, chemical adulterants, or physical contaminants.)

Dr. Bernard Schwetz on October 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. HACCP involves a system approach to identification of hazard, assessment of chances of occurrence of hazards during each phase, raw material procurement, manufacturing, distribution, usage of food products, and in defining the measures for hazard control. In doing so, the many drawbacks prevalent in the inspection approach are provided and HACCP overcomes shortcomings of reliance only on microbial testing. HACCP enables the producers, processors, distributors, exporters, etc., of food products to utilize technical resources efficiently and in a cost effective manner in assuring food safety. Food inspection too would be more systematic and therefore hassle-free. It would no doubt involve deployment of some additional finances initially but this would be more than compensated in the long run through consistently better quality and hence better prices and returns. HACCP has been endorsed worldwide by organisations such as *Codex Alimentarius* (a commission of the United Nations), the European Union, and by several countries including Canada, Australia, New Zealand and Japan. HACCP is a preventive system for ensuring food safety, but it is 'not a stand-alone system'. HACCP must be built upon key pre-requisite programs, such as Good Agricultural Practices (GAPs) and mandatory Good Manufacturing Practices (GMPs) (e.g., sanitation and personal hygiene programs) to make it work. 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 i.e.:

- Traditional methods evaluate processing practices on the day or days of inspection, while;
- 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.

9.2 FOOD CHAIN STEPS

There are different steps in the food chain:

1) Agrarian origin,

2) Transportation,

3) Storage,

4) Industrial processing, and

5) Handling by the consumer.

Every step must be covered by to ensure a high level of food safety. The whole food chain must be monitored. Various examples are cited to emphasize the care needed in the journey of the food from farm to the fork. This includes also the environment from which the food/ raw material has been sourced. Contamination/ spoilage/ bruising can occur during transportation. During faulty storage chambers/ conditions, mycotoxins can develop in cereals. During industrial processing, a minor fault in processing can lead to a major food infection outbreak for e.g. Tapeworm infection in under processed pork. Even the consumer may miss-handle the product, as in the packet needs to be stored under refrigeration but the product is kept at room temperature for a few days leading to development of bacterial toxins, or consumption after expiry date, etc.

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 the difference between HACCP and the traditional quality and safety evaluation procedures?

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2) Discuss HACCP approach in brief.

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3) What are the prerequisites in implementation of HACCP?

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4) What is meant by the term 'Farm to Fork'?

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9.3 FOOD HAZARDS

The safety of a food can be related directly to certain harmful substances that are present in food; these substances are food safety hazards. Hazard is defined as a biological, chemical, or physical agent in, or condition of, food with a potential to cause an adverse health effect. *Or* a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

There are three recognised categories of hazards. Biological hazards; Chemical hazards; and Physical hazards. The origin of these hazards can be from naturally occurring substances or agents in foods, from deterioration or decomposition of foods, or from contamination of foods with the hazard at various stages of their production, harvesting, storing, processing, distribution, preparation, and utilisation. For many hazards, government regulatory authorities have established acceptable level of the hazard in food. For some hazards, such as the pathogenic bacteria, there is zero tolerance i.e., the detection of the hazard in food is unacceptable.

The strategies used to address hazards in foods include:

1) The prevention or elimination of hazards, or
2) Reduction of the hazards to acceptable levels.

9.4 BIOLOGICAL HAZARDS

9.4.1 Bacteria

It is estimated that 30% of the food borne diseases in US are because of bacteria. In view of this, a brief discussion of the water borne/food borne bacterial pathogens is necessary before we proceed to the other type of hazards.

Gram negative pathogenic bacteria include:

1) Species of genera *Campylobacter*: *Campylobacter jejuni* and *C. coli* leading to *Campylobacter* enteritis, i.e., onset of gastroenteritis, fever, malaise, abdominal pain, headache, watery or sticky diarrhoea with minor traces of blood etc. The clinical symptoms may last for 10 days.

2) Salmonella: S*almonella typhimurium, S. paratyphi A and C* serotype*, S. sendai* can cause serious blood infection known as typhoid fever. The non-typhoidal strains of salmonella can cause intestinal infection lasting 1-2 days.

3) Diarrhoeagenic *Escherichia coli*: There are four categories of pathogenic *E.coli* viz.

   i) Enterohaemorrhagic *E. coli* (O157:H7)

ii) Enterotoxigenic *E. coli*

iii) Enteropathogenic *E.coli* (Diarrheagenic *E.coli*)

iv) Enteroinvasive *E.coli*

4) Shigella: *S. dysenteriae*

5) *Yersinia enterocolitica*: *Y. pestis* is the causative agent of plague, *Y. pseudotuberculosis* is primarily an animal pathogen but may infect humans after ingestion of contaminated food. They cause human yersiniosis, with bloody diarrhoea.

6) *Vibrio parahemolyticus*: cause gastro-enterititis including watery diarrhoea, headache, cramps

*Vibrio vulnificu*s

Vibrio cholerae: They produce heat stable enterotoxin too.

7) *Listeria monocytogenes*: Listeriosis is characterized by a severe syndrome causing meningitis, infection of central nervous system. It has a long incubation period of 2-3 months.

8) *Staphylococcus aureus*: causes infections involving the skin such as boils, wound infection, in severe cases may associate with pneumonia, meningitis, etc.

9) *Clostridium botulinum:* results in botulism causing neurological symptoms including visual disorders, paralysis.

Clostridium perfringens: may lead to symptoms ranging from simple wound infections to myonecrosis, postabortal infection, intravascular hemolysis, bacterimia, pneumonia, brain abscesses.

10) *Bacillus cereus*: Ingestion of contaminated food may lead to either diarrhoeal or emetic (nausea and vomiting) gastroenteristis. The spores are able to survive the cooking process, after which germination and subsequesnt proliferation of vegetative cells occurs at some point during storage.

11) Others like *Aeromonas* (dysentery)*, Brucella (*Brucellosis)*, Helicobacter* (Gastroenteristis, peptic/ gastric ulcers)*, Mycobacterium* (tuberculosis), *Streptococcus* (Bacteremia, endocarditis, meningitis, septic arthritis, respiratory tract and skin infection), *Pseudomonas* (infections of skin, ear, respiratory, urinary tract, bacterimia).

9.4.2 Parasites

Cyclospora cayetanensis: It is capable of causing prolonged illness with symptoms including non-bloody diarrhoea, nausea, vomiting, anorexia, bloating, malaise, fever and fatigue.

Cryptosporium parvum: In an immuno-competent individual, the symptoms may last till 23 days and be accompanied by watery diarrhoea associated with epigastric cramping, nausea and anorexia. In an immuno-compromised person, profuse diarrhoea may last for months or even years.

Giardia lamblia: After an incubation period of 12-20 days, individuals can experience subacute or chronic infections with symptoms including nausea, chills, low fever, watery diarrhoea, heartburn and reduced pancreatic function.

Sacrocystis hominis: Symptoms may include nausea, stomache and diarrhoea.

Toxoplasma gondii: Toxoplasmosis symptoms include fever, rash, headache, muscle aches and pain, swelling of lymph nodes and may persist for months.

Trichinella spiralis: It is typically associated with uncooked pork or pork products contaminated with encysted larvae. The symptoms after incubation period of 3-14 days include gastroenteritis, nausea, vomiting, headaches, fever, visual deficiencies, difficulty in breathing, chills, night sweating etc.

9.4.3 Viruses

Hepatitis A: It is associated with the fecal-oral route, and is prevalent in under-developed areas with poor sanitation. The onset of the infection is characterized by fever, malaise, nausea and vomiting. Later phase symptoms include a yellowish discoloration of mucous membranes, conjunctivae, sclera and skin, excretion of golden brown urine, and stool which is pale in colour.

Norwalk virus: Raw or slightly cooked fish and contaminated water are the major sources of this virus. Symptoms may include gastroenteritis like symptoms associated with nausea and vomiting.

Rotavirus: It is mostly associated with infection of infants and children. Infected individual, water or food may lead to this infection. Vomiting and diarrhoea for 3-8 days along with abdominal pain or fever are the major symptoms and may lead to even death.

9.5 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) Unintentional or incidental chemical contaminants
2) Naturally-occurring chemicals
3) Intentionally-added chemicals

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.

Hazards from Environmental Contaminants in Food

The United Nations Environmental Program (UNEP) identifies the 'Persistent Organic Pollutants' with two major pathways- Terrestrial and Aquatic. Some major industrial chemicals which end-up being a part of our food are listed in Table 9.1. Apart from these, radionuclides, veterinary drug residues are also important hazards to look for. Maximum residual limits are set for drug residues in milk in most countries.

Table 9.1: Major Food Contaminants of Industrial Origin

Chemical	Source	Food Contaminated
Polychlorinated biphenyls	Electric industry	Fish, Human milk
Dioxins	Impurities in chlorophenols, Incinerator emission	Fish, Milk, Beef fat
Pentachlorophenol	Wood preservative	Various foods
Dibenzofurans	Impurities in Poly Chlorophenols (PCP) and Poly Chlorobiphenyls (PCB)	Fish
Hexachlorobenzene	Fungicide by-product	Animal fat, Dairy products, Human milk
Mirex	Pesticide	Fish, Edible mammals, Human milk
DDT and related halogenated hydrocarbons	Pesticides	Fish, Human milk
Alkyl mercury compounds	Manufacture of chlorine-soda lye, acetaldehyde, seed dressing	Fish
Lead	Automobile exhaust emission, coal combustion, lead industry	Vegetables, Fruits
Cadmium	Sewage sludge, Smelter operations	Grains, Vegetables, Meat products
Arsenic	Smelter operations	Milk, Fruits, Vegetables
Tin	Canning industry	Canned foods

Naturally – Occurring Chemicals (including allergens)

These chemicals are derived from a variety of plants, animals or micro-organisms. In most cases, these naturally-occurring chemicals are found prior to or during harvest. Naturally occurring chemicals include: allergens, mold toxins and naturally occurring toxins in food.

Allergens: The common sources of allergens in food are Egg, milk, nuts, seafood and soy. Certain varieties or species produce an allergic reaction in sensitive people. It is particularly important that foods containing components that have these ingredients clearly identify on the label. Controls might also 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. Such cross-contamination of foods may be classified in unintentional contamination of foods.

Mold toxins: Molds may produce aflatoxins in some foods, most common among them are apples, nuts and cereal grains. Examples are Alternaria toxins, Fumonisin, Ochratoxin, Patulin and Vomitoxin. Most countries have regulations governing their presence in foods.

Toxic components in food: Some plants/ food have toxic parts or chemicals naturally e.g. certain mushrooms, algae etc.

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.

- **Direct additives**
  - Preservatives (e.g., sodium benzoate and sulfiting agents)
  - Nutritional additives (e.g., calcium, vitamins)
  - Color additives
- **Indirect**
  - Packaging materials
  - Processing plant chemicals like lubricants (food grade) and sanitizers

9.6 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. Physical hazards present in foods are classified as glass, plastics and metals. The common sources of these agents are also mentioned below.

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 like jewellery (bracelets, bangles, rings, earrings), pen and its cap.

Appropriate controls like filtering, magnetic separators may need to be used to avoid these hazards in food.

Check Your Progress Exercise 2

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

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

1) Define Hazard and classify them.

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2) Which biological hazards may occur in foods? What are the reasons for them being present?

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3) What are incidental chemical hazards?

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4) Give three examples of physical hazards in food.

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9.7 HISTORY OF HACCP

The development and the initial use of HACCP can be traced to joint effort of the Pillsbury Company, together with the National Aeronautics and Space Administration (NASA) and the U.S. Army Laboratories at Natick. Their objective was to develop a strategy that would ensure that foods required for the space program were free from any unacceptable health risk. The Pillsbury Company, along with NASA and the US Army Natick laboratories pioneered the development of the HACCP approach for preventing unacceptable levels of food safety hazards.

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. 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 recognised 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.

Table 9.2: Chronology of HACCP Development

Year	Event
1958	Foundation of the NASA (National Aeronautics and Space Administration)
1959	Development of the HACCP concept to assure one hundred per cent safety of food to be used in space.
1971	HACCP system was published and documented in the USA.
1985	National Academy of Science (NAS) recommended the use of the system. Worldwide the system became used and the FAO/WHO Codex Alimentarius (Food and Agriculture Organisation/World Health Organisation) cited the system in the Codex.
1993	The European regulation 93/43 EG from 14.7.93 provides the use of the system for the production of food.
1997	The *Codex Code on General Principles of Food Hygiene* was revised and included recommendations for the application of the Codex HACCP Guidelines.
1998	With coming into force on the August the 8th of 1998 the Hygiene Verordnung (German Hygiene Rule) demands the use of the HACCP system in Germany.
2007	Integration of HACCP with ISO 9001 to formulate Food Safety and Standards Act (ISO 22000).

Since then, the HACCP system has become the internationally-recognised and accepted method for food safety assurance. 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. 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.

While it was originally developed to ensure microbiological safety of foodstuffs, it has been further broadened to include chemical and physical hazards in foods. The recent growing worldwide concern about food safety by public health authorities, consumers and other concerned parties, to a great extent due to WHO's advocacy in this field, and the continuous reports of food borne outbreaks have been a major impetus in the application of the HACCP system.

The European hygiene rule defined in the paper 94/356/EG demands for an HACCP-concept which can be integrated in a quality management system. This HACCP concept has to be developed for all products of every factory.

The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems. While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

9.8 BENEFITS AND BARRIERS IN IMPLEMENTING HACCP

Worldwide, it is recognised that the application of the HACCP system to food production and preparation has clear benefits and the potential of enhancing food safety and preventing many cases of food borne diseases. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to final consumer and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety. Let us now enumerate the benefits of implementing HACCP system.

9.8.1 Benefits

There are clear benefits of implementing HACCP for all sectors: government, food industry and consumers alike. The following benefits should encourage businesses and governments to implement HACCP:

I) Benefits to consumers

- Reduced risk of food borne disease;
- Increased awareness of basic hygiene;
- Increased confidence in the food supply; and
- Improved quality of life (health and socio-economic).

II) Benefits to industry

- Increased consumer and/or government confidence;
- Reduced legal and insurance costs;
- Increased market access;
- Reduction in production costs (reduced recall/wastage of food);
- Improved product consistency;
- Improved staff-management commitment to food safety; and
- Decreased business risk.

III) Benefits to governments

- Improved public health;
- More efficient and targeted food control;
- Reduced public health costs;
- Trade facilitation; and
- Increased confidence of the community in the food supply.

9.8.2 Barriers

A number of barriers impede the implementation of HACCP in small or less developed businesses. These barriers vary from country to country or from sector to sector. Some may be due to internal factors in individual businesses, e.g. the level of knowledge or resources available to a business. Others may be due to external factors, such as the availability of government or industry support.

The barriers may include:

- Lack of government commitment;
- Lack of customer and business demand;
- Absence of legal requirements;
- Financial constraints;
- Human resource constraints;
- Lack of expertise and/or technical support;
- Inadequate infrastructure and facilities; and
- Inadequate communications.

9.9 HACCP PRINCIPLES

The HACCP system consists of the following seven principles:

Principle 1

Conduct a hazard analysis.

Principle 2

Determine the Critical Control Points (CCPs).

Principle 3

Establish critical limit(s).

Principle 4

Establish a system to monitor control of the CCP.

Principle 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

In brief, we need to first identify the likely food safety hazards in food processing beginning from the time food is harvested or animals are reared (in case of animal foods) to transportation, storage, processing, packing, warehousing, display till consumption. Thereafter, we need to see how these hazards relate to operational steps i.e., at which points of the production chain, these hazards may enter/affect the food. Then appropriate control measures are devised to prevent these hazards from entering/ affecting the food. Critical control points are identified in the processing line such that extra care is taken to ensure the absence of the hazard at that step. In case of each hazard or important step of processing, critical limits need to be set. For e.g. in case of qualitative point, whether the glass is present in the ice-cream or not, the critical limit is zero. In case of quantitative measure, say for example, the pasteurisation temperature of milk, it must not be below 71.6 ^{o}C, so this temperature is the critical limit for pasteurisation temperature else the *Mycobacterium tuberculosis* and *Coxiella burnettii* may survive in the milk. Now, we need to check whether the milk reached 71.6 ^{o}C or not so we design and incorporate some monitoring procedures like thermostats to verify it. If however, the milk does not reach the pasteurisation temperature, then corrective actions are also detailed and system is installed for the same. In case of milk, if the thermostat detects lesser temperature of the heated milk, the milk is sent to a tank and processed again. In the end, procedures for verification that the hazard is not present are laid out.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a multidisciplinary approach; this multidisciplined approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry, and engineering according to the particular study.

Guidelines for the Application of the HACCP System

Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Good Manufacturing Practices. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. HACCP should be applied to each specific operation separately. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

It is important when applying HACCP to be flexible where appropriate, given the context.

Check Your Progress Exercise 3

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

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

1) Define critical control point, control, critical limit.

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2) Enlist the principles of HACCP.

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3) How does industry benefit from implementing HACCP?

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4) Who pioneered HACCP and for whom?

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9.10 PROCESS OF HACCP CERTIFICATION

In India, BIS offers two Certification schemes to the food industry.

i) HACCP Stand-alone Certification against IS 15000:1998; and

ii) HACCP based Quality System Certification provides for two Certification through one audit Certification of Quality System against IS/ISO 9000 and Certification of HACCP against IS 15000:1998.

How to obtain licence?

1) Establish a documented quality system and /or HACCP implementation plan and ensure its effectiveness.

2) Submit application on prescribed proforma (Form IV of the BIS) along with the questionnaire (Form XI of the BIS) and necessary fees to Dy. Director General (of respective region).

3) Submit the quality manual and/ or concerned documents, when asked for.

4) Arrange audit by BIS Assessment Team.

5) Take actions on non-conformities observed by assessment team and get them verified. If found satisfactory, grant of licence is recommended.

6) Obtain the Licence.

The licence will enable the company to compete effectively in national and international markets.

1) **The Marine Product Export Development Authority**
MPEDA House, Panampilly Avenue
P.B.No.4272
Kochi- 682036
Export Inspection Agencies/Export Inspection Council

2) **Kerala Bureau of Industrial Promotion**
TC IX/2197, Kurups Lane,
Sasthamangalam P.O.
Thiruvananthanpuram-695 010
Tel: 0471-2311882
Fax: 0471-2311883

3) **QSI (India) Certification P. Ltd.**
557, Sector-1, Vidyadhar Nagar
Jaipur-302023
Rajasthan
Tel. No.0141-2236895
Fax: 91-141-2236133
E-mail: qsicert@gmail.com
Website: www.qsi.india.com

9.11 LET US SUM UP

HACCP is a safety management system which involves a systematic approach for identification of hazard, assessment of chances of occurrence of hazards during each phase, raw material procurement, manufacturing, distribution, usage of food products, and in defining the measures for hazard control. The safety of a food can be related directly to certain harmful substances that are present in food; these substances are food safety hazards. Hazard is defined as a biological, chemical, or physical agent in, or condition of, food with a potential to cause an adverse health effect. The HACCP system consists of the following seven principles, i) Conduct a hazard analysis, ii) Determine the Critical Control Points (CCPs), iii) Establish critical limit(s), iv) Establish a system to monitor control of the CCP, v) Establish the corrective action to be taken when monitoring

indicates that a particular CCP is not under control, vi) Establish procedures for verification to confirm that the HACCP system is working effectively, and vii) Establish documentation concerning all procedures and records appropriate to these principles and their application. Thus HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

9.12 KEY WORDS

Checklist : A list that contains points/elements that may be considered during assessment. It is used as an aidememoire to promote uniformity in assessment.

Control (noun) : The state wherein correct procedures are being followed and criteria are being met.

Control (verb) : To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control Measure : An action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective Action : Any action to be taken when the results of monitoring the CCP indicate a loss of control.

Critical Control Point (CCP) : A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit : A value which separates acceptability from unacceptability.

Deviation : Failure to meet a critical limit.

Flow Diagram : A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP : A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP Plan : A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard : A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Analysis : The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor : The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step : A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation : Obtaining evidence that the elements of the HACCP plan are effective.

Verification : The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

9.13 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Your answer should include the following points:

Check Your Progress Exercise 1

1) Traditional methods evaluate processing practices on the day or days of inspection, while; 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.

2) HACCP involves a avoided approach to identification of hazard, assessment of chances of occurrence of hazards during each phase, raw material procurement, manufacturing, distribution, usage of food products, and in defining the measures for hazard control. In doing so, the many drawbacks prevalent in the inspection approach are avoided and HACCP overcomes shortcomings of reliance only on microbial testing.

3) Good Agricultural Practices (GAPs) and mandatory Good Manufacturing Practices (GMPs) (e.g., sanitation and personal hygiene programs) to make it work.

4) Agrarian origin, Transportation, Storage, Industrial processing, and Handling by the consumer.

Check Your Progress Exercise 2

1) A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

2) Bacterial hazards/ Pathogenic bacteria; Virus infections and Parasites.

   Poor sanitation, infected water or food, fecal contamination, improper storage, and Improper cooking.

3) Chemicals can become part of a food without being intentionally-added.

4) Broken glass piece; Plastic cap or strand; nail.

Check Your Progress Exercise 3

1) Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A value which separates acceptability from unacceptability.

2) i) Conduct a hazard analysis.
   ii) Determine the Critical Control Points (CCPs).
   iii) Establish critical limit(s).
   iv) Establish a system to monitor control of the CCP.
   v) Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
   vi) Establish procedures for verification to confirm that the HACCP system is working effectively.
   vii) Establish documentation concerning all procedures and records appropriate to these principles and their application.

3) Increased consumer and/or government confidence; Reduced legal and insurance costs; Increased market access; Reduction in production costs (reduced recall/ wastage of food); Improved product consistency; Improved staff-management commitment to food safety; and Decreased business risk.

4) The Pillsbury Company, along with NASA and the US Army Natick laboratories.

9.14 SUGGESTED READING

HACCP *Introducing the Hazard Analysis and Critical Control Points System* (1997) Food Safety Series, Food Safety Unit, World Health Organisation.

Inteaz Ali (2004). *Food Quality Assurance: Principles and Practice*. CRC Press LLC, Florida, USA.

Schmidt, R.H. and Rodrick, G.E. (2003). *Food Safety Handbook*. Wiley Inter Science, A John Wiley and Sons Publication, New Jersey, Canada.

UNIT 10 HACCP PREREQUISITES AND GOOD HYGIENIC PRACTICES

Structure

10.0 OBJECTIVES

After reading this unit, we shall be able to:

- grasp the requirements for good hygienic practices (GHP) and sanitation for food establishment;
- understand the need for safety and quality procedures in the process and establishment as whole;
- acquire skills to implement the basic food safety and quality practices in the food plant; and
- design and develop practices and measures to ensure food is produced appropriately under hygienic conditions.

10.1 INTRODUCTION

The food chain begins from agricultural farm or animal rearing unit. Therefore for the ultimate food served or sold in the markets either in processed form or fresh, it is necessary that the steps to prevent hazards should begin there itself. Thus, primary production should be managed to ensure that food is safe and suitable for its intended use. This also includes avoiding the use of areas where the environment poses a threat to the safety of food like breeding fish in a lake situated near industry emitting heavy metal waste. The control of contaminants, pests and diseases of animals and plants needs to be done in such a way as not to pose a threat to food safety. The main objective of having pre-requisites (PRPs) in place is to reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

10.2 ENVIRONMENTAL HYGIENE

For producing safe food, we should consider potential sources of contamination from the environment throughout the food chain. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food. The plant site should be chosen such that it is free from conditions that might interfere with the sanitary operation of the plant, including:

- no land use conflicts or potential conflicts with adjacent sites; and
- set reasonably apart from barnyards, waste disposal facilities, incompatible processing facilities, and any offensive trades.

This could include excessive dust, foul odours, smoke and other similar conditions. Generally, a minimum set-back of 30 meters is recommended from potential sources of contamination. However, a greater or lesser distance could be accepted depending on specific site conditions.

10.2.1 Hygienic Production of Food

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where there are more chances of contamination. We shall need to take specific measures to minimize these chances/ instances. We have already discussed many physical, chemical and biological hazards which could contaminate food.

Specifically the producers/ processors should as far as practicable implement measures to:

- control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and
- protect food sources from faecal and other contamination.

Care should be taken to manage wastes, and store harmful substances appropriately in such a way that the wastes should not get mixed with the product at any point in the chain. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and are being encouraged as Good Agricultural Practices/ Good Animal Husbandry Practices both by government, and private retail chains through contract farming.

10.2.2 Handling, Storage and Transportation

We should install and implement procedures for:

- cleaning and sorting food and food ingredients to segregate material which is unfit for human consumption;
- disposal of any rejected material in a hygienic and controlled manner; and
- preventing food and food ingredients from being contaminated by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

10.2.3 Cleaning, Maintenance and Personnel Hygiene at Primary Production

There should be appropriate facilities and procedures to ensure that all necessary cleaning and maintenance work for raw material, plant and machinery is carried out effectively. Personnel hygiene is a very important aspect to be considered for any food safety and quality programme efficacy.

10.3 DESIGN AND FACILITIES IN THE ESTABLISHMENT

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled. Depending on the nature of the operations, and the risks associated

with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

— contamination is minimized;

— design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination;

— surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;

— where appropriate, suitable facilities are available for temperature, humidity and other controls; and

— there is effective protection against pest access and harbourage.

10.3.1 Location

Establishments

While deciding the location of the plant we need to consider any potential sources of contamination as well as the effectiveness of preventive measures to counter them if any. In particular, establishments should normally be located away from:

- environmentally polluted areas and industrial activities;
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

The general surroundings of a dairy plant should not attract rodents, flies and other insects which could then gain access to the dairy plant.

Building Exterior

- exterior structure shall be designed and maintained to prevent entry of pests.
- areas surrounding exterior of dairy plant shall be:
  - drained to minimize standing water;
  - free of uncontrolled vegetation, stored items, garbage, or any other condition in close proximity to the plant that could harbour pests; and
  - maintained to minimize creation of dust.

10.3.2 Equipment

Equipment should be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates, good hygiene practices, including monitoring.

10.4 PREMISES AND ROOMS

10.4.1 Design and Layout

Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

10.4.2 Internal Structures and Fittings

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular, the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

A) Walls

- shall be smooth, washable and light coloured;
- suitable materials would include tile, concrete, plaster, sealed brick, or other equivalent materials;
- kept in good repair and cleanliness;
- free of flakes, pitting and cracks;
- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use; and
- walls and partitions should have a smooth surface up to a height appropriate to the operation.

Properly finished walls and ceilings are more easily kept clean and as such, are more likely to be kept clean. A light coloured finish aids in the even distribution of light and the detection of unclean conditions which can then be corrected.

B) Floors

Floors of all rooms in which food materials are received, processed or stored shall:

- be constructed of sealed concrete or other equally impervious and easily cleanable material,
- be smooth and not allow for pooling of liquids,
- where applicable, be sufficiently sloped for liquids to drain. Generally, a minimum slope of 2% or more is recommended,
- floor to wall joints should be covered (generally a 15 cm extension is recommended) and sealed for ease of cleaning and maintenance, and
- be kept clean and in good repair.

Floors in storage rooms used for storing dry ingredients or packaging materials, or utility rooms (electrical service, etc.) shall be smooth and cleanable.

C) Ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles.

D) Windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed.

E) Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect.

F) Working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

G) Floor Drains

- Floor drains shall be provided, where necessary, to effectively prevent accumulation of liquids.
- Drain lines shall be sloped, individually trapped, and properly vented to outside air.
- Floor drains shall be separate from sewage drains to a point outside the plant.
- Equipped with removable covers and located so that they are accessible for cleaning and sanitizing.
- For equipment discharging large volumes of water, drainage shall be designed to prevent flooding of surrounding areas.
- Shall be constructed such that there is no cross-connection between the drains or drain lines, and
  - the water supply,
  - the food product lines or equipment, or
  - the CIP system.

The accumulation of liquids on the floor of a dairy plant can lead to an unclean environment which increases the likelihood of contamination of the food products. Properly designed drains and drain lines can eliminate the accumulation of liquids. Trapping and venting of drains prevents sewer gases and pests from entering the plant. The need for the separation of floor drains from sewage drains is to prevent the contamination of the floor drains with human wastes. Human wastes can contain pathogenic bacteria. Contamination of the floor drains with this material increases the likelihood of contamination of the food plant environment with the waste material.

H) Overhead Utility Lines

- must be suspended away from work areas or areas of exposed food products to minimize the potential for contamination;
- where appropriate, insulated to prevent condensation and covered with suitable material for ease of cleaning; and
- lines carrying contaminated or hazardous materials, such as sewer or floor drain lines, should be located sufficiently distant from any product or product contact surfaces or other appropriate actions must be taken so as to ensure there is no risk of contamination.

I) Stairs

- must be located so as to minimize the risk of product contamination;
- constructed of impervious materials that are cleanable;
- catwalks or mezzanines located over processing areas, and where splashing or dripping could pose a contamination risk; and

- must be of solid masonry or metal construction.

Where appropriate, narrow raised walkways for overseeing (catwalks) and balconies (mezzanines) must be equipped with raised edges of a height sufficient to prevent the spread of contamination. Stairs, catwalks or mezzanines over or near work areas or exposed product can act as a source of contamination (eg. dust, dripping liquids) of food products. Raised edges or properly designed splash guards of a height sufficient to contain any splashing from filling to work areas or exposed product below can be effective in minimizing the risk of contamination. Stairs, catwalks or mezzanines should be constructed of materials easy to clean.

J) Exterior Openings

- All doors leading to the outside shall be self-closing and tight fitting.
- Doors, windows and all other openings leading to the outside shall be pest proofed with effective means such as:
  - screening,
  - electric screen panels,
  - fans or air curtains which provide sufficient velocity so as to prevent entrance of flies,
  - strip curtains, or
  - any other method which prevents entrance of pests.

Freedom from pests in the dairy plant reduces the likelihood of contamination of dairy products. Pests may carry pathogenic organisms on and within their bodies. These pathogens could be spread through the plant, including in the equipment as the pests move about the plant.

K) Ventilation

- Adequate ventilation is required to prevent excessive dust accumulation, odours, aerosols or build-up of condensation droplets on equipment, walls and ceilings.
- Designed to cause the direction of air flow to be from the processing areas outward to other areas of the plant.
- Air intakes and outlets shall be located to minimize the chance of contamination.
- Air intakes and outlets and filters shall be maintained to minimize contamination.
- Control ambient temperature.
- Control humidity to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned. Unclean air, excessive dust, odours, or build-up of condensation are all potential sources of contamination for dairy products. Air supplied to the processing plant should be of sufficient quality so as not to contaminate the equipment or the dairy products, and result in a positive air pressure in the processing areas.

10.4.3 Temporary/ Mobile Premises and Vending Machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents, vending carts and marquees. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

This is more applicable in the current Indian scenario where the small scale food vendors and other such establishments are mobilized to cater safe and quality food.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

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) State the objectives of having Prerequisite progamme for HACCP.

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2) List any four suggestions for a food plant for the stairs.

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3) How does the location of the food safety plant affect food safety?

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10.5 EQUIPMENTS

10.5.1 General

Equipments and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained

to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

10.5.2 Food Control and Monitoring Equipments

In addition to the general requirements in above paragraph, equipment used to cook, heat treat, cool, store or freeze, should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP-based plans can be monitored; and
- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

For example, a dairy plant HTST pasteurizer's Safety Thermal Limit Recorder (STLR).

1) Shall be designed, installed and operated to:
    - record the temperature of the product in the sensing chamber,
    - monitor, control, indicate, and record the position of the flow diversion device, and
    - supply the source of power for the flow control device and the flow diversion device solenoid during forward flow.
2) The recording chart shall provide an accurate record of the processing temperature. Generally, this is achieved by:
    - time scale divisions that are not more than 15 minutes and spaced not less than 6.4 mm apart at the flow diversion temperature,
    - pens that produce a line not greater than 0.7 mm wide,
    - temperature charts graduated 0.5°C (1.0°F) divisions,
    - a temperature range or span on the recording chart that is not less than 17°C (30°F) with the actual diversion temperature being 7°C (12°F) within the temperature span limits,
    - where resistance thermal devices (RTD's) are used, they shall be of the fail safe type (utilizing two separate RTD's), and
    - shall be equipped with a positive mechanism to prevent chart slippage and manual rotation.
3) Shall be tested on installation and at a frequency as specified in the procedures recommended by the authorities.

4) The circular chart must rotate one revolution in not more than 12 hours.

5) The control panel for the STLR must be sealable.

10.5.3 Containers for Waste and Inedible Substances

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

- Sewage disposal systems shall meet all local or provincial requirements.
- Disposal of sewage and solid wastes shall be done in a sanitary manner and not expose the plant environment or the food products to risk of contamination.

Solid waste containers **within** the plant shall be:

- sufficient in number, accessible, and be emptied daily or when full;
- designed to prevent the attraction of pests or contribute to airborne contamination; and
- garbage storage rooms and containers shall be emptied, cleaned and sanitized on a regular basis.

Solid waste containers located **outside** the plant shall be:

- equipped with covers and closed when not in use;
- maintained in a manner not to attract pests; and
- emptied, cleaned and sanitized regularly.

10.6 UTILITIES

10.6.1 Water Supply

An adequate water supply is necessary to ensure effective cleaning and other processing operations. As such, it must be supplied in quantities that encourage adequate rinsing and cleaning. The water supply used in cleaning and other processing operations must be of a safe and sanitary quality in order to avoid the contamination of the equipment, containers, or food products.

There have been instances where cross-connections between the water supply and the CIP system have contaminated the water supply. Inadequate controls over automatic chlorinator systems could result in a water supply that is non-potable.

- An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.
- Potable water should be as specified in the latest edition of PFA Guidelines for Drinking Water Quality, or water of a higher standard.
- Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be

identified and shall not connect with, or allow reflux into, potable water systems.

- Hot and cold water, under adequate pressure, and in sufficient quantities, shall be provided.
- Water samples shall be tested at a government or accredited laboratory and at a frequency deemed necessary by the regulatory agency.
- Only potable water shall be used in contact with product or product contact surfaces.
- There shall be no possibility of a cross-contamination between the water supply and CIP systems.
- Where automatic chlorinator systems are used, controls and procedures shall be established to ensure quality control for water potability. These include:
  - an automatic metering device for adding chlorine in the correct concentration, and
  - at least once daily, tests shall be made using a reliable chlorine test kit to determine the free residual chlorine level.

  Records of residual chlorine tests should be maintained.

10.6.2 Drainage and Waste Disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided. You may recall that we have already discussed some specific points for consideration in section 10.4.2 G.

10.6.3 Cleaning

Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Cleaning facilities should be:

- adequately designed, constructed, and maintained to prevent contamination,
- provided with potable water at temperatures appropriate for the cleaning chemicals used. Generally a minimum of 60°C is recommended when hot water is required, and
- adequately separated from food storage, processing and packaging areas to prevent contamination.

The cleaning machinery should preferably be constructed of corrosion resistant materials capable of being easily cleaned.

These features provide suitable environmental conditions, permit adequate cleaning and sanitation, minimize migration of extraneous material, prevent access by pests, and allow employees to fulfil their duties. Regular maintenance of cleaning facilities is required to maintain adequacy of the premises.

There should be written procedures and specifications for the cleaning-in-place (CIP) and Cleaning-out-of-Place for all production and storage areas of the plant including specific equipment, lines etc.

- the personnel responsible,

- areas to be cleaned,
- the frequency of the activity,
- the chemicals and concentrations used,
- mixing instructions for chemical solutions,
- temperature requirements, and
- procedures for cleaning and sanitizing.

Special sanitation and housekeeping procedures required during production shall be specified within the written programme.

The effectiveness of the cleaning program should be monitored and verified. Generally, this is accomplished by (although not limited to) routine inspection of premises and equipment and/or microbiological testing. Corrective action shall be taken where deficiencies are identified through monitoring. The plant personnel should maintain records that verify the cleaning program. These should be maintained for a minimum of one year or until after expiration of the date code if more than one year or as determined by the regulatory agency.

10.6.4 Personnel Hygiene Facilities and Toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

Hand washing: There should be accessible hand washing stations at appropriate locations, with potable running water at a suitable sanitary temperature. Soap/ other hand sanitizing solutions, sanitary hand drying equipment or facilities for employees to wash and dry hand are required. The water control devices/ taps should be such that recontamination of hands is prevented. Garbage bin is to be provided if disposable hand towels are provided to dry hands. Also easily understandable signs to remind the employees to wash hands in correct manner should be installed.

Wash rooms and Toilet rooms: Wash rooms and toilet rooms should be separated from and should not open directly into the food storage, handling and processing areas. Wash rooms should be provided with adequate handwashing facilities, covered garbage bins, and easily understandable signs to serve as reminders to the employees. Separate facilities for men and women employees are recommended.

Change rooms: Change rooms for the employees to change their personal clothing into uniforms and footwear should be provided. Lockable or suitable storage racks should be provided to store clothing, footwear and other personal items. The designs to these lockers should be such as to facilitate easy cleaning. Separate change rooms for men and women should be present. Preferably, these changing rooms should be in continuum with the production area.

Lunch rooms and Break rooms: Designated lunch and break rooms should be designated for employees. The Lunch rooms should be neat, with appropriate facilities for food storage and covered garbage bins. If smoking is permitted in the lunch/ break rooms, it should be restricted to these areas and provided with ashtrays.

All such facilities should be suitably located and designated.

10.6.5 Temperature Control

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

It would be appropriate to discuss the concerns regarding ice and steam used to cool and heat the food, or other medium respectively. The ice for use in food plants should be made from potable water, and should be stored and handled such as to prevent contamination. Steam that contacts with food or food contact surfaces should also be generated from potable water. Only approved chemicals should be used in boilers which generate steam for such purposes.

10.6.6 Lighting

Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

10.6.7 Storage

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals (e.g. cleaning materials, lubricants, fuels) should be provided such as warehouses, storage rooms, silos, tanks, vats, bins.

Where appropriate, food storage facilities should be designed and constructed to:

- permit adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination, cross contamination, during storage; and
- where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food.

Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

Also, appropriate facilities for storing idle food processing equipment, tools, materials and spare parts for repair and maintenance of equipment should be provided.

10.7 CONTROL OF OPERATIONS

The primary consideration is to prevent contamination, cross-contamination and deterioration of products from the time they arrive in the plant/ establishment to storage, processing, subsequent move to designated storage areas and shipment, delivery to the point of use.

10.7.1 Transportation and Receiving

A) Receiving Location: The location for receiving raw materials should be separate from the food processing areas to prevent any likelihood of cross-contamination of products. At this location, only inspection and sorting should be done. Thereafter it should be moved to designated storage area, storage at the receiving location is not recommended.

B) Transport Vehicles: All transport vehicles for receipt and delivery of raw material or finished product should be inspected for: cleanliness and sanitation; tamper-proofness and temperature/ other requirement if any.

Before or during unloading of material, the vehicle's floor, walls, ceiling, integrity of packages, the presence of any off-odour, pests, etc. should be done.

In case of unsatisfactory condition or tampering, the problem should be addressed before transferring the material to the storage. A record of inspection of transportation vehicles should be maintained.

C) Incoming Material Requirements

The objective for this requirement is that no raw material or ingredient (including packaging materials, processing aids) should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances if the sorting/ processing is unable to reduce these contaminants/ hazards to an acceptable level.

- Where appropriate, specifications for raw materials should be identified and applied.
- Raw materials or ingredients should, where appropriate, be inspected and sorted before processing.
- Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.
- Stocks of raw materials and ingredients should be subjected to First In First Out (FIFO) concept.

10.7.2 Handling and Storage

A) Raw materials, Ingredients and Packaging materials: During handling of raw materials we should ensure that there is no damage or contamination. Raw material should be stored separately from the finished products to prevent cross-contamination.

B) Non-food Chemicals: All non-food chemicals such as cleaning and sanitizing agents and pesticides, should be stored in a secure, segregated area to prevent contamination of material, other products or equipment.

C) Semi-processed or Processed Products: Semi-processed or Processed products should be properly tagged, identifiable and be stored in designated areas immediately after processing. We need to prevent any contamination during handling or storage of these products.

D) Packaging: Packaging design and materials should:

- Provide adequate protection for products to minimize contamination,
- Prevent damage, and
- Accommodate proper labelling.

Packaging materials or gases where used, must be non-toxic and should not pose a threat to the safety of food under the specified conditions of storage and use. If reusable packaging is used, it should be suitably durable, easy to clean and, if necessary, easy to disinfect.

E) **Storage Conditions:** The storage conditions need to be appropriate to prevent contamination of products. The temperature, humidity maintenance if needed should be established. All storage requirements, including pest infestation, should be monitored and recorded routinely.

F) **Stock Rotation:** The use of stored material and ingredients and shipment of processed products should be such as to use the older material or first received (First In) earlier and shipped first (First Out).

10.7.3 Transport and Shipping

Processed products: Only those products which meet all the statutory and food safety requirements, including product specifications, packaging and labelling requirements should be prepared for transportation and delivery.

Transport vehicle: as discussed in previous section.

Delivery: During transportation, it should be ensured that there is no contamination, deterioration or damage, tampering of the product. Locks and seals on delivery vehicles should be maintained during transportation and if opened for customs checking, state border crossings etc., these should be replaced.

10.7.4 Management and Supervision

Managers and supervisors should have enough knowledge of food hygiene principles and practices such that they are able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

10.7.5 Documentation and Records

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

10.8 PERSONNEL HEALTH AND HYGIENE

Since people in the plant (personnel and visitors) come into proximity to food and the environment, their health, hygiene and cleanliness affects the food and its environment. People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers. It is therefore essential that personnel employed in the production of food products understand their duties relative to food safety. If the operations involved in

production and processing are highly technical in nature, they may require constant vigilance, attention to details, and a high degree of competence on the part of employees.

Inadequate training of personnel, or the absence of an appreciation of the importance of proper employee practices, can contribute to the production of food products which may pose a hazard to health.

We need to ensure that personnel who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness; and
- behaving and operating in an appropriate manner.

10.8.1 Health Status

Food plant employees with certain illness whether suspected, to be suffering from, or to be a carrier of a disease likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. The illness or conditions which should be reported to management (so that any need for medical examination and/or possible exclusion from food handling can be considered) include:

- jaundice;
- diarrhoea;
- vomiting;
- fever;
- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.);
- discharges from the ear, eye or nose, or
- any other disease which can be transmitted through food.

Medical examination of a food handler should be carried out if clinically or epidemiologically indicated. In addition, the supervisors in the food plant should constantly monitor food handling employees for these illnesses or injuries. The employees should be made aware of the importance of this practice.

10.8.2 Personal Hygiene

Plant employees especially food handlers should maintain a high degree of personal grooming, cleanliness and personal hygiene practices. This includes general cleanliness of clothing and body, including hair and fingernails. Where appropriate, they should wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Hand washing: Personnel should always wash their hands when personal cleanliness may affect food safety, for example:

- at the start of food handling activities.

After re-entering the product area,

- immediately after using the toilet;

- coughing or sneezing into their hands, and
- after handling raw food or any contaminated material like raw material, equipment, waste and waste containers where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

Personal behaviour: People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

- smoking;
- spitting;
- chewing or eating;
- sneezing or coughing over unprotected food;
- placing fingers in their mouth, nose or ears; and
- touching hair or other parts of the body.

Eating, drinking and smoking: Employees should eat, drink, if permitted smoke only in designated lunch rooms and break room or other authorized areas. The employees food and drinks should be placed in the designated areas and not carried into the plant. Drinking of water should be at the designated water coolers. Medications of the employees should not be taken inside the plant.

Garments and Uniform: Employees should wear outer garments or uniforms provided for their work. These clothes should be kept clean at the start of the work and changed upon getting dirty or according to the required change frequency. If gloves are used, they should be kept clean and sanitary, replaced when torn. Hair and beard nets should completely cover the hair and beard.

Personal items: Personal items such as jewellery, watches, pins or other items like artificial eyelashes, false nails, nail paints should not be worn or brought into food handling areas as they pose a threat to the safety and suitability of food.

10.8.3 Visitors and Non-company Personnel

Controlled access to the premises: The access of visitors and non-company personnel to mainly the food handling area and food plant should be controlled to avoid any potential source of contamination. This control should apply to even the family members of personnel, suppliers, customers, govt. inspectors, plant tours, non-company people working on the premises.

Personal practices: Visitors or non-company personnel who are permitted entry into the food processing and handling areas should follow same personal practices and hygiene provisions as the plant personnel.

10.9 PEST CONTROL

This programme covers the specific activities that are directed at controlling, preventing, and excluding occurrence of pests, particularly pests, rodents, insects and birds, from a food plant. Cats, dogs should not be allowed into the plant. These pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive

to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

10.9.1 Preventing Access

Building and Facilities: Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

Harbourage and infestation: The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

10.9.2 Pest Control Programme

There should be formal, documented pest control programme that is maintained for the establishment. The programme cover all preventive measures taken to exclude and eliminate pests, the various pest control devices and pest control chemicals that are used, monitoring of pest activity, and compliance with Govt. regulations on use of pesticides and pest control devices.

Pest Control Devices: This programme should include outside bait stations for rodent control, netting, bait stations or mechanical traps for birds, inside devices such as mechanical traps, glue boards for rodents, insect light traps for flying insects.

These devices should be located at appropriate locations where they are most effective for removing pests from the building. There should be an updated diagram map to show actual locations of all pest control devices both inside and outside the building.

Monitoring and Maintenance of Devices: The pest control devices should be monitored at an established frequency for any pest activity and for the status of the devices. If this monitoring shows any anomaly, the appropriate follow up action should be undertaken immediately and serviced if required.

A written report of this monitoring and maintenance should be kept.

10.9.3 Pest Control Personnel

The personnel responsible for placement, monitoring and maintenance of the pest control devices, and handling and use of pesticides, should have the required qualification and training including food safety training. If the pest control activity is conducted by an external agency, appropriate licence or certification should be obtained.

10.9.4 Pest Control Chemicals

Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. Only chemicals

approved as pesticides by appropriate regulatory agency should be used for pest control in the food plant. 'Restricted Use' pesticides should be used only with the required supervision and General Use pesticides should only be used by personnel with required training.

All efforts should be made to prevent the likelihood of contamination of food and food contact surfaces with pesticides.

All pesticide and pesticide application equipment must be clearly identified with labels and stored in a protected, locked area far removed from food processing areas and storage areas for raw materials, ingredients, packaging materials, cleaning materials and products.

10.9.5 Monitoring Effectiveness

Pest control systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed. Whenever any pest activity is evident, the source of the pest should be identified and eliminated as soon as possible. The programme should be reviewed to determine whether the preventive aspects of the programme are effective.

Check Your Progress Exercise 2

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

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

1) Waste bins located outside the food plant should be:.

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2) Food handling personnel should be subjected to routine medical check up. Is this a requirement under pre-requisite programme. True or False

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3) What type of records are present for pest control programme?

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10.10 TRAINING

Employees in a food plant play a critical role in ensuring the safety of foods produced at the plant. In addition, employees should not contaminate or be a source of cross-contamination of foods. The primary consideration for this pre-requisite is that those engaged in food operations who come directly or indirectly into contact with food should be adequately trained, supervised and follow their work related tasks, personal hygiene reuirements and acceptable personal hygiene practices to a level appropriate to the operations they are to perform.

10.10.1 Food Safety Awareness

Food safety training is fundamentally important for all food plant employees including temporary employees. This training should cover basic principles and practices that are required to prevent contamination and cross-contamination of foods, hygienic handling practices, personal hygiene requirements. The dangers associated with the poor personal hygiene and unsanitary personnel practices should be elaborated. The training of supervisory staff to recognize injuries or infectious illnesses among the plant employees should also be conducted. The food safety training should be reviewed periodically, and if necessary refresher training should be provided.

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

Technical Training: Employees whose tasks involve operation, maintenance, and cleaning of food processing equipment, and sanitation and cleaning activities should be provided with adequate technical training required to carry out their specific tasks so that all food safety requirements are met.

Training Records: Records should be kept as evidence that the relevant food safety training was provided to employees, and that they were evaluated after completion of the training. Records for reviewing of training needs of the employees should be kept.

10.10.2 Roles and Responsibilities

All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

10.11 TRACEABILITY AND RECALL PROCEDURES

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. This should include:

Lot Identification

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The Food Safety and Standards Act 2006 applies in India.

Product Information and Labelling

All food products should be accompanied by or bear adequate and clear information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

10.12 LET US SUM UP

Prerequisite programmes are procedures including good manufacturing practices that address operational conditions providing the foundation for the HACCP system. The prerequisite programmes must be developed and implemented before an effective HACCP system can be implemented. These include: facilities, supplier control, specifications, production equipment, cleaning and sanitation, personal hygiene, training, chemical control, receiving, storage and shipping, traceability and recall, pest control. These topics are covered in the Codex General Principles of Food Hygiene as design and facilities control of operation; maintenance and sanitation; personal hygiene; transportation; product information and consumer awareness and training.

10.13 KEY WORDS

Primary Production : "Primary food production" means the growing, raising, cultivation, picking, harvesting, collection or catching of food.

Sanitation : is a process capable of reducing the number of microbial contaminants to a relatively safe level. It provides the lowest safety margin because it does not require or necessarily produce the complete destruction of any particular micro-organisms.

Cleaning : The removal of soil, food residue, dirt, grease or other objectionable matter.

Traceability : Ability to trace the history, application or location of that which is under consideration (ISO 9000:2000). The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification (ASQ, 1998).

Record : Document stating results achieved or providing evidence of activities performed.

10.14 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Your answer should include the following points:

Check Your Progress Exercise 1

1) To reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

2) Stairs in a food plant should

- be located so as to minimize the risk of product contamination;
- constructed of impervious materials that are cleanable;
- catwalks or mezzanines located over processing areas, and where splashing or dripping could pose a contamination risk;
- must be of solid masonry or metal construction; and
- where appropriate, narrow raised walkways for overseeing (catwalks) and balconies (mezzanines) must be equipped with raised edges of a height sufficient to prevent the spread of contamination.

3)
- exterior structure shall be designed and maintained to prevent entry of pests.
- areas surrounding exterior of dairy plant shall be:
  - drained to minimize standing water;
  - free of uncontrolled vegetation, stored items, garbage, or any other condition in close proximity to the plant that could harbour pests; and
  - maintained to minimize creation of dust.

Check Your Progress Exercise 2

1) Solid waste containers located **outside** the plant shall be:

- equipped with covers and closed when not in use;
- maintained in a manner not to attract pests; and
- emptied, cleaned and sanitized regularly.

2) False. The supervisors in the food plant should constantly monitor food handling employees for these illnesses or injuries.

3) There should be an updated diagram map to show actual locations of all pest control devices both inside and outside the building. A written report of monitoring and maintenance of pest control equipment should be kept.

10.15 SUGGESTED READING

Canadian National Dairy Regulation and Code Processing Sector Interpretive Guidelines (2006)

Inteaz Ali (2004). *Food Quality Assurance: Principles and Practice*. CRC Press LLC, Florida, USA.

Recommended International Code of Practice *General Principles of Food Hygiene* CAC/RCP 1-1969, Rev. 4-2003

UNIT 11 PRINCIPLES AND IMPLEMENTATION OF HACCP

Structure

11.0 OBJECTIVES

After reading this unit, we shall be able to:

- outline the steps for implementation of HACCP;
- construct decision charts and decide a critical control point;
- develop a system to implement HACCP; and
- formulate ways to ensure the critical points are in check.

11.1 INTRODUCTION

The HACCP system is a scientific, rational and systematic approach for identification, assessment and control of hazards during production, processing, manufacturing, preparation and use of food to ensure that food is safe when consumed (i.e. it does not present a risk to health). With the HACCP system, food safety control is integrated into the design of the process rather than the present ineffective system of end-product testing. Therefore, the HACCP system provides a preventive and thus a cost-effective approach to food safety. The main responsibility for the implementation of a HACCP-based approach to food safety lies with industries involved in all stages of the food chain, policy makers and planners who have the mandate to facilitate the adoption of HACCP systems, and government authorities, including legislators, regulatory food control officials and health education bodies.

The prerequisites for implementation of HACCP include Good Manufacturing Practices (GMP) and other requirements as per Good Hygienic Practices (GHP). These have already been discussed in the previous Unit. Henceforth we shall elaborate the implementation of HACCP in any industry/ establishment.

11.2 IDENTIFICATION OF HAZARDS AND CONTROL MEASURES

11.2.1 Assemble HACCP Team

The food operation should assure that the product specific knowledge and expertise is available for the development of an effective HACCP plan. Usually, a multidisciplinary team is preferred to ensure that informed unbiased assessments with each aspect of hazard analysis are made. Where such expertise is not available on site, expert advise should be obtained from other sources such as trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector specific guidelines).

Each team member should have been trained in HACCP and have a working knowledge of the process/ product under study. A typical HACCP team consists of:

i) a manager or supervisor responsible for the process under study,

ii) an engineer,

iii) a Quality Assurance manager, and

iv) a microbiologist.

This team will be the core group; other experts can be called in as required. A team leader should be appointed to guide the discussions, and a secretary to record the decisions. The conclusions reached by the team can be summarized on a HACCP data sheet (see Table 11.2).

Defining the scope

The scope of HACCP plan should be identified, such that the segment of the food chain involved is properly defined and the general classes of the hazards to be addressed.

The potential food safety concerns of the study, including the types of microorganisms, chemicals and foreign materials of concern must be defined. It is important to limit the extent of each HACCP study in order to keep it manageable. Each study should examine specific pathogens, chemicals and physical contaminants that may affect the safety of a particular product or group of products. In this way, it can be precisely defined for which hazards controls have to be established. For example, the scope of four different studies might be:

- *Listeria* and *Salmonella* species, which are infectious pathogens, as potential hazards in soft cheese,
- Allergens in residues of other products in shared processing lines,
- Pesticides as contaminants in raw materials and in the line environment, and
- Foreign material in finished products.

Often, several studies are needed to establish a complete HACCP plan.

11.2.2 Describe Product

A very essential part of each HACCP study is the collection and evaluation of data concerning the raw materials, the formulation of the product, the processing, storage, distribution, sales, preparation and use conditions. This involves an in-depth study of the processing and supply chain and expected use by the consumer. A full description of the product should be drawn up, including relevant safety information such as: composition, physical/ chemical structure (including aw, pH, etc.), microcidal/ static treatments such as heat treatment, freezing, brining, smoking etc.; packaging, shelf life and storage conditions, and method of distribution.

The major points to be considered are:

1) **Formulation**: the raw materials and ingredients to be used and the parameters which may influence the product's safety or stability.

2) **Processing:** the process parameters and conditions which affect or may create the hazards.

3) **Packaging**: protection against contamination with chemicals or (re)contamination and growth of microorganisms (permeability, integrity, tamper protection are relevant aspects).

4) **Storage/handling**: the time and temperature conditions and handling in distribution centres, retail outlets and kitchens.

5) **Customer practices**: use by the consumers, caterers or professional cooks (cooking, reheating, thawing, reconstitution, storage, re-use).

6) **Target groups**: the end user (infants, adults, the elderly, immuno-compromised or sick people).

All of these factors must be taken into account to determine the probability of the presence of unacceptable levels of hazards at the moment of consumption if they are insufficiently controlled.

11.2.3 Construct Flow Diagram

The next task is to produce a process flow diagram to serve as a guide for the study. The diagram should cover all steps in the operation for a specific product i.e., it should describe all the raw materials and the processing and packaging steps. It should include the data needed for microbiological, chemical and physical hazard analysis; for example, information on the likelihood of contamination with chemicals and foreign materials, as well as microorganisms and their toxins. Data are needed on time and temperature throughout the process and distribution, as well as on acidity (pH) and water activity (aw) conditions.

Table 11.1: Examples of technical data that may be required for a HACCP study

Epidemiological and legal data on microbial pathogens, toxins and chemicals	Incidence of food borne illness (especially if related to similar product).
	Results of surveillance programmes and sentinel studies.
	Legal microbiological food safety criteria and Maximum Residue Limits.
Food Safety data	Likely presence of microbiological and chemical hazards in raw materials.
	Growth rates of pathogens in food products.
	Death rates of pathogens under a range of conditions.
	Fate of chemicals and toxins during processing, storage, distribution and use.
Raw material, intermediate and final product data	Formulation
	Acidity (pH)
	Water activity (aw)
	Packaging materials
	Product structure
	Processing conditions
	Storage and distribution conditions
	Shelf life
	Consumer use instructions, package labelling, including code dating practices.
Processing data	Number and sequence of all processing stages including storage.
	Range of product time/temperature conditions.
	Handling of rework (recycled material from the manufacturing process).
	High/low risk area separation.
	Flow conditions (for liquids).
	Presence of void spaces in processing equipment.
	Efficacy of cleaning and disinfecting.

Hygienic design, equipment characteristics, intermediate storage conditions and instructions for consumer use (Table 11.1). The same flow diagram may be used for a number of products manufactured using similar processing steps. When applying HACCP to a particular operation, considerations should be given to steps preceding and following the specified operation.

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) Name the specialisations of people in HACCP implementation team?

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2) List the points to be considered for describing the product for HACCP implementation.

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3) With whom does the responsibility for HACCP implementation lie?

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4) What type of data is required for microbial pathogens, toxins and chemicals' evaluation of food?

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On-site confirmation of the flow diagram

The team should confirm the flow diagram by examination at the production site of all stages and hours operation or the manufacturing process, e.g. inspecting processing lines and storage facilities. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

11.3 DETERMINATION OF SIGNIFICANT HAZARDS

First, the HACCP team should list all the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. Then, to identify significant hazards, a number of questions, such as those in the decision tree of Fig. 11.1, have to be answered for each hazard that could be of concern at each food production step. One of the first questions would be: is it probable that the potential hazard is present in the raw material? When the answer is NO, this potential hazard in this raw material is of no concern (indicated with "no hazard" in Fig. 11.1). This is also the case when the hazard under study is not likely to be in the processing line or environment. Equally, if the hazard may be present, but the product itself will not be contaminated, it is not a significant hazard. However, if contamination was possible, further questions would have to be considered at each process step. For instance is the presence at an unacceptable level probable or is survival, persistence or increase possible that leads to an unacceptable level of the hazard? Again the potential hazard does not need to be addressed in the HACCP plan at this step if the answer is NO. When the answer is YES, the next question would be is the reduction, if any, at a later step adequate to reduce the hazard to the acceptable level? If YES, the potential hazard is not further considered at this step (but the reduction step becomes a CCP). If the answer is NO, a significant hazard has been identified, for which control measures have to be established.

11.3.1 Determination of Acceptable Levels

For many agents of a biological or chemical nature, a potential hazard is not always a significant hazard with regard to the safety of the food. Many chemicals may only have an effect when ingested in a "high dose". Acceptable Daily Intake (ADI) and Maximum Residue Levels (MRL) have been established for these. Even for certain potential carcinogens tolerable/acceptable levels have been set; often the "as low as reasonably achievable" (ALARA) concept is used in practice when no limits have been established. For microorganisms the concept of acceptable levels is less applied, but here also the ALARA concept is practiced; different levels are accepted as tolerable for different pathogens, mainly depending on the severity of the potential health impact. For instance, it is widely accepted that pathogens such as *B. cereus* and *C. perfringens* cause only illness when present at high levels in a food (about 105-106 CFU/g). For *L. monocytogenes* many countries apply an acceptable level of <100 CFU/g at the moment of consumption. A similar reasoning may apply to physical hazards. The concept of acceptable levels is crucial for HACCP, as is clear from the definitions of control measures and CCP. It is also inherent to the definition of hazard: the potential to cause an adverse health effect. Whether it is causing harm will, amongst other factors, depend on the level.

11.3.2 Consideration of Control Measures

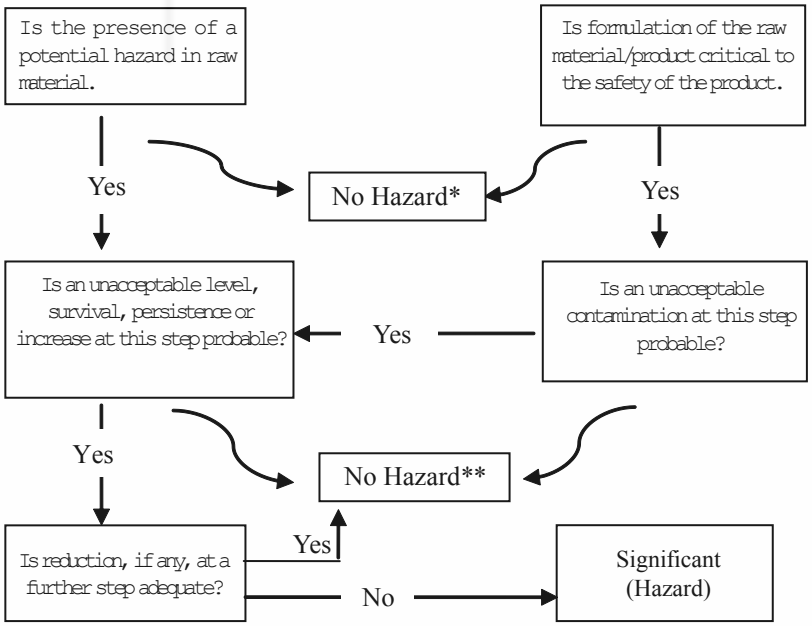
Hazards can be controlled in many ways. Heating can kill micro-organisms and their growth can be prevented or limited by low or high temperatures, low water activity, by preservatives, etc. Residues of veterinary drugs and pesticides can often be controlled by keeping a certain time between application and slaughter, milking or harvest which would reduce the residue to an acceptable level. Strict separation between raw materials and processed foods is a control measure that prevents or limits cross-contamination with pathogens. Cross-contamination in processing lines with allergens can be eliminated through appropriate validated cleaning procedures and/or sensitive consumers can be informed by appropriate labelling. Visual inspection, sieving, metal detectors etc. may be effective in controlling physical hazards. The various options for control measures have to be considered for each significant hazard.

11.4 DETERMINATION OF CRITICAL CONTROL POINTS

Once the significant hazards have been identified and control measures considered, the study team must determine the Critical Control Points (CCPs). The team should examine the entire process, and ask for each identified hazard, at each step, questions such as:

- Can the hazard be introduced into the product via the raw material under study? If this is the case, is it likely to be at, remain at, or increase to, unacceptable levels?
- Is the formulation/ composition of the raw material/ product critical to the safety of the product?
- Does the process under study make the final product safe by reducing the hazard to an acceptable level, or by keeping it from increasing to dangerous levels?
- At this step, can the hazard be introduced into the product from the processing line or the environment, and if so, is it likely to be at, remain at, or increase to, unacceptable levels?

Questions to be answered for each potential hazard at each step



* Not a hazard to be controlled at this step.

** Reduction step thus becomes a CCP.

Fig. 11.1: Hazard determination

The decision tree in Fig. 11.2 can be helpful to identify CCPs. Questions 1 and 2 in Fig. 11.2 apply to the raw materials, and questions 3 to 6 apply to the process stages. Clearly, some of the questions are similar to the ones used to identify the significant hazards because of the conceptual link between hazards and CCPs. Hazard determination emphasises identification of hazardous agents which may reach the consumer when not properly controlled; during the determination of CCPs, the emphasis is on the identification of the sources of, or conditions leading to, the hazards, and on the measures to control them. At each process step, the team should consider the possible consequence of a deviation from the "normal". Good manufacturing practices (GMP) procedure, whether such a consequence could be unacceptable with regard to food safety, and the probability that it will occur. Moreover, the team must consider what happens to the product later on, to determine whether the process step is critical. A large amount of technical data may be needed for making decisions (Table 11.1). If the analysis suggests that it is not possible to control the hazard at a certain step, and that the hazard (or product) should be modified to eliminate the point. HACCP may be a raw material, formulation, location, practice or process stage, but it must be specific, for example:

- a raw material with regard to the "absence" of specified contaminants,
- acidification of a food to a specified pH,
- drying a food under conditions that prevent pathogen increase,
- the chlorination step of can cooling water, or
- product pasteurisation step.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

11.5 ESTABLISHING THE CRITICAL LIMITS

The team must define the critical limits that assure that a hazard is under control. The critical limit is the value that separates acceptability from unacceptability for each CCP. They are the maximum values that should never be exceeded. In order to assure this, target values may be established. They take into consideration the variability of control measures. By making these target values more stringent they ensure that critical limits are always met. This can be seen in Table 11.2, which illustrates how a HACCP data sheet might be compiled. These target values are the process parameters necessary to achieve the required performance criteria that need to be validated.

In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, water activity (aw), available chlorine and sensory parameters such as visual appearance and texture.

Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable.

Check Your Progress Exercise 2

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

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

1) Elaborate:

ADI ……

ALARA ……..

2) How are critical limits for any hazard determined?

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3) If a hazard is present in raw material, what is the next question to be asked for decision making in HACCP decision tree?

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11.6 ESTABLISHMENT OF A MONITORING SYSTEM

A monitoring system must be established, to ensure that each CCP is always under control, that is, that the critical limits or target values are met. This is illustrated in Table 11.2, which identifies the CCPs (what must be controlled and where control is achieved) and describes the associated control procedures (how the hazard will be controlled). Data derived from monitoring must be sufficient to guarantee that the CP is in control. Monitoring methods should be rapid to be effective. Physical/ chemical tests and observations are preferred, even for microbiological purposes, because microbiological methods tend to be time consuming. Ideally, they should allow adjustments to be made before the situation becomes unacceptable. In practice this means that the frequency of monitoring is linked to the volume of a product that is produced between two monitoring measurements. If a monitoring result shows that an unacceptable deviation occurred (i.e. the critical limit was exceeded), the product should not reach the consumer. The amount of product to be rejected, reworked or further investigated depends on the time passed since the last monitoring result showed that the situation was under control. Full records must be kept of all monitoring data for management, audits, trend analysis and scrutiny by inspectors.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

11.7 ESTABLISH CORRECTIVE ACTIONS

When critical limits are not met, the "out of control" situation should be rectified immediately and appropriate follow-up actions taken. These actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping. All these actions should be planned and described during the HACCP study.

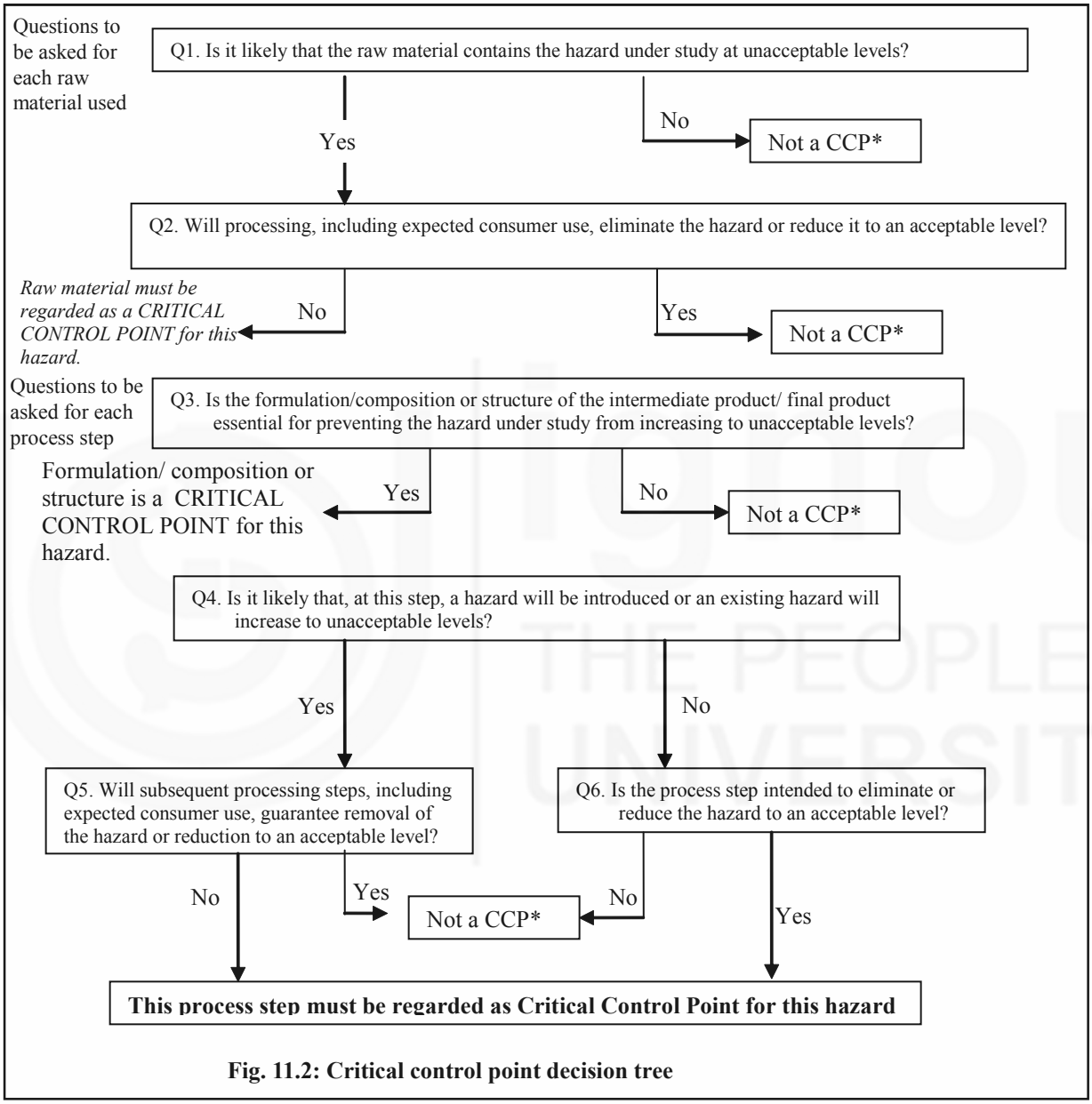

Fig. 11.2: Critical control point decision tree

From Table 11.2 two examples are taken, chlorination of cooling water and pasteurisation of milk. At the CCP where the chlorine level of the cooling water is critical, a concentration of less than 1 ppm should lead to an immediate adjustment of the chlorine dosing. If chlorine is absent, the batch should not be released until further examination has demonstrated that the product is safe.

At pasteurisation, a temperature drop below 71.7°C should result in re-pasteurisation (via a flow diversion valve), adjustment of the heating equipment and an examination of the pasteurisation operation to find out why it happened. Once the cause of the problem has been identified, further corrective actions should be taken to prevent it from happening again.

Monitoring data should be examined systematically to identify the points where controls should be improved or where other modifications are needed. In this way, the system can adapt to changes by constant fine-tuning.

11.8 ESTABLISH VERIFICATION PROCEDURES

Verification is a very important element of HACCP and should always be included. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP system. Example of verification activities include:

- Review of the HACCP system and plan and its records;
- Review of deviations and product dispositions; and
- Confirmation that CCPs are kept under control.

It is intended to provide additional information to reassure the producer (and the inspector) that application of HACCP results in the production of safe foods. It comprises two distinct activities, i.e. demonstrating conformity with the HACCP plan (are we doing what we planned to do?) and data gathering (did we meet our objectives, can things be improved?). It includes activities such as inspections and audits as well as the use of classical microbiological and chemical contaminant tests to confirm that the control measures operate as designed. Samples examined by inspection services and reviews of customer complaints can in certain cases also provide insight into the proper design and implementation of the system. Verification is different from monitoring. The gathered data may indicate, for instance, that certain things were overlooked in the HACCP plan or that the monitoring procedure is not good enough to assess the level of control. It may also indicate that the quantity of product that is kept on hold for further investigation, to determine release or no release, is too large, indicating that the frequency of monitoring should be increased. It may provide information that, in practice, the product is used in a manner other than was foreseen during the HACCP study. As a consequence, changes in the HACCP plan need to be made. Verification is an ongoing activity, some aspects, e.g. environmental and product sample testing, may be specified in the HACCP plan, others may be done whenever there is a need. Certification is a specific form of verification. It is performed by independent third parties; it deals with checking that a certain HACCP system, as described in a "HACCP Standard", was applied. An auditor from a certification body will report on the business' performance in relation to the standard, but will normally not provide a judgement concerning the product's safety.

11.9 ESTABLISH DOCUMENTATION AND RECORD KEEPING

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to assist the business to verify that HACCP controls are in place and being maintained. This ensures that information gathered during the installation, modification and operation of the system would be readily

accessible to everyone involved in the process as well as to outside auditors. It also helps to ensure the long-term continuity of the system. Records should include explanations of how the CCPs have been defined, descriptions of control procedures and modifications to the system, monitoring and verification data, a file of deviations from normal practice and corrective actions.

Documentation examples are:

- Hazard analysis,
- CCP determination, and
- Critical limit determination.

Record examples are:

- CCP monitoring activities,
- Deviations and associated corrective actions,
- Verification procedures performed, and
- Modifications of the HACCP plan.

An example of a HACCP worksheet for the development of a HACCP plan is provided in Table 11.2. A simple record-keeping system can be effective and easily communicated to the employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperature.

11.10 VALIDATION

Before the HACCP plan can be finalised and implemented essential elements need to be validated. Evidence must be obtained that the control measures indeed achieve what was intended. For example, does the heat treatment carried out to render a canned product safe achieve the 12 decimal reduction (12D) of *C. botulinum* spores as required? Is the description on the label for preparing a frozen meal in a microwave oven sufficient for the purpose? Does the formulation of the product keep growth of the hazard under control? In simple terms, validation means: does the evidence show the hazard(s) will be controlled? This is different from verification where the question is: were the things done correctly? Validation is in principle carried out before control measures or changes in control measures are implemented and as such it is putting the proverb "look before you leap" into practice.

11.11 GENERAL ERRORS IN HACCP PLANS

Some common anomalies were pointed out during one study carried out in Italy*, in HACCP systems in various retail, hospitality and food industry sectors. These included:

Voluminosity: Well-packaged self-monitoring plans were examined with good typographical layout and coloured sheets, but that were filled with superfluous elements such as the legislation, philosophy and the history of HACCP. These elements invalidated rapid consultation of the plan, making the plan lack in the

***Panunzio1 M.F., Antoniciello1 A., Pisano1, A. and Rosa G. (2007).** *Int. J. Environ. Res. Public Health 4(3): 228*

inspiring motto "only write what you have to do, do what you have written".

Redundancy: A few plans did not follow a precise table of contents for their subjects but rather many things were repeated in different parts of the plan. This resulted in rather difficult specific, immediate and unambiguous comprehension of the procedures to be followed.

Besides **Confusion of critical limits**, hazard non-specificity and lack of a time plan for the control were also observed.

The sheets were not drawn up following the production flow chart but rather by homogeneous phases of the production process. The application of the **decision tree** in identifying the CCP was ignored. The decision tree is a diagram indicating a few questions/answers, built on the flow of the production activity. Its use is an essential tool to remove the inherent subjectivity in self-monitoring.

Non-specificity of the hazard refers to the generic wording such a biological, physical or chemical contamination. If the hazard is non-specific, it goes without saying that the rest of the plan can only be generic and therefore useless.

Finally, a few plans did not indicate a **time plan** for the controls to carry out, therefore there was no precise agenda to follow for hazard self-monitoring measures.

11.12 QUANTITATIVE APPROACH IN HACCP

HACCP is quantitative by nature, and in its simplest form descriptors are used to determine the probability/ likelihood that something may happen. Such descriptors are, for instance, found in the hazard determination tree: is the presence of a potential hazard in a raw material probable? The same question could be worded as: is presence possible or likely? Using these three different descriptors, often different answers will be obtained. For example, the presence of *Salmonella* in sugar is possible, but normally not likely. Examination of raw materials may provide numerical values that can be used to decide whether presence will be possible, probable or likely.

Another example deals with the selection of significant hazards from the list of potential hazards. This selection is based on the likelihood of their occurrence in the final product at levels that are unacceptable. Thus, judgements have to be made and decisions have to be taken based on quantitative considerations.

When determining CCPs, for example, the seriousness of a deviation from the normal Good Manufacturing Practices has to be estimated. If the deviation would have little or no impact on a product's safety, the process step would remain to be covered by GMP. However, if the deviation would have a major impact on the product's safety, the process or handling would become a CCP. Inherent to this decision is that the magnitude of this impact is related to the size or the seriousness of the deviation. Furthermore, at each CCP, the critical limits that have to be established are of a quantitative nature.

However, at present, the implementation of a truly quantitative approach to HACCP in relation to defined food safety goals is difficult because the indication

of what is acceptable and what is not with regard to the safety of a food is not specified in most regulations or guidance documents. This hampers are the clear definition of the level of control that is needed to ensure that the appropriate level of protection of the consumers is achieved. In practice, a "benchmarking" approach often provides a useful indication of product safety. Most foods that have been processed to assure safety have an excellent record.

Thus the level of a hazard obtained with GMP and HACCP can, based on the epidemiological evidence, be considered to be acceptable without expressing explicitly in quantitative terms what this level is. New products or changes in raw materials, processes, formulation, commercialisation, preparation and use, can be evaluated using such a benchmarking approach.

Recently, the concept of Food Safety Objectives (FSOs) has been introduced to provide a more formal guidance on the level of control necessary.

11.12.1 Food Safety Objectives

A Food Safety Objective (FSO) is a statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection. Although, the FSO concept is relatively new and is still evolving, it offers a practical means to convert public health goals into quantitative values that can be used by regulatory authorities and by food producers and manufacturers to manage food safety all along the food chain.

FSOs are established according to a participative, interactive and transparent process involving the regulatory authorities, the industry at large, the consumers and other interested parties. The limits indicated in an FSO reflect the best available scientific information, as well as technical and societal considerations from other sources. In particular, it should be evidenced that FSOs can be met by adequate GMP and HACCP systems.

As an example, an FSO could be expressed as: "the level of *Listeria monocytogenes* in ready-to-eat foods must not exceed 100 CFU/g at the time the foods are consumed". FSOs can be used by health authorities to communicate clearly to producers/manufacturers what is expected of foods produced in properly managed processes. The FSOs form the basis on which these authorities can establish standards and guidelines. These should form the basis of assessments whether an operation is producing safe foods, i.e. whether the food does not exceed, under normal conditions of commercialisation and use, the established FSO.

The food industry at large (primary food producers, processors, retailers, caterers etc.) can use FSOs as a basis to manage food safety throughout the food production chain. This is done by translating the FSOs into a set of quantitatively stated requirements that would assist in the appropriate design of products, processes and control measures, i.e. compliance with the appropriate level of protection as expressed through the FSOs, while providing for flexibility of operation. FSOs also provide the necessary basis for validation.

11.12.2 Numerical Calculations in HACCP

An FSO (or a benchmark) indicates the maximum level of a hazard at the time of consumption that should not be exceeded. In order to achieve this, it is necessary to consider the possible initial level of a hazard in a (semi-) raw product from primary production, and how this level may change (potential for growth, inactivation and recontamination) during the different steps in production, distribution, storage, preparation and final use of a product.

The hazard level which is acceptable at a specified step earlier in the food chain (which is called Performance Objective, PO) can be established using FSO as a guide. Knowing the contamination level at the start of a particular step, the effect (for example in terms of number of decimal reductions of a given pathogen) required in order to meet the acceptable level at the end of the step can be determined. One or more control measures may need to be applied at one or more steps in the food chain, or within a given process, in order to achieve this effect. The required effect of the control measure(s) that need to be applied (for example in terms of number of decimal reductions of a given pathogen) in order to meet the acceptable level can be determined. Within the framework of HACCP, the determined effect of the control measure is used as a guide to establish the critical limits at the relevant CCPs.

For example, if an FSO for *Listeria monocytogenes* in a ready-to-eat product that does not support growth of this pathogen were to be set at 100 CFU *L. monocytogenes*/g at the moment of consumption, the acceptable level (PO) at the moment of commercialisation should be the same or targeted lower. An example is given in Fig. 11.3. It is assumed that:

a) The initial number is around 1 CFU/g of the raw material;

b) The heat treatment achieves a 3-decimal reduction;

c) Re-contamination of the product cannot be prevented, but does not reach a level of more than 1 CFU/100g of product when GHP is effectively applied, and

d) The condition of the product does not allow multiplication of *Listeria* during commercialisation and use.

In this situation, the PO could be set at 1 CFU of *L. monocytogenes*/100g to restrict the recontamination as much as possible. Clearly, with this PO, the FSO will not be exceeded. When such calculations are made, the critical limits needed to achieve the required acceptable levels can be determined and validated.

11.12.3 Validation of Numerical Values

The expression of the result of control measures in quantitative terms greatly facilitates their validation, i.e. obtaining evidence that they are effective. In principle all requirements that have been set to assure that a safe product is obtained should be validated. For example, if the initial number of *Listeria monocytogenes* in a raw product should be less than 1 CFU/gram, this must be validated. If the re-contamination of a product with *Listeria monocytogenes* should be less than 1 CFU/100 gram, this must be validated. If the maximum increase of *Listeria monocytogenes* in a certain product that supports growth should be no more than a factor of 1000 before the food is eaten, this should be validated.

Data providing evidence on the performance of control measures can be found in historical data, scientific literature, codes of GMP, generic HACCP plans, growth models, small scale tests, etc. but it must be made sure that these are pertinent for the specific product and manufacturing or preparation conditions. Experimental studies such as challenge and storage tests may need to be carried out to obtain this pertinent information.

Recently, much progress has been made in applying microbial modelling and computer simulation techniques to quantify the behaviour of microbial hazards associated with certain specific process steps used in the food industry. When properly validated, these techniques are of value in the development of numerical calculations for validation of control measures and the effectiveness of HACCP plans.

11.12.4 HACCP and Microbiological Risk Assessment (MRA)

Microbial growth and inactivation models and computer simulations of the fate of pathogens in the food chain are also applied in the framework of Microbiological Risk Assessment (MRA). MRA is a procedure used by regulatory authorities to understand the likelihood of adverse effects as a consequence of the consumption of a certain pathogen/food combination.

There are many similarities between an MRA and the hazard analysis which is a part of a HACCP study. Both procedures identify hazards, study where and how they appear in the food chain, what the effect of potential control measures will be and determine the seriousness of potential health effects. The result of a MRA is primarily utilized by public authorities to decide whether the estimated risk would be acceptable or, if not, what would be the best options for its management. It is also one of the scientific bases that the public authorities would consider when establishing FSOs.

In this way, MRA may be indirectly linked with HACCP: outcomes of MRA and/or FSOs can be used to target the control measures at CCPs in a HACCP study. However, MRA is not needed to conduct a HACCP study.

Check Your Progress Exercise 3

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

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

1) What are the requirements for monitoring systems recommended for detecting hazard?

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2) What is the difference between verification and validation?

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11.13 WHEN TO IMPLEMENT HACCP PLAN

Ideally, a HACCP study should be carried out as part of product and process development, so that potential hazards can be "designed out" at the earliest stage. In any case, a HACCP study results in a HACCP plan that should be correctly implemented to ensure that the appropriate control measures are put in place before products are put on the market. A HACCP plan is the result of a HACCP study carried out for a specific product at a specific production site and is thus to be used for that product only. So-called generic or model HACCP plans can be used, however, to give guidance to the study team. After industrialisation or scaling up of the processing line, the HACCP study should be reviewed and the HACCP plan complemented when necessary. The study should consider all the differences in conditions between the pilot plant and factory.

For products currently manufactured without a HACCP plan, a HACCP study should be best carried out according to the guidelines described in this document. This ensures that no critical point has been overlooked, that appropriate control measures have been identified and implemented and that the required monitoring procedures and record keeping systems have been put in place.

A HACCP study should be carried out again prior to implementing any significant changes in, for example, raw materials and packaging materials, production line layout, product formulation or product use. Evidently, the existing HACCP plan should be updated to reflect the findings of the new study. Ideally, a HACCP study should be carried out as part of product and process development, so that potential hazards can be "designed out" at the earliest stage. In any case, a HACCP study results in a HACCP plan that should be correctly implemented to ensure that the appropriate control measures are put in place before products are put on the market. A HACCP plan is the result of a HACCP study carried out for a specific product at a specific production site and is thus to be used for that product only. So-called generic or model HACCP plans can be used, however, to give guidance to the study team. After industrialisation or scaling up of the processing line, the HACCP study should be reviewed and the HACCP plan complemented when necessary. The study should consider all the differences in conditions between the pilot plant and factory. For products currently manufactured without a HACCP plan, a HACCP study should best be carried out according to the guidelines described in this document. This ensures that no critical point has been overlooked, that appropriate control measures have been identified and implemented and that the required monitoring procedures and record-keeping systems have been put in place. A HACCP study should be carried out again prior to implementing any significant changes in, for example, raw materials and packaging materials, production line layout, product formulation or product use. Evidently, the existing HACCP plan should be updated to reflect the findings of the new study.

Table 11.2: HACCP Data sheet (Data in table are presented as examples only)

Point of Control (Raw material or process step)	Hazards or condition leading to hazards	Control measures	CCP Parameters	Critical Limits	Target values	Monitoring	Corrective Actions
Egg product (ingredient in mayonnaise)	Salmonella	Supplier's Quality Assurance	"Absence" of Salmonella in eggs	Negative in 5 random samples of 25 g	No target value	Supplier certification with shipping records, supplier audits, microbiological testing	Rejection of suspected lots
Incoming raw milk	Mycotoxins	Farmer's education, feed, supplier's QA	Aflatoxin M	Less than 0.1 ppb	No target value	Testing	Reinforcement of prevention programmes
Pasteurizer (in milk plant)	Salmonella, Listeria, Campylobacter etc.	Correct design and operation of the pasteurizer	Temperature and Time of pasteuri-sation	Not less than 71.7°C for 15 secs	73°C for 15 secs	Temperature/ flow rate recording; record of plant sensor calibration and diversion system operation	Repasteurisation
Chlorination of can cooling water	Recontamination with pathogenic microbes	Correct functioning of chlorine doser and monitor	Free available chlorine	1 ppm after cooling	1-3 ppm	Continuous chlorine monitor	Doser adjustment (Blocking of batch and investigation)
Endpoint of Jam	Inconsistency in heating system	Correct design and operation of heater and heating agent (steam)	TSS	68° Brix	68-70° Brix	Testing for TSS, or product temperature	Steam/ heating duration adjustment

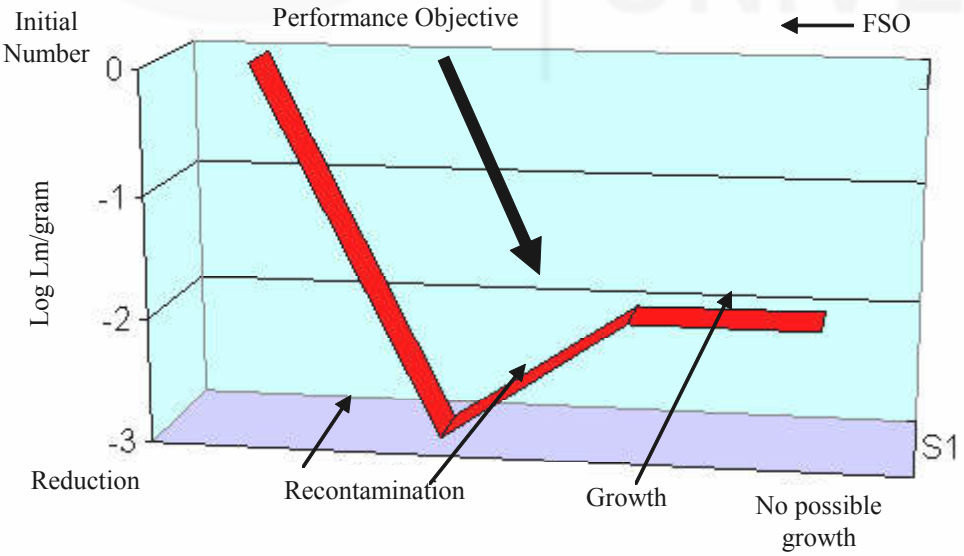

Fig. 11.3: This figure represents the fate of *Listeria monocytogenes* in a ready to eat shelf-stable food. The initial level of the pathogen in the raw material is around 1 CFU/g and a heat treatment is applied which achieves a 3-decimal reduction. Unfortunately, recontamination of the product cannot be prevented, but does not reach a level of more than 1 *L. monocytogenes*/100g of product which is set as the Performance Objective. The condition of the product does not allow multiplication of *Listeria* during commercialisation and use, therefore the situation described is consistent with an FSO of 100 *Listeria monocytogenes*/g

11.14 LET US SUM UP

HACCP is a scientific, rational and systematic approach for identification assessment and control of hazards during production, processing, manufacturing preparation and use of food to ensure that it is safe when consumed. It include assembling of HACCP team, describing the product and construction of flow diagram. It also include of determinate of hazards their acceptable limits and control measures and also the critical control points, their limit and monitoring system corrective actions for the hazards and verification procedures and creating documents and their record keeping is also a part of HACCP.

11.15 KEY WORDS

ADI : The acceptable daily intake (ADI) for man, expressed on a body weight basis, is the amount of a food additive that can be taken daily in the diet, even over a lifetime, without risk.

ALARA : ALARA or As Low As Reasonably Achievable; is also a concept which links risk management approaches with acceptability considerations. Both the level of risk and the severity of cases are used to categorize risk into intolerable, tolerable or acceptable regions.

Decision Tree : A logical reasoning approach to determine the CCP.

Epidemiology : Epidemiology is the study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of public health and preventive medicine. The work of epidemiologists range from outbreak investigation to study design, data collection and analysis including the development of statistical models to test hypotheses and the documentation of results.

Food Safety Objective : "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)". It transforms a public health goal to a concentration and/or frequency (level) of a hazard in a food. The FSO sets a target for the food chain to reach, but does not specify how the target is to be achieved.

GHP : Good Hygienic Practices.

GMP : Good Manufacturing Practices.

Microbiological Risk Assessment : It has as its objective a characterisation of the nature and likelihood of harm resulting from human exposure to agents in food. The

characterisation of risk typically contains both qualitative and quantitative information and is associated with a certain degree of scientific uncertainty.

There are four very distinct steps in the risk assessment process. The first step is hazard identification, which involves the collection, organisation, and evaluation of all information pertaining to a pathogen or a nutrient. Second is hazard characterisation, which determines the relationship between a pathogen and any adverse effects. Third is exposure assessment, which involves determining how much of pathogen might be ingested in a serving of food. The fourth, and last step, is risk characterisation, which involves evaluating the risk and related information.

Monitor : The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Performance Objective : The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or an appropriate level of health protection, as applicable.

Validation : Obtaining evidence that the elements of the HACCP plan are effective.

Verification : The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

11.16 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Your answer should include the following points:

Check Your Progress Exercise 1

1) (i) a manager or supervisor responsible for the process under study, (ii) an engineer, (iii) a Quality Assurance manager, (iv) a microbiologist (v) team leader, and (vi) a secretary.

2) Formulation, Processing, Packaging, Storage/handling, Customer practices, Target groups.

3) Food industries involved in all stages of the food chain; Policy makers and Planners; Government authorities, including legislators, regulatory food control officials; and Health education bodies.

4) Incidence of food borne illness; Results of surveillance programmes and studies; Legal microbiological food safety criteria and Maximum Residue Limits.

Check Your Progress Exercise 2

1) Acceptable Daily Intake; As Low As Reasonably Achievable.

2) For chemical hazards, Acceptable daily intake (ADI) and Maximum residue levels (MRL), for certain potential carcinogens tolerable/acceptable levels have been set; often the "as low as reasonably achievable" (ALARA) concept is used. For biological hazards, ALARA concept is practiced; different levels are accepted as tolerable for different pathogens, mainly depending on the severity of the potential health impact. Similar reasoning is applied to physical hazards.

3) Is the presence at an unacceptable level probable or is survival, persistence or increase possible that leads to an unacceptable level of the hazard?

Check Your Progress Exercise 3

1) Monitoring methods should be rapid Physical/ chemical tests and observations are preferred, even for microbiological purposes. The frequency of monitoring should be linked to the volume of a product that is produced between two monitoring measurements.

2) Validation is obtaining evidence that the elements of the HACCP plan are effective while verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

11.17 SUGGESTED READING

HACCP Introducing the Hazard Analysis and Critical Control Points System (1997) Food Safety Series, Food Safety Unit, World Health Organisation.

Inteaz Ali (2004). *Food Quality Assurance: Principles and Practice*. CRC Press LLC, Florida, USA.

Jogeneel Susan (Ed.) (1999). *HACCP Principles and Practices: A WHO/ ICD Training Manual in collaboration with WHO*.

UNIT 12 CASE STUDIES ON HACCP

Structure

12.0 OBJECTIVES

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.

12.1 INTRODUCTION

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.

12.2 GUAVA JUICE PRODUCTION PLANT

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.

12.3 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 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.

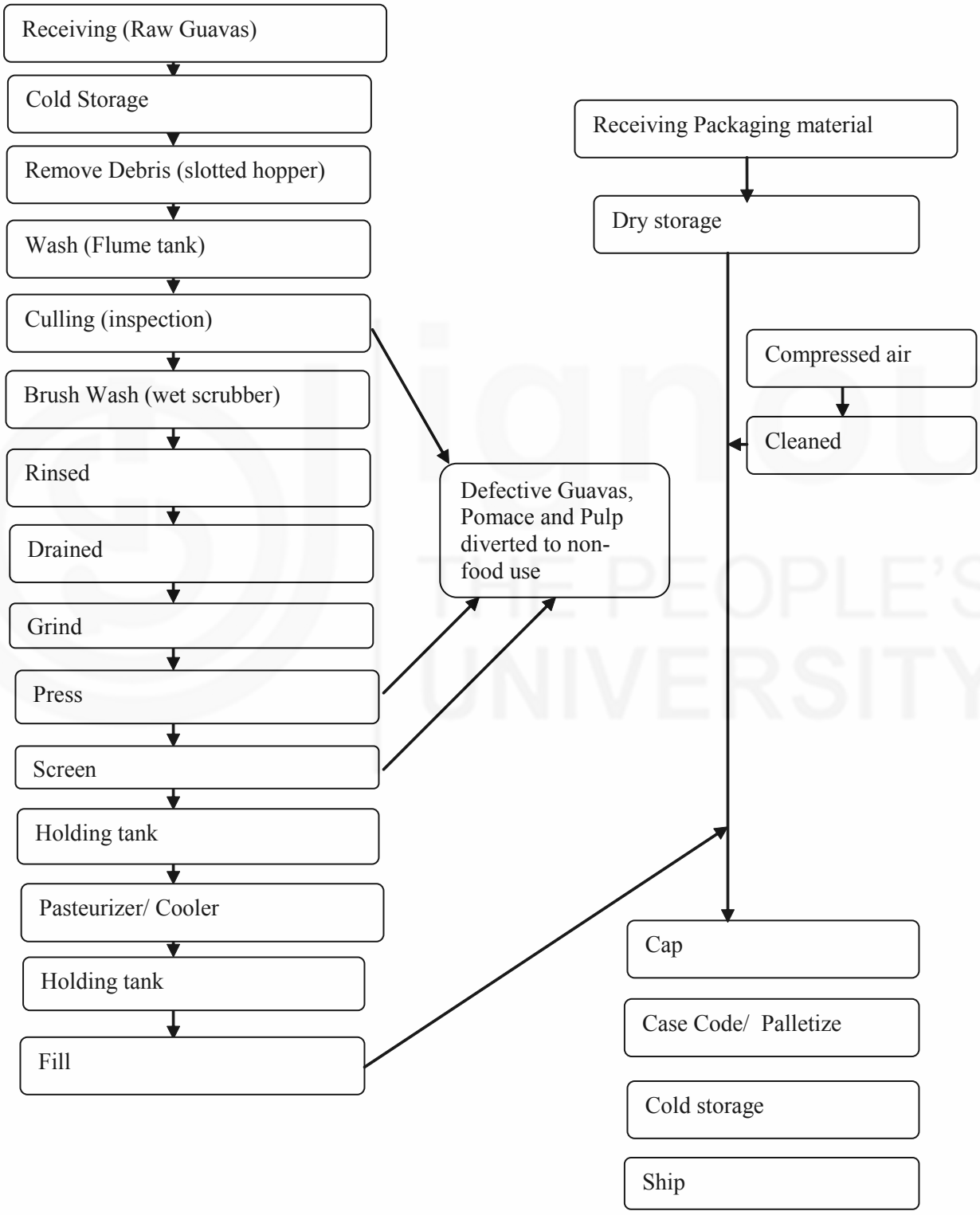

Fig. 12.1: Process Flow Diagram for Guavapure Juice Company

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.

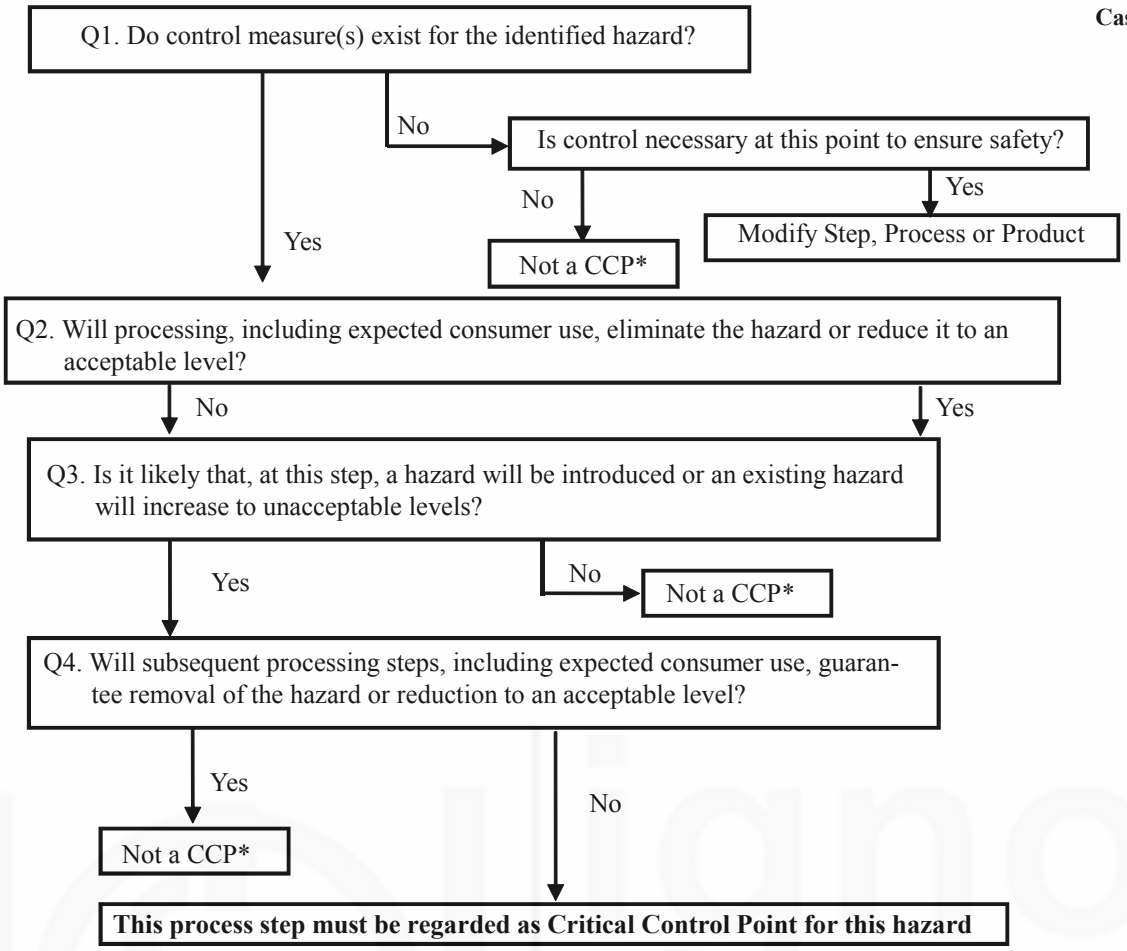

Fig. 12.2: CCP Decision Tree

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 72ºC 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.

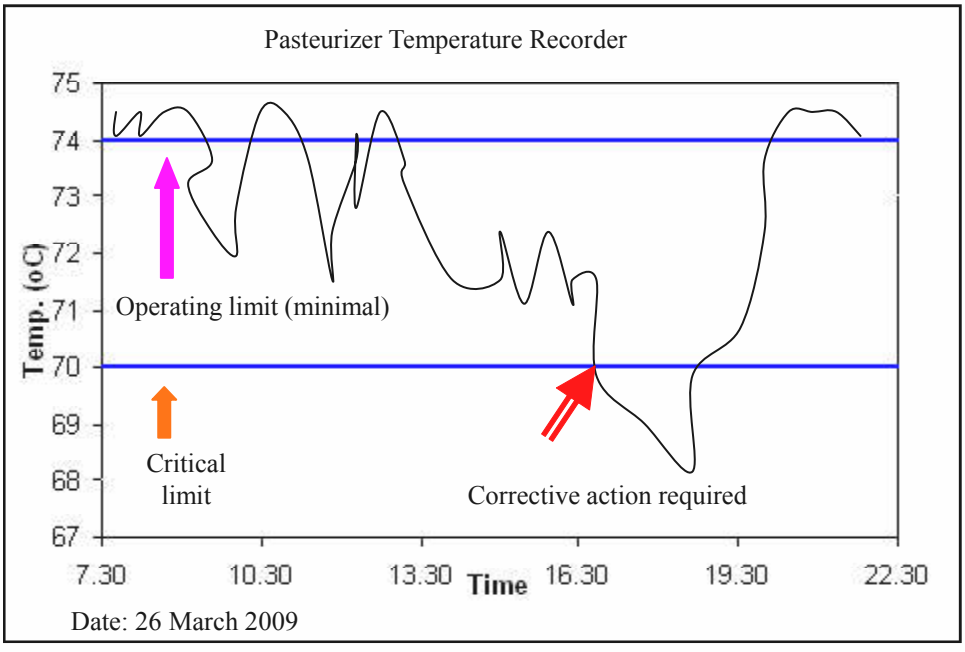

Fig. 12.3: Example of Operating and Critical Limits

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	*E coli* and Protozoan pathogens	> 72°C for > 6 s

Example of HACCP Plan Worksheet

Critical Control Point (CCP)	Hazard (s)	Critical limits	Monitoring				Corrective action	Verific-ation	Valid-ation
			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°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°C and 45°C. This can be achieved through rapid heating and/or cooling of the product through these critical temperatures and maintaining temperatures below 4°C (or above 45°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 ± 0.5°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 spoilt 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	*E coli* 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	The untreated juice will be segregated and held for further disposition (diverted to non-food use or destroyed. Check the operation of the pump, heating/ cooling units, flow diversion valve to determine the reason for temperature deviation. Repair/ correct, Re-establish control and resume production.

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 >72ºC 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	Verific-action	Valid-ation
			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	*E. coli* 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.	Documenta-tion 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.	

12.9 RECORD KEEPING PROCEDURES

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

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.

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

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.

12.11 KEY WORDS

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.

12.12 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

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 eryptosporidium, 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.

12.13 SUGGESTED READING

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.

(Feedback Response Sheet)

Dear Student,

Welcome to the PG Diploma in Food Safety and Quality Management.

The School intends to upgrade and strengthen the study material continuously as the subject is dynamic in nature. Please arrange to give you inputs to improve the self learning study material. We wish to know your difficulties and suggestions in order to improve the contents. A response sheet for a block of the course has been enclosed for your kind persual and consideration please. Kindly fill in this response sheet pertaining to a block and send the inputs for various blocks of the programme to the school. If you find the space provided is insufficient, please use a separate sheet.

Enrolment No. ☐☐☐☐☐☐☐☐☐☐

Name of the Course and Block _____

1) How many hours did you need for studying the units of this block?

Unit No.	**9**	**10**	**11**	**12**
Number of Hours				

2) Please give your observations to the following on quality of contents after going through the block.

Items	**Yes**	**No**	**Requires Changes/Additions if any**
Contents are complete	☐	☐	
Factual mistakes in the contents	☐	☐	
Additional inputs required	☐	☐	

3) Please give your observations to the following items after reading the block.

Items	**Excellent**	**Very Good**	**Good**	**Poor**	**Give Specific Examples, if Poor**
Presentation Quality	☐	☐	☐	☐	
Language and Style	☐	☐	☐	☐	
Conceptual Clarity	☐	☐	☐	☐	

4) Any other comments:

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Please mail either through post or email to:

a) Programme Coordinator (PGDFSQM), School of Agriculture, Academic Complex, Block-G, Room No.2, Indira Gandhi National Open University (IGNOU), Maidan Garhi, New Delhi-110068 02

or

b) pgdfsqm@ignou.ac.in

or

c) Post your comments at SAFE (www.ignouonline.ac.in/ safe)

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MVP-003
Principles of Food Safety and Quality Management

HACCP

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