Food Safety

Prepared By:

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Acknowledgments

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The course aims to provide knowledge and practical applications of the principles and procedures of food safety. Students will learn about foodborne hazards like chemical, physical and biological hazards, also identify essential control measures applicable to ensure food safety at all stages of the food chain. This course covers prerequisite programmes of food safety which needed prior implementation Hazard Analysis Critical Control Points plan (HACCP), also preliminary steps and HACCP principles through several examples for flow diagrams of food processing steps and identifies critical control steps and applies effective control measures to prevent or eliminate a food safety hazard.

- Recognizes the importance of food safety in food production chains.
- Identifies the common sources of chemical, physical and biological hazards.
- Recognizes the factors influence the growth of bacteria in food.
- Describes the main sources of cross-contamination of food and effective control steps to prevent it to reduce hazards.
- Recognizes the connection between product quality and hygiene measures.
- List of examples for practical biological hazard control measures in food process steps.
- List of examples for demonstrating the importance of design and facilities for the food establishment.
- Identifies prerequisite programmes of food safety such as personal hygiene, cleaning and sanitation, waste management and pest control.
- Describe the method by which hazard analysis may be carried out and appropriate control measures ascertained to assess the practical problems.
- Identify critical control points, including critical limits to ensure their control.
- Demonstrate an understanding of the practical application of HACCP principles.
- Applies effective, creative and innovative solutions, both independently and cooperatively, to current and Online Learning in the field of food quality and safety.
- Integrate knowledge and understanding of the content and techniques of a chosen discipline at advanced levels that are internationally recognized applied in food safety.
- Analyze, evaluate and synthesize information from a wide variety of sources in a planned and timely manner to serve food quality enhancement and safety improvement.
- Evaluate control measures for biological, chemical and physical hazards associated with food safety.
- Evaluate cleaning and sanitizing programmes shall be established to ensure that the food processing equipment and environment are maintained in a hygienic condition.
- Identify integrated pest management (IPM) steps and evaluate applied preventive actions and effectiveness of the overall pest control program.
- Evaluate applied procedures for selection and monitoring of food suppliers and justified this procedure by hazard assessment.
- Practical applies of HACCP plan through prerequisite controls, hazard analysis, and risk assessment.
- Design, implement, and manage appropriate programs for verification and maintenance of HACCP systems.

- A proficiency in the appropriate use of contemporary technologies.
- Communicate clearly and convincingly about science and technology ideas, practice and future contributions to expert and non-expert audiences, matching the mode of communication to their audience.

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### Online Learning

Teaching materials and course documentation will be posted on the institute website.

From time to time information about Assignments and Practical’s are disseminated to students via Blackboard. Lecture PowerPoint files will be available on request via Blackboard.

### Learning & Teaching Modes

Lectures supported by practical to develop the material covered in the lectures. Time allocated to lectures and practical’s can be used for tutorials on request.

Not applicable

### Final Exam:

- questions from all the lectures, oral topics and practical’s

<table>
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<td>week 6</td>
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Total term work includes:

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| D- دوريات علمية أو نشرات ..... الخ. |
The course aims to provide knowledge and practical applications of the principles and procedures of food safety. Students will learn about foodborne hazards like chemical, physical and biological hazards, also identify essential control measures applicable to ensure food safety at all stages of the food chain. This course covers prerequisite programmes of food safety which needed prior implementation Hazard Analysis Critical Control Points plan (HACCP), also preliminary steps and HACCP principles through several examples for flow diagrams of food processing steps and identifies critical control steps and applies effective control measures to prevent or eliminate a food safety hazard.

Core Knowledge
By the end of this course, students should be able to:

- Recognizes the importance of food safety in food production chains.
- Identifies the common sources of chemical, physical and biological hazards.
- Recognizes the factors influence the growth of bacteria in food.
- Describes the main sources of cross-contamination of food and effective control steps to prevent it to reduce hazards.
- recognizes the connection between product quality and hygiene measures.
- List of examples for practical biological hazard control measures in food process steps.
- List of examples for demonstrating the importance of design and facilities for the food establishment.
- Identifies prerequisite programmes of food safety such as personal hygiene, cleaning and sanitation, waste management and pest control.
- Describe the method by which hazard analysis may be carried out and appropriate control measures ascertained to assess the practical problems.
- Identify critical control points, including critical limits to ensure their control.
- Demonstrate an understanding of the practical application of HACCP principles.

Core Skills
By the end of this course, students should be able to:

- Evaluate control measures for biological, chemical and physical hazards associated with food safety.
• Evaluate cleaning and sanitizing programmes shall be established to ensure that the food processing equipment and environment are maintained in a hygienic condition.
• Identify integrated pest management (IPM) steps and evaluate applied preventive actions and effectiveness of the overall pest control program.
• Evaluate applied procedures for selection and monitoring of food suppliers and justified this procedure by hazard assessment.
• Practical applies of HACCP plan through prerequisite controls, hazard analysis, and risk assessment.
• Design, implement, and manage appropriate programs for verification and maintenance of HACCP systems.

Course Overview

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<th>Interactive Lecture</th>
<th>Field Work</th>
<th>Class Assignments</th>
<th>Research</th>
<th>Practical</th>
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<td>9</td>
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<td>0</td>
<td>30</td>
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Chapter 1

Introduction to Food Safety

Objectives

- After reading this chapter, you should be able to:
  - Explain the definition and classification of foodborne illness.
  - Explain the main conditions, which bacteria need to grow in foods.
  - Define causes of cross contamination of foods.

Importance of Food Safety

Food safety is the utilization of resources and strategies to ensure that foods are properly produced, processed, and distributed so they are safe for consumption. Food safety is related to the presence of foodborne hazards like chemical, physical, and biological hazards in food at the point of consumption. The introduction of food safety hazards can occur at any stage of the food chain and adequate control throughout the food chain is indispensable.

Food safety means protection of consumer health

Therefore, measures to ensure food safety are necessary at all stages of the food chain

Fig. 1.1 Food Chain
Food safety concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

**Foodborne Illness**

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

The term ‘food poisoning’ is commonly used to cover a wide variety of illnesses or clinical conditions affecting the gastrointestinal tract.

The types of food poisoning may conveniently be grouped on the basis of the causative agent as follows:

1. Bacteria
2. Fungi
3. Viruses
4. Chemicals

**Statistical Food Poisoning Cases**

United States Centers for Disease Control and Prevention (CDC) estimates that each year 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die:

- Researchers have identified more than 250 foodborne diseases.
- Most of them are infections, caused by a variety of bacteria, viruses, and parasites.
- Harmful toxins and chemicals also can contaminate foods and cause foodborne illness.
- Economists estimate that foodborne costs the U.S. between $10 billion and $83 billion each year. A foodborne illness outbreak can cost a restaurant about $75,000. Specific costs include lost business, lawsuits, and medical costs.
Definitions of terms used are:

‘Food Poisoning’ Any acute illness attributable to the recent consumption of food.

‘A case’ A person affected with food poisoning.

‘Sporadic case’ An affected person whose illness is not connected with a similar illness of any other person.

‘Household outbreak’ An outbreak affecting two or more persons in the same private household, not connected with any other cases or outbreaks.

‘General outbreak’ An outbreak affecting two or more persons which are not confined to one private household.

According to the United States Centers for Disease Control (CDC), investigations of foodborne illness disease outbreaks often identify the following five risk factors that result in foodborne illness:

- Improper hot and cold holding of foods
- Inadequate cooking of foods
- Dirty and/or contaminated equipment
- Poor employee health and personal hygiene
- Food from unsafe sources

• There are many areas within the food production chain, from the farm to the retail establishment, where foods may be contaminated and/or mishandled. It is therefore important for all areas of food production to be carefully monitored and controlled so that the risk of foodborne illness is decreased.

• Many foodborne illnesses occur because of mishandled foods in foodservice and food retail establishments.

• Foods can be contaminated by biological, chemical, or physical hazards.

• Symptoms of foodborne illness are not pleasant and usually include one or more of the following: diarrhea, vomiting, headache, nausea, and dehydration.

• Foodborne illness is generally classified as infection or intoxication.

There are approximately 1,415 species of microorganisms known to produce disease to humans. From this total, 60% of the species are zoonotic and the majority (72%) originates in wildlife. Approximately 175 pathogenic species are associated with diseases considered to be emerging, and approximately 54% of emerging infectious diseases are caused by bacteria (Table 1.1)
Basic knowledge about microorganisms

- Microorganisms are living organisms that are individually too small to see with the naked eye.
- The unit of measurement used for microorganisms is the micrometer (μm); 1 μm = 0.001 millimeter; 1 nanometer (nm) = 0.001 μm.
- Microorganisms are found everywhere (ubiquitous) and are essential to many of our planet's life processes.
- Concerning the food industry, they can cause spoilage, prevent spoilage through fermentation, or can be the cause of human illness.
- There are several classes of microorganisms, of which bacteria and fungi (yeasts and molds)
- Another type of microorganism, the bacterial viruses or bacteriophage.
- Bacteria
  Bacteria are relatively simple single-celled organisms. Bacteria come in a wide variety of shapes.
  One method of classification is by shape or morphology:
  - Cocci: spherical shape (0.4 - 1.5 μm)
    Examples: *staphylococci* - form grape-like clusters; *streptococci* - form bead- like chains.
  - Rod: (0.25 - 1.0 μm width by 0.5 - 6.0 μm long)
    Examples: *bacilli* - straight rod.
  - Spirally - spiral rod.

There exists a bacterial system of taxonomy, or classification system, that is internationally recognized with family, genera and species divisions based on genetics.

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**Table 1.1. Species of microorganisms known to be pathogenic to humans**

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of infectious organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria and rickettsia</td>
<td>538</td>
</tr>
<tr>
<td>Helminths</td>
<td>287</td>
</tr>
<tr>
<td>Viruses and prions</td>
<td>217</td>
</tr>
<tr>
<td>Protozoa</td>
<td>66</td>
</tr>
<tr>
<td>Fungi</td>
<td>30</td>
</tr>
</tbody>
</table>

Adapted from Taylor et al. (2001)
Classification Based on the Activity:

- **Beneficial Microbes** - Used in process of making foods such as Yoghurt and bread.
- **Spoilage Microbes** - Spoil foods; not harmful to humans.
- **Pathogenic Microbes** - Disease causing microorganisms, organism or toxin must be consumed to cause symptoms.

**Yeast**

- Yeasts are members of a higher group of microorganisms called fungi.
- They are single cell organisms of spherical, elliptical or cylindrical shape.
- Their sizes vary greatly but are generally larger than bacterial cells.
- Unlike bacterial spores, yeast form spores as a method of reproduction.

**Molds**

- Molds are filamentous, multi-celled fungi with an average size larger than both bacteria and yeasts (10 X 40 μm).
- Each filament is referred to as a hypha. The mass of hyphae that can quickly spread over a food substrate is called the mycelium.

- **Bacteria** are most important biological foodborne hazard for any foodservice establishment.
- All bacteria exist in a vegetative state (the active state of a bacterium where the cell takes in nourishment grows and produce wastes).
- Some bacteria have the ability to form spores (the inactive or dormant state of some rod-shaped bacteria).
Bacteria Growth in Foods

- Bacteria are the most troublesome and important biological foodborne hazard for the food industry.
- Bacteria are living microorganisms that are a single cell.
- Bacterial cells can exist in two different states: the vegetative state and the spore state, the differences are listed in Table 1.2.
- All bacteria live in a vegetative state which can grow and reproduce.
- Few bacteria can change into a special state called the spore state.
- Spores are produced when the bacterial cell is in an environment where it cannot grow (frozen foods, dried foods).
- Spores are not able to grow or reproduce.
- Instead, spores are a means of protection when bacteria are in an environmental they cannot grow.

Table 1.2. Comparison between vegetative state and the spore state of bacteria.

<table>
<thead>
<tr>
<th>Presence</th>
<th>Vegetative State</th>
<th>Spore State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproduction</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Growth</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Produce toxin</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Resistance to stress</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Dangerous if ingested</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

- Bacteria are usually classified by their requirements needed for growth and as a spoilage or pathogenic microorganism.

I. Spoilage bacteria - degrade (break down) foods so that they look, taste and smell bad. They reduce the quality of food to unacceptable levels that cause waste.

II. Pathogenic bacteria - disease-causing microorganisms that can make people ill if they or their toxins are consumed with food.

- Both spoilage and pathogenic bacteria are important to those preparing and serving foods.
- Keep in mind, however, that the more effort taken to ensure that foods are safe will generally lead to a better quality food as well. Bacteria have different required temperatures for growth (Figure 1.3).
• **Psychrophilic** bacteria grow within a temperature range of 0 - 20°C. These microorganisms are particularly important since they can grow at room temperature and at refrigerated temperatures. Most psychrophilic bacteria are spoilage microorganisms, but some are pathogenic.

• The next group, **mesophilic**, grows between 30 and 40°C with best growth at human body temperature (37°C). There are many examples of spoilage and pathogenic mesophilic.

• Bacteria growing above (55 - 65°C) are called **thermophiles**. All thermophiles are spoilage microorganisms.

![Fig. 1.3. Optimum temperatures for bacteria growth](image-url)
Bacteria also differ in their requirements for oxygen:

- **Aerobic bacteria** require an oxygen level normally present in the air (about 21%) for growth. These microorganisms grow only in presence oxygen.
- **Anaerobic bacteria**, on the other hand, cannot tolerate any oxygen; it is toxic to them. Anaerobic bacteria grow well in vacuum packaged foods or canned foods where oxygen is not available.
- **Facultative anaerobic bacteria** can grow with or without oxygen (0-21% Oxygen). Most pathogenic foodborne microorganisms are facultative anaerobes.
- **Microaerophilic bacteria** require a specific amount of oxygen for growth. They must have between 3-6% oxygen to grow and will not grow outside this narrow oxygen range.

**Bacterial Growth Cycle**

- Bacteria reproduce by dividing.
- During each cycle of growth, each bacterial cell divides into two cells.
- This is called binary fission. The reproduction of bacteria, or increase in number, is referred to as bacterial growth. This means that during each growth generation, each cell gives rise to another cell (Figure 1.4).

![Fig. 1.4. Reproduction of bacteria](image)

- Generation time or time for cell numbers to double, for bacterial cells are typically 20-30 minutes but can be as quick as 15 minutes.
- Under optimal conditions, this means that a single cell can generate over 1 million cells in just 5 hours.
- That is why it is very important not to give bacteria an opportunity to grow. **Proper storage and handling of foods help to prevent bacterial growth.**
What Do Bacteria Need to Grow?

There are six factors influence the growth of bacteria

- They need a source of **Food**, on **Acidic** environment above pH 4.6, a **Temperature** between 5 and 60°C, 5 hours' **Time**, different **Oxygen** requiring environments, and **Moisture**.

- Remember this requirements with the acronym **F.A.T.T.O.M**.

- Since many foods inherently contain microorganisms, we need to be sure to control these six conditions to prevent bacterial growth.

Table 1.3. Factors influence the growth of bacteria

<table>
<thead>
<tr>
<th>Food</th>
<th>High protein</th>
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<tbody>
<tr>
<td>Acid</td>
<td>Foods with pH 4.6 or higher</td>
</tr>
<tr>
<td>Temperature</td>
<td>(5°C - 60°C) Temperature Danger Zone (TDZ)</td>
</tr>
<tr>
<td>Time</td>
<td>About 3 million for 5 hours in ideal condition.</td>
</tr>
<tr>
<td>Oxygen</td>
<td>Aerobic, Anaerobic, Facultative anaerobic, Microaerophile.</td>
</tr>
<tr>
<td>Moisture</td>
<td>Water activity ($a_w$) greater than 0.85</td>
</tr>
</tbody>
</table>

**A. Source of Food**

- The presence of a suitable food supply is the most important condition affecting bacteria growth. The food must contain the appropriate nutrients needed for grow.

- Bacteria generally prefer foods that are high in protein like meats, eggs, fish and dairy products, which called **Potentially Hazardous Foods (PHF)**.

**B. Acidity**

- Most foods are in the acidic range, or less than pH 7.0. Bacteria grow best in an environment that is neutral or slightly acidic. Most bacterial growth is inhibited in very acidic conditions. That is why **acidic foods**, like vinegar and fresh fruits (especially citrus), seldom provide a favorable climate for pathogenic bacteria.

- Most bacteria will not grow at pH levels below 4.6. Microorganisms thrive in a **pH range between 6.6 and 7.5**.
C. Temperature

- Temperature is probably the most critical factor affecting growth of bacteria in foods. Most disease causing bacteria grow within a temperature range of $5^\circ C - 60^\circ C$. This is commonly referred to as the "Temperature Danger Zone".
D. Time
Because bacteria grow in such a fast manner, it doesn’t take long before many cells are produced. A rule of thumb in the food industry is that bacteria need about 4 hours to grow to high enough numbers to cause illness. This includes total time that a food is between 5 - 60°C. Remember, a single bacterial cell can produce over 3 million cells in just 5 hours under ideal conditions.

E. Oxygen
As discussed earlier, different bacteria require different amounts of oxygen to grow. Some require a lot of oxygen (aerobic), others cannot tolerate oxygen (anaerobic), some only grow within a narrow oxygen range (microaerophilic), while others can grow with or without oxygen (facultative anaerobes).

F. Moisture
• Just like most other forms of life, moisture is an important factor affecting bacterial growth. That’s why humans have been preserving foods for thousands of years by drying them. Scientists have determined that it isn’t how much moisture is in a food that most affects bacterial growth. Growth is influenced most by the amount of “available water” which is designated with the symbol $a_w$.
• Water activity is water that is not bound to the food and is available for bacterial growth. $a_w$ is measured on a scale from 0 - 1.0. Disease causing bacteria can only grow in foods with $a_w$ greater than 0.85. There are many preservation processes that can be done to reduce the $a_w$ of foods including drying and freeze drying. The addition of salt or sugar can also be used as a...
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means to reduce available water. However, very high amounts need to be used making this method impractical.

The winner team against microorganisms (Temperature and Time)

Above 65°C/ 30 min: microorganisms stop multiplying
Above 70° C/ 15 sec: most sensitive microorganisms die
Above 85°C, 10 min: microorganisms are killed (pasteurization)
Above 121°C, 1-2 sec: spores are killed (sterilization)

Classification of Foodborne Illness:

I. Infection

• Ingestion of a harmful microorganism (bacteria, virus or parasites) within a food.
• An infection is caused when a living microorganism is ingested as part of a food.
• After ingestion, the microorganism can then attach to the gastro-intestinal tract and begin to grow.
• This can lead to the common symptoms of foodborne illness like diarrhea. In some instances, microorganisms may be carried in the blood stream from the gastro-intestinal tract to other parts of the body.

• Some common bacteria responsible for infection
  o Salmonella spp.
  o Shigella spp.
  o Campylobacter spp.
  o Escherichia coli (E. coli)
  o Listeria monocytogenes
  o Vibrio spp.

• Some common viruses responsible for infection
  o Norwalk
  o Hepatitis A
  o Rotavirus
  o Norovirus

• Some common parasites responsible for infection
  o Cryptosporidium parvum
  o Cyclospora
  o Giardia lamblia
  o Toxoplasma gondii.
  o Entamoeba histolytica
• Prevention of infections
Cooking and reheating are critical control points for controlling infectious agents. The destruction of bacteria, virus and parasites through pasteurization (cooking), will reduce infectious microorganisms to safe levels. The failure to pasteurize foods, and the subsequent survival of bacteria, virus and parasites results in many cases of illness.

II. Intoxication
• There are a few foodborne pathogenic bacteria that produce illness not by infection but by intoxication. These organisms are able to grow in certain foods under favorable conditions and produce toxins as a by-product of growth.
• The most important and potentially serious cause of intoxication is Clostridium botulinum. Intoxications usually have much shorter incubation times than infections, because the toxins are pre-formed in the food.

Toxins
The term toxin is just another name for poison. Certain microorganisms produce poisonous chemical compounds as by-products or wastes. Toxins may also occur naturally in some foods or may be unintentionally introduced during production. Foods may become toxic or poisonous through exposure to chemicals like pesticides, sanitizer, degreasers, unsafe metal containers, or through unapproved additives such as sulfates.

Toxigenic bacteria, however, cause most foodborne intoxication and preventing their growth in foods is often a critical control point. Unfortunately, many bacterial toxins are heat stable substances that maintain their disease causing ability even after being exposed to cooking temperatures. Therefore, while cooking and reheating measures are critical for controlling infectious bacteria, you must support cooking with time and temperature control at other steps to control toxins.

Spores
Three of the food related toxin producing bacteria are also capable of producing spores. Bacterial spores are forms of bacteria having a hardened cell wall around them. When conditions are unfavorable for growth, the cell walls help the bacteria to survive in a dormant state. When conditions become favorable for growth, the bacteria are capable of re-germination. Spores may lie dormant for centuries in dust, soil or sediments. Spores are typically found in foods grown in soil but may also be found in your common dry stored foods such as rice, powdered milk, beans, or grains. Normally, cooking does not destroy spores but actually activates them increasing the likelihood for foodborne intoxication at later steps.
Toxigenic bacteria

- *Staphylococcus aureus*
- *Clostridium perfringens* (spore former enterotoxins) *
- *Clostridium botulinum* (anaerobic spore former)
- *Bacillus cereus* (spore former)

*enterotoxins* is caused when a living microorganism is consumed (like on infection) and then the microorganism produces a toxin in the body, as opposed to in the food, that leads to illness. It is different from intoxication.

It is important to understand that, under the right set of circumstances, anyone can become ill due to eating contaminated foods. A healthy adult may be without symptoms or may have gastrointestinal symptoms. In most cases, the healthy adult host will recover in a few days. However, the risks and dangers associated with foodborne illness are much greater for the elderly, infants, pregnant women, and people who have a weakened immune system. For these groups of people, symptoms and length of foodborne illness can be much more severe, even life-threatening.

**Foodborne Hazards**

- **Biological hazards** are dangers from disease causing microorganisms. They are causing the most foodborne illnesses, and include bacteria, viruses, and parasites. These hazards are the most important foodborne hazard in food establishments and food retail.
- **Chemical hazards**; Chemicals that are a potential hazard are very diverse such as microbial toxins, lubricants, sanitizers Soaps, pesticides, antibiotics and additives.
- **Physical hazards** are dangers posed by the presence of particles that are not supposed to be a part of the food, such as glass, metal, or bone and foreign objects.

**Potentially Hazardous Foods**

- Foods that are high in protein contain a pH greater than 4.6 and have an aₜ greater than 0.85 are called potentially hazardous foods.
- If these foods are stored between 5-60 °C for enough time, they can permit the growth and/or toxin production of disease causing foodborne bacteria.
- Potentially hazardous foods pose the highest risk of foodborne illness.
- There are many examples of potentially hazardous foods prepared in food retail establishments. For example, beef, chicken, milk, eggs, seafood etc.
• Therefore, it is critical to control the handling and storage of potentially hazardous foods to prevent bacterial growth.

Ready to Eat Foods
• Ready to eat foods can also cause foodborne illness.
• Include raw or processed products that can be eaten immediately such as:
  - Vegetables
  - Delicatessen Items
  - Hard-boiled eggs
  - Salad Items

What is Cross Contamination?
Cross Contamination is the term used to indicate as to how bacteria are spread from one food product to another. This is especially true when handling raw meat, seafood, so keep these foods and their juices away from ready-to-eat foods.

What is the most common cause of foodborne illness?
The most commonly reported causes of foodborne illness are:
  - Preparation of food by an ill food service worker.
  - Poor personal hygiene of food service workers.
  - Failure to cooks and/or holds foods at proper temperature.
  - Failure to properly cool foods.
  - Issues of cross-contamination.

There are three main ways cross-contamination can occur:
• Food to food
• Equipment/Utensil to food
• People to food

How to Fight Bacterial?
• Separate raw meat, poultry and seafood from other foods in your grocery shopping bag and in your refrigerator.
• If possible, use a different cutting board for raw vegetables and meat products.
• Always wash hands, cutting boards, dishes and utensils with hot water and cleaning agents come in contact with raw meat, poultry and seafood.
• Never place cooked food on a plate that previously held raw vegetables, meat, poultry and seafood.

Preventing Cross-Contamination
Follow these steps to prevent cross-contamination and reduce hazards to food:
I. Wash your hands between handling different foods.
II. Wash and sanitize all equipment including utensils, knives, chopping boards and work surfaces before and after use when preparing different foods, e.g. raw meat and cooked meat.
III. Avoid touching your face, skin, and hair or wiping your hands on cleaning cloths.
IV. Store foods properly by separating washed or prepared foods from unwashed or raw foods.
V. Try preparing each type of food at different times and then clean and sanitize food contact surfaces between each task.

Fig. 1.8. Sources of cross-contamination
Food Safety

Table 1.4. The main sources of cross-contamination

<table>
<thead>
<tr>
<th>Source to Food</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Food to Food** | Food can become contaminated by bacteria from other food. This type of cross-contamination is especially dangerous if raw foods come into contact with cooked foods. Some examples of food to food cross-contamination.  
  - In a refrigerator, meat drippings from raw meat stored on a top shelf might drip onto cooked vegetables placed on a lower shelf.  
  - Raw chicken placed on a grill touching a steak that is being cooked. |
| **People to Food** | People can also be a source of cross-contamination to foods. Some examples are:  
  - Handling foods after using the toilet without properly washing your hands.  
  - Touching raw meats and then preparing vegetables without washing hands between tasks.  
  - Do not wear head coverings and gloves during preparing and handling food. |
| **Equipment to Food** | Contamination can also be passed from equipment and utensils to food. This type of contamination occurs because the equipment or utensils were not properly cleaned and sanitized between each use. Some examples are:  
  - Using unclean equipment such as slicers, can openers and utensils to prepare food.  
  - Using cutting boards and the same knife when cutting different types of foods, such as cutting raw chicken followed by salad preparation.  
  - Storing a cooked product, such as a sauce, in an unsanitized container that previously stored raw meat. |
Ethics in a Food Safety Field

The most common consumer concerns on ethical issues include the safety of food (e.g. the use of hormones and antibiotics in animal feed, use of chemical pesticides and fertilizers, technological advancement (e.g. GM crops, nanotechnologies, irradiation), the quality of the food, the healthiness of the food (e.g. labelling, chemical preservatives, adverse health effects).

For a long time, the ethics of food was only concerned with food security and consequently with distribution of food within developed and developing countries. Technological advances and organizational changes affecting food systems in recent years have been radical and rapid and have created many ethical dilemmas and social responsibility gaps. Food safety and its regulation are becoming a major international concern from the ethical point of view. Ethics of food safety is a dynamic area that continues challenging our precipitation of food consumption, health risks, and public responsibility for foodborne illness. Ethics refers to the values, principles, and codes by which people live. The word “ethics” is derived from the Greek word “ethos” meaning conduct, customs, or character and can be described as the application of morals to human activity. The issue of food safety and foodborne risk is gaining widespread public attention. For building and maintaining the confidence in food safety systems, there is a need to define the role of ethics in food safety policy development, because in these days ethical and moral values are often neglected and intentionally forgotten. Highly publicized food safety problems have given rise to general state of distrust among consumers, the food industry, and the institutions established to safeguard the food supply. Managing food safety hazards and risks is a top priority for any who is involved at any step in food supply chain including consumers.
Objectives

After reading this chapter, you should be able to:

- Identify the three main types of food safety hazards and give examples, of each.
- Explain how the growth of bacteria can be controlled.
- Describe control measures of food safety hazards.

Food Safety Hazard

A food safety hazard can be defined as any factor present in food that has the potential to cause harm to the consumer, either by causing illness or injury.

Classification of food safety hazards

Biological hazards refer to pathogens that can be bacterial or nonbacterial in nature (e.g., viruses, parasites, protozoa) and that would pose a public health threat.

Chemical hazards include residues from agricultural chemicals (e.g., pesticides), naturally occurring toxicants (e.g., mycotoxins), and environmental and/or industrial contaminants (e.g., mercury, lead, dioxin, or polychlorinated biphenyls).

Physical hazards include foreign matter (e.g., pieces of metal, glass, wood) and inedible parts of some foods (e.g., fruit stones).

1. Biological Hazards

It is generally biological hazards that pose the greatest immediate food safety threat to the consumer. For example, the ability of food-poisoning bacteria to cause large outbreaks of acute illness within a short time is a threat with which most food businesses are likely to have to contend. There are few foods that are not vulnerable to biological hazards at some point in their manufacture, storage and distribution.

Technically, biological hazards may include larger organisms, such as insects and rodents. However, these rarely present a direct threat to health. It is microorganisms and certain foodborne parasites that are of most concern as food safety hazards.
Among all illnesses attributable to foodborne transmission:
A. 30% caused by bacteria
B. 3% caused by parasites
C. 67% caused by viruses

Of the deaths associated with foodborne transmission:
A. 72% due to bacteria
B. 21% due to parasites
C. 7% due to viruses

Foodborne Disease Outbreaks
A. Two or more people developing the same illness after consuming the same food.
B. Most cases of foodborne disease are single cases not associated with a recognized outbreak.

Foods involved in Outbreaks
- Primarily of animal origin (48% from Beef, Poultry, Eggs, Pork, Fish, Dairy Products)

Why animal products?
I. High in nutrients
II. High water activity
III. Provide an excellent “Food” for microorganisms
IV. Intestinal tract is a source of pathogens

Foodborne illness caused by bacteria

Spore-forming bacteria
1. Bacillus cereus
2. Clostridium perfringens
3. Clostridium botulinum

non-spore forming bacteria
1. Campylobacter jejuni
2. Escherichia coli 0157:H7
3. Listeria monocytogenes
4. Salmonella spp.
5. Shigella spp.
6. Staphylococcus aureus
7. Vibrio spp.
Viruses
Viral gastroenteritis is very common worldwide. There are a number of viruses that are capable of causing foodborne infections, although in most cases, other forms of transmission are more common. Perhaps the best known are noroviruses and hepatitis A, which has been responsible for a number of serious foodborne disease outbreaks, often because of poor personal hygiene by infected food handlers.

“New” viruses may also pose a threat to food safety. For example, highly pathogenic avian influenza viruses primarily affect birds, but in some cases may be transmitted to humans and cause serious disease. So far, there is no direct evidence that this transmission can be foodborne, but these viruses are a source of the great concern to the poultry industry and there is still much to learn about them.

Parasites
A wide range of intestinal parasites can be transmitted to humans via contaminated foods, although for most, fecal-oral, or waterborne transmission are more common. These organisms are much more prevalent in developing countries with poor sanitation, but the increasingly global nature of the food supply chain may increase their importance in the developed world. Currently, protozoan parasites are the most important, but other types also need to be considered as food safety hazards.

The protozoan parasites that can cause foodborne illness in humans include several well-known species, such as Entamoeba histolytica, the cause of amoebic dysentery, and Cryptosporidium parvum. However, in recent years, some unfamiliar species have emerged as threats to food safety, especially as contaminants in imported produce. An example is Cyclospora cayetanensis, the cause of several outbreaks of gastroenteritis in the USA associated with imported fruit.

An example of a prominent microbiological nonbacterial food incident is the massive 1993 waterborne cryptosporidiosis outbreak. About 403,000 illnesses were reported and 100 AIDS patients died in that occurrence. The estimated total cost of illnesses associated with this outbreak up to $96.3 million, $31.7 million in medical costs and $64.6 million in productivity losses, with an average total cost for persons with mild, moderate, and severe illness at $116, $475, and $7,808, respectively. This outbreak was caused by a protozoan that was spread by water (Corso et al. 2003).
Spore-Forming Foodborne Bacteria

The following group of bacteria can produce a spore structure. Recall that a spore structure allows a cell to withstand environmental stress such as cooking, freezing, high salt foods, dried foods, and very acidic foods. Generally, bacterial spores are not harmful if ingested. However, if conditions of the food are changed that permit the spore to turn into a vegetative cell, the vegetative cell can grow in the food and cause illness if eaten.

Spore-forming bacteria are generally found in ingredients that are grown near the soil like vegetables and spices. They can be particularly troublesome in food retail-type environments because they can survive on foods as a spore. When conditions are improved, such as the addition of dried spices to a beef stew mixture, spores can become vegetative cells.

To keep spore-forming bacteria from changing to the dangerous vegetative state, it is critical that hot foods are maintained at 60°C or above and cold foods are maintained at less than 5°C.

Cooking, reheating, and cooling of foods should also be done as quickly as possible. Important spore-forming pathogens in the food retail industry include Bacillus cereus, Clostridium perfringens, and Clostridium botulinum.

**Bacillus cereus**

Description: *Bacillus cereus* is gram-positive, facultative anaerobic, sporeforming bacterium. Food poisoning is caused by toxins produced during the growth of the bacteria and these toxins cause two distinctly different forms of food poisoning - the emetic or vomiting type, and the diarrheal type.

Both forms of food poisoning require the bacteria to reach high numbers in the food (usually >10⁵ colony-forming unit (CFU/g) before sufficient toxin to cause illness can be produced.

The more common emetic type is caused by the presence of a pre-formed toxin (a heat- and acid-stable) in the food. It is important to note that live cells of *B. cereus* do not need to be ingested for this form of *B. cereus* food poisoning to occur and foods containing a toxin, but no viable cells, can still cause illness. This form of intoxication is characterized by rapid (between 0.5-6 h) onset of symptoms, which include nausea, vomiting and sometimes abdominal cramps and/or diarrhea. Symptoms usually last less than 24 h.
The less common **diarrheal type** is caused by the formation and release of heat- and acid-labile enterotoxins in the small intestine, although enterotoxin can also be pre-formed in food. This “intermediate” form of food poisoning has an incubation time of between 6-24 h (typically 10-12 h). Typical symptoms, which last for between 12-24 h, are primarily watery diarrhea, abdominal cramps and pain, with occasional nausea and vomiting.

**Common foods:** A wide variety of foods, including **meats, milk, vegetables, and fish** have been associated with the diarrheal-type disease. The vomiting-type illness is usually associated with **starchy foods** such as rice, potatoes, and pasta products.

**Growth and Survival in Foods:** The optimum growth temperature range for *B. cereus* is around 30-35 °C with an upper limit of up to 55 °C. Some strains, particularly from milk and dairy sources, are reported as being able to grow at chill temperatures, having a minimum temperature for growth of 4 °C (these are described as **psychrotrophic**). These psychrotrophic strains usually have a maximum temperature for growth of 37 °C. Psychrotrophic *B. cereus* strains have been shown to produce **enterotoxins** and research suggests that this may occur at temperatures of 7 °C. Emetic toxin production at refrigeration temperatures is thought not to occur.

*Bacillus cereus* can grow under otherwise ideal conditions at pH values between 4.3 and 9.3. The emetic toxin is stable over the pH range 2-11, but the **diarrheal enterotoxin is less stable at acid pH values.**

**Thermal Resistance:** The vegetative cells of *B. cereus* are fairly heat sensitive, being readily destroyed by typical pasteurization processes; however, *Bacillus* spores are moderately heat resistant and can survive quite harsh heat treatments. The *B. cereus* emetic toxin is heat stable (126 °C for 90 min), whereas the diarrheal enterotoxins are heat sensitive, being inactivated at 56 °C for 5 min.

**Control Measures**

**Processing**

- Ensuring a low initial level of the micro-organism in the product. This can be done by using ingredients with low levels of *Bacillus*, as well as by using well-designed equipment with effective cleaning regimes to prevent biofilm formation.

- Further control of *Bacillus* numbers is achieved by the appropriate use of temperature, either to destroy spores (sterilization temperatures used for many low-acid canned products are effective), or to minimize the germination and outgrowth of spores during the manufacture of chilled foods. Heat processes sufficient to inactivate the very heat stable emetic toxin are...
not practical, and the preferred approach is to prevent its formation before heat is applied. For many refrigerated products, heating processes should be devised so that foods reach processing temperatures quickly, and are cooled rapidly, particularly over the temperature range 10–55 °C. The cooling of small portions is easier to control than large volumes of product. Published cooling processes devised to control Cl. perfringens will usually also control the growth of B. cereus and other Bacillus species.

Product Use
Manufacturers should ensure that B. cereus levels do not reach hazardous levels (>10³ CFU/g) during the shelf life of the food. Cooked foods should be held hot (minimum 63 °C) prior to consumption, and refrigerated foods should be held at chill temperatures (ideally 4 °C or below) throughout the shelf life of the product.

Clostridium botulinum

Description: Clostridium botulinum is gram-positive, an anaerobic, sporeforming bacterium that produces neurotoxins. It is these toxins (the most potent natural toxins known) that cause the severe illness known as botulism. In recent years, some strains of Clostridium butyricum and Clostridium baratii have also been found to produce botulinum neurotoxins and there have been outbreaks of foodborne illness associated with these species.

There are at least two types of foodborne botulism:

Classic botulism - an intoxication caused by the ingestion of pre-formed toxins in food.

Infant botulism (also known as floppy baby syndrome) - a condition arising from toxin produced when Cl. botulinum grows in the intestines of unearned infants.

Common foods: Foods with a pH greater than 4.6, that are not properly heat processed and then packaged anaerobically (can or vacuum pouch), and held at above 4 °C.

Botulinum toxins are neurotoxins that affect the neuromuscular junction, leading to muscle paralysis. Prompt treatment can reduce this mortality rate to below 10%. The presence of live organisms is unnecessary for “classic” foodborne botulism to occur and very small concentrations of pre-formed toxin (possibly as low as a few nanograms) in food can cause illness. The ingestion of viable Cl. botulinum spores, at levels as low as 10 to 100 spores, is
required for infant botulism to occur.

All individuals are susceptible to classic foodborne botulism and onset times and the severity of symptoms depend on the amount of toxin ingested. Typically, the onset of symptoms occurs within 12-36 h, although the recorded range is 4 h-8 days. Early symptoms may include abdominal distension, mild diarrhea and vomiting, before more severe neurological symptoms develop. These include blurred or “double” vision, dryness of mouth, weakness, and difficulties in talking, swallowing and breathing. Death is usually the result of respiratory paralysis. General paralysis may also develop in some cases.

Infant botulism is associated with babies under a year old and symptoms include constipation, poor feeding, lethargy, and an unusual cry as well as a loss of head control.

Growth and Survival in Foods: Illness due to Clostridium botulinum is usually attributed to ingestion of foods that were not heat processed correctly and packaged anaerobically.

Thermal Resistance: Vegetative cells of Cl. botulinum are not particularly heat resistant. Heat processes designed to inactivate Cl. botulinum targets the much more heat resistant spores of this pathogen. Although heat resistance of spores varies between different strains the most heat resistant spores are found from Cl. botulinum types which can be eliminated at (121 °C/ 0.21 min). All toxins produced by Cl. botulinum are heat labile and can be inactivated by heating at 80 °C for at least 10 min. However, toxins may be more heat stable at lower pH values.

Control Measures:

Processing

Prevention of spore outgrowth and subsequent toxin production in foods can be achieved both by applying an effective thermal process and by careful product formulation.

The toxin may be destroyed in foods by heating at 100 °C for greater at 5 minutes. Controls include acidification below pH 4.6 and time and temperature control.

Preservatives can effectively control the growth of Cl. botulinum in foods. For example, nitrite is used in cured-meat products. Sorbates, parabens, polyphosphates, phenolic antioxidants, ascorbates, EDTA, metabisulfite, lactate salts and liquid smoke (in fish) can all be used in the control of Cl. botulinum under certain circumstances, although specific use should always be validated. The natural bacteriocin nisin is sometimes used to prevent the germination of Cl. botulinum spores in products such as canned vegetables and processed cheese.
Product Storage and Use
Foods stored at ambient temperatures should never rely on shelf life as a control for *Cl. botulinum*. These products should be formulated, and/or heat processed, to ensure the prevention of growth of the pathogen, or the destruction of spores. For chilled foods where the pH and water activity could potentially permit the growth of psychrotrophic *Cl. botulinum* (e.g. many ready meals, chilled low-acid sauces and cooked-meat products).

Infant botulism is controlled by advice to parents not to give their infants potentially hazardous foods. These foods, notably honey, are recommended to carry warnings on their labels that they are not suitable for infants under 12 months of age.

**Clostridium perfringens**

*Clostridium perfringens* can be found in low numbers in many raw foods, especially meat and poultry, as the result of soil or fecal contamination. Spores of *Cl. perfringens* will survive many heating and drying processes, and the presence of low numbers of the spores in raw, cooked and dehydrated products is not necessarily a cause for concern because high numbers of vegetative cells are required to cause illness.

*Clostridium perfringens* food poisoning is a relatively mild form of food poisoning and is caused by strains that produce enterotoxins (it is important to note that not all strains of *Cl. perfringens* are enterotoxin producers). The enterotoxins are produced when vegetative cells of the bacterium start to multiply in the human intestine and then sporulate. During sporulation, the organism also releases the enterotoxin that causes the symptoms associated with food poisoning.

High numbers (>10^5/g, usually 10^6-10^8/g) of viable vegetative cells of enterotoxin producing *Cl. perfringens* are necessary to cause food poisoning. Symptoms generally appear 8-22 h (typically 12-18 h) after ingestion of contaminated food and usually comprise profuse watery diarrhea and...
severe abdominal pain. Vomiting and nausea occur only rarely. The duration of illness is short, usually lasting for 24 h and not exceeding 48 h.

**Common foods:** Cooked-meat and poultry products are often associated with *Cl. Perfringens* food poisoning because spores of *Cl. perfringens* are likely to be present and protected from extreme heat at the center of stuffed poultry, rolled meats and meat pies cooling at the center of these products can be slow, oxygen levels are low, and the food is protein-rich, providing ideal conditions for the outgrowth of surviving spores. Non-meat-derived foods such as vegetable curries and soups have also been associated with outbreaks of *Cl. perfringens* food poisoning, although fish and fish products are rarely implicated.

**Transmission in foods:** Illness due to *Clostridium perfringens* is most often attributed to foods that are temperature abused. Foods that are improperly cooled food in the temperature danger zone for greater than 4 hrs.) and then not reheated properly create an ideal condition for the growth of *Clostridium perfringens*.

**Growth and Survival in Foods**
- *Cl. perfringens* can grow over the temperature range 15-55 °C, and growth does not occur below 10-12 °C. The optimum temperature for growth is 43-47 °C.
- *Cl. perfringens* vegetative cells die out relatively rapidly (93.5% were killed after 30 days at -17.7 °C) at freezing temperatures. However, they die out less quickly during storage at chill temperatures. Spores survive both refrigeration and freezing.
- The optimum pH for the growth of *Cl. perfringens* is 6.0-7.0, the pH of most cooked meat and poultry products. The organism is able to grow over the pH range 5.0-8.3 under otherwise ideal conditions. The spores can survive more extreme pH values.
- The minimum water activity for spore germination and growth of *Cl. perfringens* is between 0.94-0.95.

**Thermal Resistance**
Vegetative cells of *Cl. perfringens* are not very heat resistant and will usually be inactivated at temperatures exceeding 60 °C. The enterotoxins are heat labile and heating food to >70 °C throughout will inactivate enterotoxin.
Control Measures

A HACCP approach to the control of *Cl. perfringens* in food is preferred and control measures focus on effective temperature control.

**Processing**

The key control for *Cl. perfringens* during processing is the rapid cooling of “high risk” product after cooking, especially through the temperature range from 55-15 °C, followed by storage at temperatures below 4 °C (although below 10 °C ensures no growth of *Cl. perfringens*, refrigeration below 5 °C is essential to control other pathogens).

**Product Use**

Food to be served hot should either be freshly cooked and kept hot at temperatures not permitting the growth of *Cl. perfringens* (> 63 °C), or if cooked product is reheated, it should reach temperatures that inactivate vegetative cells and enterotoxin (at least 72 °C throughout the product).

**Non spore - Forming Foodborne Bacteria**

The following group of bacteria is not capable of producing a spore structure; they are always in the vegetative state. Compared to spore-forming bacteria that are in the spore state, vegetative cells are easily destroyed by proper cooking. There are numerous examples of non-spore forming foodborne bacteria that are important in the food industry.

*Campylobacter jejuni*

**Description:** *Campylobacter* spp. are gram-negative, non-spore-forming bacteria, although most cases of human campylobacteriosis are caused by *Cl. jejuni*. Campylobacter is now the leading cause of bacterial gastroenteritis in many developed countries. *Campylobacter* is unique amongst food-poisoning bacteria in that it is not normally able to grow in foods. This is because it has specific atmospheric requirements (microaerophilic conditions) for growth and can only grow at temperatures above ambient.

The infective dose for *Campylobacter* may be less than 500 cells. Symptoms associated with *Campylobacter* infections appear between 1 to 11 days (typically 2-5 days) after infection. Symptoms can vary widely and usually start with muscle pain, headache and fever. Most cases
involve diarrhea, and both blood and mucus may be present in stools. Nausea occurs, but vomiting is uncommon. Symptoms can last from 1 to 7 days (typically 5 days).

*Campylobacter* enteritis is most commonly associated with children (less than 5 years) and young adults. Death rarely occurs, particularly in healthy individuals.

**Common foods:** This microorganism is commonly found in raw milk and in raw chicken. Documented outbreaks are relatively rare but have been linked to raw and inadequately pasteurized milk, raw clams, garlic butter, fruits and contaminated water supplies. In one recorded incident in 2005, at least 80 people at offices in Copenhagen were made ill by contaminated *chicken salad* in canteen meals.

**Transmission in foods:** *Campylobacter jejuni* is often transferred from raw meats to other foods by cross-contamination. This is typically done by transfer from a food contact surface (such as a cutting board) or from food worker's hands.

**Growth and Survival in Foods:**
- *Campylobacter* is unable to grow at temperatures normally used to store food. The temperature range for growth is 30-45 °C, with an optimum of 42 °C. Although survival at room temperature is poor, *Campylobacter* can survive for a short time at refrigeration temperatures up to 15 times longer at 2 °C than at 20°C. The organism dies out slowly at freezing temperatures.
- The optimum pH for growth is 6.5-7.5, and the organism does not grow below pH 4.9.
- The minimum water activity for growth is ≥ 0.987.
- *Campylobacter* is microaerophilic, requiring reduced levels of oxygen (5-6%) to grow. The cells usually die out quickly in the air but survive well in modified or vacuum packaging.

**Thermal Resistance**
*Campylobacter* is heat sensitive and the cells are destroyed at temperatures above 48 °C. Therefore, they do not survive normal pasteurization processes applied to milk.

**Control Measures**
**Processing**
Poultry and poultry products are considered to be the main source of *Campylobacter* food poisoning and controls focus on measures to minimize the level of contamination during primary production and processing of poultry meat. Although prevent cross-contamination during the processing of poultry.
Food Safety

Product Use

- Cook raw meats properly. Do not use raw (unpasteurized) milk.

- Consumer education and domestic hygiene training can help prevent the transfer of *Campylobacter* from raw to ready-to-eat foods. Consumers should be advised not to wash meat and poultry carcasses prior to cooking to help prevent water splashes and aerosols from contaminating kitchen surfaces. Any surfaces that could be potentially contaminated, such as in meat-preparation areas, as well as chopping boards, should be thoroughly disinfected after use.

*Escherichia coli*

**Description:** *E. coli* are gram negative, non-spore-forming bacteria belonging to the family Enterobacteriaceae. Microbiologists recognize a small number of genera within the Enterobacteriaceae, including *Escherichia* species, as the coliform group. *E. coli* are found as part of the normal human gut flora, as well as in the environment, and the presence of *E. coli* in processed product can indicate *fecal contamination* (the reason why *E. coli* is used as an “indicator” organism).

There are four different groups of diarrhea-causing *E. coli* grouped by virulence characteristics as follows:

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enteropathogenic (EPEC)</td>
<td>Causing infantile gastroenteritis or summer diarrhea mostly in the developing world.</td>
</tr>
<tr>
<td>Enterotoxigenic (ETEC)</td>
<td>Causing diarrhea</td>
</tr>
<tr>
<td>Enteroinvasive (EIEC)</td>
<td>Causing a form of bacillary dysentery</td>
</tr>
<tr>
<td>Enterohaemorrhagic E. coli (EHEC)</td>
<td>EHEC can cause hemorrhagic colitis (bloody diarrhea).</td>
</tr>
</tbody>
</table>

The EHEC most frequently associated with causing foodborne illness is the serotype *Escherichia coli* O157:H7.

**Common Foods:** *E. coli* are usually associated with foods derived from cattle such as beef products, particularly minced/ground beef, and dairy products derived from raw milk. Although EHEC could be present on any raw-beef product, minced-meat products are considered...
more of a risk because the pathogen is transferred from the surface to the center of the product during the mincing process.

EHEC outbreaks, particularly those caused by E. coli O157:H7, have frequently been associated with undercooked minced (ground) beef products such as hamburgers - it has been dubbed “hamburger disease”

Transmission in foods: E. coli is usually transferred to foods like beef by contact with the intestines of animals. Transmission can also occur if employees are carriers and do not wash their hands properly after going to the bathroom.

Growth and Survival in Foods
- EHEC can grow over the temperature range 7-46 °C with an optimum of 37 °C. EHEC survive well at chilled and frozen temperatures.
- The minimum pH for the growth of E. coli O157 under otherwise optimum conditions is reported as 4.0-4.4. The organism is able to survive acid conditions (down to 3.6) and has been reported to survive for two months at 4 °C at a pH of 4.5.
- The minimum reported water activity for the growth of EHEC is 0.95. Salt (NaCl) at 8.5% inhibits the growth of E. coli O157.
- EHEC are facultative anaerobes (able to grow with or without the presence of oxygen). Modified-atmosphere packaging has little effect on the pathogen although it is reported that it is inhibited on meat packaged under 100% CO₂.

Thermal Resistance
EHECs are not heat-resistant organisms. EHEC present on the surface of the product are likely to be inactivated rapidly during cooking, but cells at the center of ground-meat products and rolled meat joints will only be inactivated if the center of the product is sufficiently heated. Cooking temperature is recommended that 70 °C for 2 min, or the equivalent, in all parts of every burger.

Control Measures
The control of EHEC starts on the farm with the implementation of good agricultural practices. This can help reduce the shedding of E. coli O157 from cattle. Good agricultural practices are extremely important for the production of fresh fruits, salad stuffs and vegetables. It is very important to minimize fecal contamination of all food commodities.
Processing

It is safe to assume that raw products of bovine origin (such as fresh meat and raw milk) are potentially contaminated with EHEC and to treat them accordingly using a HACCP approach. **Good hygienic practices (GHP)** should be implemented when handling beef carcasses and the controlled use of **chilled temperatures** will prevent the growth of EHEC in these products. **Cross-contamination between raw and processed product must be avoided.**

Product Use

Consumers should be advised of the risks associated with raw-meat products, in particular those made from minced/ground meat, and that all beef products need to be thoroughly cooked. Consumers should be advised to avoid unpasteurized dairy products, juice or cider, and to wash fruit and vegetables well (although washing may not remove all contamination).

**Listeria monocytogenes**

**Description:** The genus *Listeria* are gram-positive, non-spore-forming rod-shaped bacteria. All cases of *Listeria* infection are caused by *L. monocytogenes*, usually causes gastrointestinal symptoms for the healthy adult. However, disease complications can be life threatening (septicemia, meningitis, encephalitis) for people with weakened immune systems. Those most at risk of acquiring the disease are pregnant women (20 times greater risk than healthy individuals).

The incubation period is 1 to 90 days (mean 30 days). Symptoms in pregnant women can lead to infection of the fetus, which can result in miscarriage, stillbirth, or the birth of an infected infant, although the mother usually survives. During the first few years of the 21st century, there have been a number of large *Listeria* outbreaks caused by ready-to-eat (deli) poultry products in the USA. In 2000, a multistate outbreak (29 cases, with 7 deaths) was linked to turkey deli meat, and during 2002, another outbreak (at least 46 cases with 11 deaths) was linked to poultry deli products. This outbreak resulted in the recall of 27.4 million pounds of product, the largest meat recall in US history.

**Common foods:** *Listeria monocytogenes* has the potential to be present in all raw foods. Cooked foods can also be contaminated, usually as the result of **post-process contamination**. *L. monocytogenes* has been isolated from a very wide range of processed foods including milk,
soft cheeses, ice cream, ready-to-eat cooked and fermented meats, smoked and lightly processed fish products and other seafood products.

**Transmission in foods:** Transmission to foods can occur by cross-contamination. Also, foods that are not cooked properly can contain live cells.

**Growth and Survival in Foods**
- *Listeria monocytogenes* is psychrotrophic and the ability to grow at chill temperatures is why it is a particular risk in extended-shelf-life chilled foods that can support its growth. Extremely slow growth of *L. monocytogenes* has been recorded at temperatures as low as 1.5 °C and the maximum temperature for growth is generally accepted as 45 °C.
- The pH range for the growth of *L. monocytogenes* is 4.3–9.4. However, *L. monocytogenes* can survive for extended periods in acid conditions, particularly at chilled temperatures.
- The minimum water activity for the growth of *L. monocytogenes* is 0.92. The organism is tolerant of high sodium chloride levels and is able to grow in environments of up to 10% salt, and to survive in concentrations of 20–30%.
- *L. monocytogenes* grows well in aerobic and anaerobic conditions. Its growth is unaffected by many modified atmospheres even at low temperatures. High concentrations of carbon dioxide are necessary to inhibit growth.

**Thermal Resistance**
*L. monocytogenes* is not particularly heat resistant. It is readily inactivated at temperatures above 70 °C and heat processes such as normal commercial milk pasteurization will destroy numbers typically found in milk.

**Control Measures**
The control of *Listeria* in foods relies largely on a HACCP approach and the establishment of effective critical control points in the process.

**Processing**
The careful design and layout of processing equipment in conjunction with the implementation of regular, thorough cleaning regimes of the processing environment can significantly reduce the level of *Listeria* contamination in many processed foods.

The organism should be inactivated by heat applied during the cooking process and the presence of *Listeria* in cooked products can indicate poor hygiene, either during manufacture, distribution or at retail.
Other critical controls include strict temperature control, the prevention of cross-contamination between raw and processed foods.

**Product Use**

Clear cooking instructions are needed on the packaging of many chilled foods requiring reheating prior to consumption, to ensure that all parts of the product receive a needed heating process.

In the US the Food and Drug Administration (FDA) also includes hot dogs, luncheon meats, cold cuts and smoked seafood (unless thoroughly reheated) to the list of foods that at-risk consumers should definitely avoid.

*Salmonella spp.*

**Description:** *Salmonellae* spp. are gram-negative, non-spore-forming rod-shaped bacteria belonging to the family Enterobacteriaceae, which cause the disease known as salmonellosis. The source for *Salmonella* is the intestinal tracts of warm blooded animals. Some *Salmonella* serotypes have a limited host spectrum (i.e. they cause specific and often serious clinical disease in one or a few animal species), such as *S. typhi* and *S. paratyphi* in humans (causing typhoid fever).

Many studies to determine *Salmonella* contamination rates in food commodities have been conducted. For example, in 2005 a Europe-wide study found that about one in five large-scale commercial egg-producing facilities had hens infected with *Salmonella*, with the lowest levels of infection being found in Sweden and Luxembourg, and the highest levels in Portugal, Poland and the Czech Republic. A UK study reported contamination levels in poultry of 5.7% in 2001, and a 2003 study of UK produced shell eggs found contamination levels of 0.34%. In the US, testing during 2003 found that 3.6% of raw meat and poultry samples were contaminated with *Salmonella*.

The incubation time is between 6 and 48 (usually 12-36) h. The infective dose is thought to vary widely and can depend on the individual consuming the infected food, the type of food involved and possibly the serotype involved. In general, however, it is thought that high numbers (between $10^5$-$10^6$ cells) of *Salmonellae* need to be consumed to cause illness.

**Common foods:** This microorganism exists in many foods, especially raw meat and poultry products, eggs, milk, dairy products, pork and cream-filled desserts.
Cooked ready-to-eat foods can become contaminated as the result of cross-contamination from raw foods. Although contamination can occur as the result of direct contact, it can also occur via food-preparation surfaces or equipment used for both raw and cooked foods. Individuals recovering from salmonellosis can continue to shed Salmonella in their stools for some time. Food handlers reporting Salmonella gastroenteritis should be excluded from work until shedding has stopped.

Foodborne Salmonella outbreaks are commonly associated with inadequately cooked eggs and poultry, or products containing these ingredients, such as egg mayonnaise. However, many other food types have been linked with outbreaks. These include dairy products (such as milk, cheese and ice cream), fruit juice, tomatoes, melons, lettuce and other salad leaves, sprouted seeds, cereals, potato crisps, coconut, black pepper, chocolate, almonds, peanut butter, cooked meats, fermented meats such as salami, and reconstituted dried infant formula.

Growth and Survival in Foods

- Most Salmonella serotypes can grow over the temperature range 7-48 °C, although growth is reduced at temperatures below 10 °C. Most Salmonella serotypes are unable to grow at refrigeration temperatures, the organism is able to survive for extended periods at chill temperatures, particularly under freezing conditions.
- The optimum pH range for the growth of Salmonella spp. is 6.5-7.5.
- Salmonella are able to grow at water activities down to 0.94.
- Salmonella are facultative anaerobes (can grow with or without oxygen) and growth is only slightly reduced under nitrogen. The organism is able to grow in atmospheres containing high levels of carbon dioxide (possibly up to 80% in some conditions).
- Salmonella is not especially resistant to sanitizers used in the food industry but is able to form biofilms that may reduce the efficacy of a sanitizer if cleaning is inadequate.

Thermal Resistance
The majority of Salmonella serotypes are not particularly heat resistant and are usually inactivated by pasteurization or equivalent heat processes.

Control Measures
A HACCP approach is essential for the effective control of Salmonella in food production.

Processing
The control of Salmonella in food should start on the farm with the careful production of fresh produce and animal-derived raw materials, such as eggs, poultry and pork. Many countries have
policies that encourage measures to reduce the levels of *Salmonella* in egg-production units, in poultry houses, during the growing of fresh produce and during transport of raw commodities. Such measures are especially important for products that will not receive a heat treatment prior to consumption. Food manufacturers should carefully source their ingredients and supplies from producers implementing such measures or purchase pasteurized products (such as milk or egg) to reduce the risk of *Salmonella* entering their facilities or reaching the consumer. *Salmonella* can be effectively controlled by relatively mild heat processing (e.g. milk pasteurization), but it is essential that adequate measures are in place to avoid cross-contamination between raw and cooked product. Take into consideration Practice good personal hygiene

**Product Use**
Cook foods thoroughly, clean and sanitize food contact surfaces after use with raw foods.

*Shigella spp.*

**Description:** *Shigella* species are gram-negative, non-spore-forming bacteria belonging to the group Enterobacteriaceae, which cause the disease known as shigellosis (also called bacillary dysentery). *S. dysenteriae* is the cause of epidemic dysentery. Although the most common route of transmission is from person-to-person via the faecal-oral route, all have been linked to foodborne outbreaks. *Shigella* infections can also occur as the result of drinking, or swimming in, contaminated water.

The infective dose can be very low — as few as 10 cells can cause illness. The incubation time for illness ranges from 12 h to 7 days (usually 1–3 days). *Shigella* species can cause an asymptomatic infection, mild diarrhea, or can cause acute dysentery. Typical symptoms are abdominal pain and cramps, fatigue, fever and diarrhea with mucus and sometimes blood occurring in the feces.

In Europe in 2005, just less than 7500 cases of shigellosis were reported across 26 countries and in England and Wales, approximately 1000 cases are reported each year. In developing countries, where hygiene standards are low, shigellosis is much more common, and each year an estimated 1.1 million people die from *Shigella* infections.
Common foods: This microorganism is common in salads, lettuce, green onions, uncooked baby maize, milk, soft cheese, cooked rice, poultry, raw vegetables and chocolate pudding.

Growth and Survival in Foods

- *Shigella spp.* have a minimum temperature for growth of 6.1 °C, and a maximum of 47 °C. *Shigella spp.* survive at frozen and chill temperatures, although the time of survival depends on the type of food environment as well as the temperature.

- The reported pH range allowing growth of *Shigella spp.* is 4.8-9.3. *Shigella spp.* are gradually inactivated at pH values <4.0.

- *Shigella spp.* can grow at water activities down to 0.96 (maximum salt concentration 5.2% NaCl). The organism dies out slowly at low water activities.

- *Shigella spp.* are facultative anaerobes (can grow with or without oxygen).

Thermal Resistance

*Shigella spp.* are easily inactivated by heat and death is rapid at temperatures above 65 °C.

Control Measures

Control measures to prevent food becoming contaminated with *Shigella spp.* should focus on preventing fecal contamination of raw and processed foods and using safe or treated water supplies for irrigation of crops and for food processing.

Processing

Washing of fresh produce, even in water containing a disinfectant does not ensure inactivation/removal of any *Shigella* present. Good hygiene standards in countries supplying salad crops and fruit are very important to prevent the import of contaminated produce. Minimizing handling, and insisting on good levels of personal hygiene, both reduce the risk of food becoming infected by food handlers.

Food handlers suffering or suspected of suffering from *Shigella* infections or individuals who have been in contact with people suffering from shigellosis should be excluded from food-handling areas until it is ensured they are free from the pathogen (typically three consecutive negative stool samples are required).

Product Use

The importance of good hygiene should be emphasized to consumers. When travelling to developing countries where shigellosis is endemic, consumers should be advised to only drink treated or boiled water, only eat cooked foods and fruits that they have peeled themselves.
**Staphylococcus aureus**

**Description:** *Staphylococcus aureus* is a gram-positive, non-spore-forming bacterium that is able to grow both aerobically or anaerobically (a facultative anaerobe). Some strains of the organism have the ability to produce **toxins (enterotoxins)** in food, and it is the ingestion of these pre-formed enterotoxins that causes the symptoms associated with *staphylococcal* food poisoning. **The toxins are heat-stable**, water-soluble proteins that resist most proteolytic enzymes, such as pepsin or trypsin, therefore retaining their activity in the digestive tract after ingestion.

Foods that have caused outbreaks of *staphylococcal* food poisoning have usually been temperature abused either during processing or refrigerated storage.

**Common Foods:** Foods involved in outbreaks have included milk and milk-based products, such as chocolate milk, cream, custard or cream-filled pastries and butter. Cooked meats and poultry products are also commonly implicated, as are cheeses - especially where there has been a slow start in the fermentation process leading to a delay in acid production.

*Staphylococcal* food poisoning is considered a mild form of the foodborne disease, although all individuals are thought to be susceptible. **The toxin is pre-formed in the food**, so the onset of symptoms is rapid, 30 min-7 h (average 2-4 h). The severity of symptoms is related to the amount of enterotoxin ingested and the susceptibility of the individual to the particular enterotoxin. However, for sufficient quantities of enterotoxin to be produced to cause illness, the organism needs to reach levels of $10^5$-$10^6$ CFU/g in food. It is thought that the amount of enterotoxin needed to cause illness is between 0.1-1 mg.

Symptoms are usually nausea and vomiting with abdominal cramps, sometimes followed by diarrhea. In more severe cases, headache, muscle cramping, and dehydration occur, but patients usually recover within 2 days. Although deaths have occurred amongst children and the elderly, these are rare. A mass outbreak (>$10,000$ cases) of *staphylococcal* food poisoning occurred in Japan during 2000 and was **linked to milk**

**Transmission in foods:** Since humans are the primary source, **cross-contamination** from the worker's hands is the most common way the microorganism is introduced into foods. Foods requiring large amounts of food preparation and handling are especially susceptible.
Growth and Survival in Foods

- *Staph. aureus* can grow over the growth range 7-46 °C and the optimum temperature for growth is 37 °C. Enterotoxin can be produced over the temperature range 10-45 °C, with an optimum temperature for production of around 40 °C. Also, cells survive frozen storage well.

- The pH range for the growth of *Staph. aureus* is 4.5-9.3, and the optimum is around 7.0. Enterotoxin can be produced between pH4.8-9.0, although production is usually inhibited below pH 5.0. The optimum pH for enterotoxin production depends on strain and type of toxin and is between pH 6.5 and 7.3.

- *Staph. aureus* is noted amongst food-poisoning bacteria as being unusually tolerant of low water activities. It is also more tolerant of salt (NaCl) than many other organisms and is generally able to grow in 7-10% NaCl. The minimum water activity for growth is generally considered to be 0.86. Enterotoxin can be produced at aw values as low as 0.87, but the optimum is ≥0.90. *Staph. aureus* is very resistant to drying and can survive for extended periods in dried foods.

- *Staph. aureus* is best able to grow and produce enterotoxin in the presence of oxygen, but it also able to grow and produce small quantities of enterotoxin under anaerobic conditions. High concentrations of carbon dioxide (80%) effectively inhibit *Staph. aureus* growth.

**Thermal Resistance**

*Staph. aureus* is not particularly heat resistant and cells are inactivated by normal pasteurization temperatures. *Staphylococcal* enterotoxins are very heat resistant. Inactivation of enterotoxin is affected by the water activity and pH of the substrate. Although heating at 100 °C for a minimum of 30 min will generally inactivate enterotoxin, the time for inactivation will be extended at lower water activities. If enterotoxins are present in sufficient quantities, it is possible for them to survive heat processes used in the sterilization of low acid products.

It is important to remember that heating of product is likely to inactivate *Staph. aureus* cells but may not inactivate enterotoxin. Temperature abuse of product prior to heat processing could result in staphylococcal food poisoning even though no viable *Staph. aureus* is detectable in the product.
Control Measures

Processing

The presence of low levels of *Staph. aureus* in raw products is not necessarily a cause for concern; it is the prevention of *staphylococcal* enterotoxin production that should be considered in risk assessments. However, control measures to reduce the risk of *Staph. aureus* food poisoning during processing should focus on keeping levels low. This can be achieved by minimizing the physical handling of product, keeping work preparation areas clean and by the implementation of good temperature control.

Using utensils and disposable gloves can help reduce direct human contact with food products. Individuals suffering from infected cuts and sores and from colds should temporarily be excluded from dealing with ready-to-eat products.

Product Use

“Potentially Hazardous Foods” should either be kept well refrigerated (<5 °C) or kept hot (>63 °C): under these conditions any contaminating *Staph. aureus* cells will be unable to grow.

Vibrio cholera

*Description:* *Vibrio cholerae* is a gram-negative, non-spore-forming bacterium. It is the causative organism of cholera, a serious human disease responsible for many fatal outbreaks throughout history. Although cholera is usually associated with poor hygiene and fecal contamination, the disease can also be foodborne.

![Image of Vibrio cholerae](image)

The infective dose is thought to be $10^6$–$10^8$ cells. Those most at risk of developing severe cholera are individuals with impaired or undeveloped immunity, such as the immunocompromised and young children, and those suffering from malnutrition. Typically, symptoms start with mild diarrhea, leading to more severe diarrhea typified by the production of grey “rice water” stools. Nausea, abdominal pains and low blood pressure can also occur. If untreated, the infection can lead to dehydration, and in severe cases, this can result in death. Healthy individuals usually recover in 1-6 days.

*Common foods:* most cholera outbreaks are caused by contaminated water. Although primarily associated with shellfish, other fish, as well as vegetables, fruit, meat, frozen coconut milk and...
cooked rice have been implicated as vehicles for the pathogen. A cholera outbreak in Zambia during 2004, in which raw vegetables were implicated as the vehicle, involved an estimated 2500 cases.

Transmission in foods: *Vibrio cholerae* can be present on food if it is contaminated by polluted water, or by food handlers carrying the pathogen. Contaminated water used to make ice can lead to the contamination of beverages.

Growth and Survival in Foods

- *V. cholerae* can grow over the temperature range 10-43 °C, with an optimum of 37 °C. The organism can increase rapidly in temperature-abused processed foods where there is little competing microflora. It can also survive for extended periods under refrigeration and is reported to survive in moist, low acid chilled foods for 2 or more weeks. It can also survive for long periods at freezing temperatures.
- The pH range for the growth of *V. cholerae* is 5.0-9.6, with an optimum value of 7.6. It is tolerant of high pH conditions but not acid and is rapidly inactivated at pH values of < 4.5 at room temperature.
- *V. cholerae*, unlike other *Vibrio* spp., does not have an absolute requirement for salt to grow, although its growth is enhanced in the presence of low concentrations of salt. The organism is sensitive to desiccation and survives for less than 48 h in dry foods.
- *V. cholerae* is a facultative anaerobe (grows with or without oxygen). It grows best, however, under aerobic conditions.
- The organism is not resistant to sanitizers normally used in food processing environments.

Thermal Resistance

*V. cholerae* is not heat resistant and is killed by pasteurization temperatures. Cooking to 70 °C is normally adequate to ensure inactivation of *V. cholerae*.

Control Measures

Control measures to prevent food becoming contaminated with *V. cholerae* should focus on preventing fecal contamination of raw and processed foods and using safe or treated water supplies for irrigation of crops and for food processing. Raw sewage should not be used as a fertilizer for crops.

The World Health Organization (WHO) advises that there need not be an embargo on importing foods from cholera-affected areas. It is suggested that importers agree with food exporters on
the good hygienic practices that need to be implemented during food handling and processing to prevent, minimize, or reduce the risk of any potential contamination.

**Foodborne Viruses**

Foodborne viruses differ from foodborne bacteria. They are the smallest and simplest form of life known. Viruses require a living host (animal, plant, or human) to grow and reproduce. Unlike bacteria, they do not reproduce or grow in foods. They are usually transferred from one food to another, from a food handler to a food, or from a water supply to a food. Viruses that are important in food retail preparation; Hepatitis A and Rotavirus.

**Hepatitis A**

*Description:* The hepatitis A virus (HAV) is an enteric virus, which causes a liver disease in humans now known as hepatitis A. There are a number of different hepatitis viruses but only the HAV, and possibly the hepatitis E virus, can cause foodborne disease.

Although HAV is most commonly spread by direct person-to-person contact via the fecal-oral route, there are many documented foodborne outbreaks in the literature. Foodborne outbreaks can often be traced back to an infected food handler or foods that have come into contact with faecally contaminated water.

The HAV can only be present in foodstuffs as the result of fecal contamination. This means the food is handled under poor hygienic practices.

The incubation time for symptoms to appear is on average about 4 weeks, but it can vary from 2-6 weeks. This long incubation time before the illness becomes evident can mean that it can be difficult to trace the exact source of the infection, and it can also mean that large numbers of individuals are affected before it is evident that there is viral contamination in the food chain.

Many cases of HAV infection are asymptomatic, particularly in children. Initial symptoms include headache, fatigue, fever, poor appetite, abdominal discomfort, nausea and vomiting. After a week or so, virus can be detected in the blood stream and occur liver disease.
The largest recorded foodborne outbreak of hepatitis A infections, involving 290,000 cases, was in Shanghai, China in 1988 and was caused by clams harvested from waters polluted by raw sewage.

Common Foods: Ready-to-eat foods that are washed with a non-potable water supply or foods that are handled excessively can be contaminated with Hepatitis A. Examples include raw vegetables and raw seafood. Due to the long incubation period, it is very difficult to identify the food source of a Hepatitis A infection.

Transmission in foods: The virus is primarily transmitted from person-to-person contact, by cross contamination, and by fecal contamination.

Survival Characteristics

- HAV cannot grow in food or water, it can survive in many environments for some time. When excreted in human feces the HAV can survive in the environment in water or soil for at least 12 weeks at 25 °C.
- HAV has a high resistance to many chemicals and solvents and it is more resistant to heat and drying than other enteroviruses. It can survive refrigeration and freezing for up to two years and it is resistant to acid (pH 1 for 2 h at room temperature).
- The HAV is resistant to low levels of free chlorine (0.5-1 mg free chlorine/Liter for 30 min). It is also resistant to chloroacetic acid (300 mg/L) and chloramines (1 g/L) for 15 min at 20 °C. The virus can be inactivated on surfaces with a 1:100 solution of sodium hypochlorite.

Thermal Inactivation

The HAV is relatively heat resistant, although thorough cooking at higher temperatures will usually inactivate the virus. It is resistant at 70 °C for up to 10 min but is inactivated at temperatures of 85 °C for 1 min.

Control Measures

Strategies to reduce the risk of foodborne outbreaks of hepatitis A should focus on preventing foods from becoming contaminated. In developing countries young children should be kept away from areas where fresh produce is grown and harvested, and clean water should be used for the irrigation, washing and processing of foods. Shellfish-harvesting areas should be monitored for sewage contamination.
Processing
Food handlers should implement frequent hand washing and the wearing of gloves particularly at points in the food chain where foodstuffs that will receive no further cooking are handled. In addition, those suffering from symptoms of hepatitis A should be removed from the food-production area until they have a medical release.

Product Use
Consumers should be advised only to eat thoroughly cooked foods from known sources and not to eat uncooked vegetables that they have not peeled or prepared themselves.

Rotaviruses

Description: The name rotavirus is derived from the characteristic wheel-like appearance of the viruses when viewed under an electron microscope. There are seven described species or “serotypes” of rotavirus (known by the letters A-G). Group A rotaviruses are a major cause of acute diarrhea; it is thought that only a small percentage (around 1%) of cases are actually foodborne.

Common Foods: Raw seafood, raw fruits and vegetables were washed with a contaminated water supply. Non-heated foods that are handled by people who are shedding the virus.

The incubation time is 1–3 days and initial symptoms include vomiting and watery diarrhea for about 2–3 days, often leading to dehydration. The diarrhea can sometimes persist for 5–8 days.

In developing countries, rotaviruses cause an estimated 125 million cases annually in infants and young children. Some 18 million of these are severe cases resulting in almost 900,000 deaths each year.

Transmission in foods: Most infections occur as the result of person-to-person transmission through the fecal-oral route.

Foods can be contaminated by infected food handlers, by the use of fecal matter to fertilize crops, or through the use of contaminated water for irrigation of fresh produce.

Water contaminated with infected feces can also act as a source of the virus. Shellfish cultivated in contaminated waters can accumulate rotavirus particles.
Survival Characteristics

- Rotaviruses can persist in the environment, and they are known to survive in river water at 20 °C and at 4 °C for several weeks.
- Rotaviruses can survive for some time on hard surfaces and can remain infective in anaerobically stored animal waste for up to 6 months. Bovine rotaviruses have been shown to survive processes used to produce soft cheese.
- Rotaviruses are reported to be sensitive to drying and to extremes of pH.
- Rotaviruses are relatively resistant to many disinfectants, but they are susceptible to 95% ethanol, 2% sodium hypochlorite (with a long contact time), and to 5% Lysol.

Thermal Inactivation

Rotaviruses are reported to be relatively heat sensitive. Although there is little data on the heat inactivation of these viruses, it is thought that normal cooking processes should inactivate them. A study found that rotavirus infectivity is reduced by 99% when heated at 60 °C for at least 30 min.

Control Measures

Strategies to reduce the risk of foodborne outbreaks of rotavirus infections should focus on preventing foods from becoming contaminated by the use of clean water for the irrigation, washing and processing of foods, and preventing shellfish-harvesting areas from becoming contaminated with sewage.

Processing

Food handlers should implement frequent hand washing (rotaviruses are most effectively controlled using alcohol-based hand-cleaning agents) and the wearing of gloves, particularly at points in the food chain where foodstuffs that will receive no further cooking are handled. Food handlers suffering from viral gastroenteritis should be excluded from work and advised not return for at least 48–72 h after symptoms have ceased.

Product Use

Consumers should be advised not to eat raw or inadequately cooked shellfish.
Foodborne Parasites

Foodborne parasites are another important foodborne biological hazard. Parasites are small or microscopic creatures that need to live on or inside a host to survive. There are many examples of parasites that can enter the food system and cause foodborne illness. Included here are lists of a few of the most troublesome ones that may appear in food industry. Parasitic infection is far less common than bacterial or viral foodborne illness.

Protozoa

*Cryptosporidium*

**Description:** *Cryptosporidium* is a single-celled protozoan parasite. It is a cause of gastrointestinal infection in humans. *Cryptosporidium* has a complex life cycle, most of which takes place within the gastrointestinal tract (mainly in the small intestine) of a single host. The transmissible stage in the cycle is a highly resistant, thick-walled spore, known as an oocyst.

**Common Foods:** *Cryptosporidium* cannot grow in foods or in water and does not multiply in the environment outside of a suitable host. *Cryptosporidium* is mainly associated with water that has been polluted by human or animal feces, but oocysts have also been found in a number of unprocessed foods, notably raw milk, meat and shellfish and fresh fruit and vegetables. Oocysts are easily destroyed by heat and *Cryptosporidium* is not normally associated with cooked and processed foods. Any food that may come into contact with contaminated water during production, and where there is no subsequent process that will destroy oocysts, is at risk from *Cryptosporidium* contamination. However, food is not considered to be a major vehicle for the transmission of the parasite. The person-to-person and animal-to-human transmission routes are likely to be much more common.

The main symptom is profuse watery diarrhea, often accompanied by abdominal pain. Vomiting, fever and weight loss may also occur.

**Control Measures**

**Processing**

- Control measures for *Cryptosporidium* in food processing focus largely on the control of contamination in the water supply.
Heat processing is an effective control against *Cryptosporidium* oocysts in food. Normal milk-pasteurization processes are effective, as are recommended processes for meat products (70 °C for at least 2 min). Reheating cooked foods to at least 74 °C will destroy oocysts immediately.

Freezing foods for at least 7 days is an effective control measure, as is drying. Oocysts were reported to lose infectivity in 7 days when stored at a water activity of 0.85 at 7 °C.

**Hygiene**

*Good personal hygiene practice*, especially hand washing, is an essential control and any staff suffering from gastroenteritis should be excluded from processing areas.

**Nematodes**

*Anisakis*

**Description:** The anisakids are a family of parasitic marine nematode worms that can cause a potentially serious infection in humans following consumption of infected seafood.

The principal species identified in human infection is *Anisakis simplex*.

*Fresh fish* is the principal vehicle for *A. simplex* infection in humans, especially if it is eaten raw or

**Control Measures**

Fish that will be eaten raw or lightly cooked should be frozen at -20 °C or less for at least 24 h to kill the Anisakids. This should also apply to fish intended to be cold smoked, fermented, or marinated before consumption.

Hot smoking processes where an internal temperature of at least 60 °C is attained will destroy the Anisakids, as will cooking to a temperature of 70 °C for at least 2 min.
### Table 2.1 Examples of practical hazard control options—biological hazards

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Control measures</th>
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| All types of biological hazards | - Prerequisite programs/support systems, e.g., SSOP*  
- Effective trace and recall procedures |
| **Raw materials** | |
| Bacteria | **People** |
| (a) Heat-stable preformed toxins, e.g., *Staphylococcus aureus*, *Bacillus cereus* emetic toxin | | **Build-up during process** |
| | - Specification for organism and/or toxin.  
- Evidence of control during supplier process.  
- Testing (positive release with statistically valid sampling).  
- Certificate of analysis (checked for compliance with specification)  
- Hand wash procedures.  
- Covering cuts/wounds, etc.  
- Occupational health procedures.  
- Management control of food handlers.  
- Control of rework loops |
| (b) Vegetative pathogens, e.g., *Salmonella* spp., *L. monocytogenes*, *V. parahaemolyticus*, *Y. enterocolitica*, *E. coli*, etc. | **Raw materials** |
| | - Lethal heat treatment during process.  
- Specification for organism.  
- Evidence of control during supplier process.  
- Testing (as previous)  
- Certificate of analysis.  
- Temperature control to prevent growth to hazardous levels  
- Intrinsic factors such as pH and acidity; aw—salt, sugar, drying; organic acids; chemical preservatives. |
| **Processes/during processing** | **Cross-contamination at the facility (from the environment and raw materials)** |
| | - Intact packaging  
- Pest control  
- Secure building (roof leaks, ground water, etc.)  
- Logical process flow, including where necessary:  
  1. Segregation of people, clothing, equipment, air, process areas  
  2. Directions of drains and waste disposal |
| *SSOP: Sanitation Standard Operating Procedures* | (Continued)
### Table 2.1 continued

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Control measures</th>
</tr>
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| **Raw materials** | • Specification  
• Evidence of control during supplier process  
• Certificate of analysis. |
| **Processing/during process** | 1. Lethal combination of heat treatment and acidity or sugar level for high-acid/sugar products for ambient storage.  
2. For products to be stored at chilled conditions (<5°C) a sub-lethal heat treatment may be used but this must be accompanied by intrinsic factors which will prevent the growth of psychrotrophic organisms (e.g., *Cl. botulinum*) during the product shelf-life.  
3. For all the above processes, pack integrity, cooling water chlorination, and handling practices for cooling container are essential. |
| **Cross-contamination at the facility (from the environment and raw materials)** | • Temperature control to prevent growth to hazardous levels.  
• Intrinsic factors such as pH and acidity; a<sub>w</sub> salt, sugar, drying; organic acids; chemical preservatives.  
• Other processes lethal to the organism of concern, e.g., irradiation, etc. |
| **Foodborne viruses, e.g., Norovirus, hepatitis A** | • Strict Supplier control concerning irrigation and wash water of salads and vegetables, and sourcing of filter-feeding shellfish—avoidance of shellfish likely to be grown sewage-contaminated water.  
• Consideration given to proven lethal treatments such as irradiation or heat treatment.  
• Stringent personal hygiene procedures among food handlers. |
| **Parasites** | • Supplier Quality Assurance (SQA) procedures to include farm animal husbandry and veterinary inspection for control of parasites such as *Toxoplasma gondii*, *Taenia in beef*.  
• Freezing (<-18 °C), heating (>76 °C), drying, and salting. |
| **Protozoa, e.g., Cryptosporidium, Giardia, Cyclospora** | • Use of filtered water.  
• Pasteurization of raw milk.  
• Heat treatment of water and raw milk used as ingredients. |

Supplier Quality Assurance (SQA) procedures should include maximum acceptable levels in specifications. Sampling and visual inspection will supplement control measure.
2. Chemical Hazards

Chemical contamination can happen at any stage in food production and processing. Chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. 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 may not always represent a hazard. The amount 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.

**Types of chemical hazards**

2.1 Naturally Occurring Chemicals

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

2.1.1 Biological toxins

2.1.1.1. Fungal toxins (Mycotoxins)

A. Aflatoxins

Aflatoxins are **highly toxic compounds** produced by certain molds of the genus *Aspergillus* growing on a number of raw food commodities. Several types of aflatoxin (14 or more) occur in nature, but four aflatoxins B1, B2, G1 and G2 are particularly dangerous to humans and animals as they have been found in all major food crops. *Aflatoxin B1* is the most common, the most toxic and the most potent in terms of causing **liver cancer** in human.

Where are Aflatoxins Found?

Aflatoxins occur mainly in the tropical regions of the world. The **high humidity, high temperature** of the environment, combined with less than ideal handling and storage of crops after harvest in developing countries, cause them to be more commonly found in a variety of crops like peanuts, maize, cereals, cottonseeds, tree nuts and some spices etc. On the other hand, when aflatoxins B1 and B2 contaminated crops are fed to cows, they are converted to the less potent aflatoxins M1 and M2 respectively and can be found mainly in milk and dairy products.
Aflatoxins and Human Health

- Aflatoxins are best known for their potential in causing liver cancer. The International Agency for Research on Cancer (IARC) has classified all naturally occurring aflatoxins to be carcinogenic and aflatoxin M1 to be possibly carcinogenic to humans. Some researchers suggest that the effect of aflatoxin B1 in causing cancer is stronger in people carrying hepatitis B virus or hepatitis C virus. Researchers reported that out of 550,000 - 600,000 liver cancer or Hepatocellular carcinoma (HCC), cases worldwide each year, about 25,200-155,000 may be attributable to aflatoxin exposure.

- Aflatoxins are mutagenic in bacteria (affect the DNA), genotoxic, and have the potential to cause birth defects in children.

- Aflatoxins cause immunosuppression, therefore, may decrease resistance to infectious agents (e.g. HIV, tuberculosis).

Fig. 2.1. Aflatoxin contaminated nuts

Acute poisoning can be life threatening

Large doses of aflatoxins lead to acute poisoning (aflatoxicosis) that can be life threatening, usually through damage to the liver. Outbreaks of acute liver failure (jaundice, lethargy, nausea, death), identified as aflatoxicosis, have been observed in human populations since the 1960s. Most recently deaths attributed to aflatoxins were reported during the summer of 2016 in the United Republic of Tanzania. Adults are more tolerant to acute exposure than children.
The consumption of food containing aflatoxin concentrations of 1 mg/kg or higher has been suspected to cause aflatoxicosis. Based on past outbreaks it has been estimated that, when consumed over a period of 1-3 weeks, an aflatoxin B1 dose of 20-120 μg/kg body weight per day (μ gram is one billionth [1×10⁻⁹] of a kilogram) is acutely toxic and potentially lethal.

Stability in Foods

- Aflatoxins are quite stable compounds and survive relatively high temperatures with little degradation. Their heat stability is influenced by other factors, such as moisture level and pH, but heating or cooking processes cannot be relied upon to destroy aflatoxins. For example, roasting green coffee at 180 °C for 10 min gave only a 50% reduction in aflatoxin B1 level.
- The stability of aflatoxin M1 in milk fermentation processes has also been studied and although appreciable losses do occur, significant quantities of the toxin were found to remain in both cheese and yoghurt.
- Aflatoxins can be destroyed by alkaline and acid hydrolysis and by the action of oxidizing agents. However, in many cases, the resulting by-products also carry a risk of toxicity, or have not been identified.

Reduction of Aflatoxins in Food

The ability of aflatoxin producing fungi to grow on a wide range of food commodities and the stability of aflatoxins in foods mean that control is best achieved by measures designed to prevent the contamination of crops in the field and during storage, or detection and removal of contaminated material from the food supply chain.

Pre-harvest

Pre-Harvest control of aflatoxins is best achieved through general good agricultural practice (GAP) to include such measures as:

- Land preparation, crop waste removal, fertilizer application and crop rotation.
- Use of fungus- and pest resistant crop varieties.
- Control of insect pests.
- Control of fungal infection.
- Prevention of drought stress by irrigation.
- Harvesting at the correct moisture level and stage of maturity.
**Post-harvest Handling and Storage**

Post-harvest interventions include preventive measures to address adequate storage conditions (moisture, temperature, mechanical or insect damage, and aeration), which influence contamination and toxin production by mold. Food manufacturers should also ensure that the aflatoxin level in raw materials they received complies with the safety standards. Consumers should store food under dry and cool condition and discard food with signs of mold infestation.

**Testing**

A number of analytical methods have been developed based on TLC (thin layer chromatography), HPLC (high-performance liquid chromatography) and ELISA (enzyme-linked immunosorbent assay) and there are also rapid screening kits available.

**B. Ochratoxins**

Ochratoxins are a small group of chemically related toxic fungal metabolites (mycotoxins) produced by certain molds of the genera *Aspergillus* and *Penicillium* growing on a wide range of raw food commodities. Some ochratoxins are potent toxins and their presence in food is undesirable.

The most important and most toxic ochratoxin found naturally in food is ochratoxin A (OTA). OTA is genotoxic (damages DNA) and teratogenic (damages the fetus) and is considered a probable carcinogen, causing renal carcinoma and other cancers.

**Control Options**

The ability of OTA-producing fungi to grow on a wide range of food commodities and the persistence and ubiquity of OTA in the food chain mean that control is best achieved by measures designed to prevent the contamination of foods using HACCP-type techniques. Detection and removal of OTA-contaminated material from the food supply chain is also important for imported products.

**Pre-harvest**

Both *A. ochraceus* and *P. verrucosum* are considered to be storage fungi rather than field fungi. Pre-Harvest controls are therefore limited to harvesting susceptible crops at the correct moisture level and stage of maturity.

**Post-harvest Handling and Storage**

- For cereals, ensuring that susceptible crops are harvested at a safe moisture level, or are dried to a safe level immediately after harvest is vital to prevent mold growth and OTA production during storage. In tropical and subtropical climates stored grains must be dried...
rapidly to an aw value of below 0.8 and this level must be maintained throughout storage to prevent.

- Other important cereal storage factors are effective cleaning of grain stores and handling equipment between crops, and fumigation to prevent insect infestation. In tropical regions, the use of controlled atmosphere storage to control insects may also help to inhibit mold growth.

- Rapid and effective drying is also important in the control of OTA production in other commodities, especially coffee. For dried fruits, minimizing mechanical and insect damage during handling and storage helps to prevent the entry of molds into the fruit before drying.

- **Monitoring raw material quality** is the most effective control for processed foods. Any ingredient that displays visible mold growth should not be used.

### 2.1.2 Plant Toxins

Natural toxins are biochemical compounds produced by plants in response to certain conditions or stressors. Some of these toxins are listed in Table 2.2

### 2.1.3 Marine toxins

Marine toxins are a group of toxins that sometimes accumulate in fish and shellfish. There are two sources of marine toxins:

**A. Decomposition**

When certain fish, especially scombroid fish (i.e. tuna, bonito and mackerel), start to decompose, histamine is formed. Histidine, a naturally-occurring amino acid, is converted into histamine by an enzyme produced by certain bacteria during decomposition. Histamine, in small doses, is necessary for the proper functioning of the human immune system. However, histamine in higher doses may trigger severe reactions when consumed similar to those seen in allergic reactions such as rash, nausea, vomiting, diarrhea, headache, dizziness, burning throat, stomach pain and itchy skin. The presence of high levels of histamine indicates that decomposition has occurred, even if the decomposition is not obvious. Toxic amounts of histamine can form before a fish smells or tastes bad.

**B. Microscopic Marine Algae**

Many fish toxins are produced by and can accumulate in fish and shellfish if they ingest certain types of algae.

### 2.1.3.1 Polychlorinated Biphenyls

Polychlorinated biphenyls (PCBs) are members of a group of organic compounds that have been used in a number of industrial applications. Because these compounds are toxic and
environmentally stable, their use has been limited to closed systems and their production has been banned in a number of countries. The most significant source of PCBs in foodstuffs is through absorption from the environment by fish. PCBs then accumulate through the food chain and can be found in high levels in tissues with high lipid content. This issue should be considered by HACCP teams dealing with raw materials of marine origin.

Table 2.2. Some Natural Toxins in Food Plants

<table>
<thead>
<tr>
<th>Food commodity</th>
<th>Toxin</th>
<th>Control criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>cucumber family</td>
<td>cucurbitacins</td>
<td>Ensure that the plants are watered carefully during growth, and to harvest the crop as early as possible. Note: heat stability and poor solubility of cucurbitacins mean that cooking the vegetables in water has little effect.</td>
</tr>
<tr>
<td>(cucumber, courgettes, marrows and melons).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Almonds, sorghum, flaxseed, and stone fruit</td>
<td>Cyanogenic Glycosides</td>
<td>Adequate processing of cyanogenic glycoside-containing plants should be sufficient to significantly reduce or remove the toxic agents prior to consumption. Note: Treatments for removing cyanogenic compounds from flaxseed include boiling in water, dry and wet autoclaving and acid treatment followed by autoclaving.</td>
</tr>
<tr>
<td>parsnips, celery and parsley</td>
<td>Furocoumarins</td>
<td>If furocoumarin-containing vegetables are cooked in water, the levels in the vegetable can be appreciably reduced.</td>
</tr>
<tr>
<td>potatoes</td>
<td>Glycoalkaloids</td>
<td>Peeling, Cooking (deep frying).</td>
</tr>
<tr>
<td>Green beans, red kidney beans, white kidney beans</td>
<td>Lectins</td>
<td>safe cooking of red kidney beans as following steps: 1. Soak in water for at least 5 h. 2. Pour away the soaking water. 3. boil briskly in fresh water, with occasional stirring, for at least 10 min.</td>
</tr>
</tbody>
</table>
2.2. Intentionally Added Chemicals

These chemicals are intentionally added to food at some point during the plant growth and distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded.

The following are examples of food additives that may be chemical hazards if used improperly:

<table>
<thead>
<tr>
<th>Source</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food coloring</td>
<td>Can produce an allergic-type reaction in sensitive people.</td>
</tr>
<tr>
<td>Sodium nitrite (preservative)</td>
<td>Can be toxic in high concentrations.</td>
</tr>
<tr>
<td>Vitamin A (nutrient supplement)</td>
<td>Can be toxic in high concentrations.</td>
</tr>
<tr>
<td>Sulfite agents (preservative)</td>
<td>Can cause allergic-type reaction in sensitive people.</td>
</tr>
</tbody>
</table>

Note:

- **World Health Organization (WHO)** regulates use of intended food additives.
- A symptom of chemical poisoning will vary depending on the type of poisoning and the amounts consumed, in many cases, it affects the nervous system.
- Large amounts of the toxic substances - illness will occur quite quickly in other cases (small amounts) effects may be cumulative.

2.2.1 Nitrites, Nitrates, and N-nitroso Compounds

Historically, nitrites and nitrates have been added to a number of food products as constituents of their preservation systems. This deliberate addition of nitrite and nitrate to food is closely governed by legislation as high levels of nitrites, nitrates, and N-nitroso compounds in food can produce a variety of toxic effects. Specific examples include infantile methemoglobinemia and carcinogenic effects.

N-nitroso compounds can be formed in foods from reactions between nitrites or nitrates and other compounds. They can also be formed in vivo under certain conditions when large amounts of nitrites or nitrates are present in the diet. In common with a number of other chemicals,
nitrate can cause additional problems in canned products, where it can cause lacquer breakdown, allowing tin to leach into the product.

The HACCP team must ensure that nitrite and nitrate were added to products do not exceed the legal, safe levels and must consider the risk of contamination from other sources and other ingredients, giving an increased overall level.

2.3. Unintentionally or Incidentally Added Chemicals

- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones).
- Toxic elements and compounds (e.g., lead, zinc, arsenic, mercury, cyanide).
- Secondary direct and indirect chemicals (e.g., lubricants, cleaning compounds, sanitizers, paint).

Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received. For example, certain seafood may contain small but legal residues of approved antibiotics. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as sanitizers or inks. Most incidental chemicals have no effect on food safety, and others are only a concern if they are present in too high an amount. Incidental chemicals also include accidental additions of prohibited substances such as poisons or insecticides that may not be allowed at any level.

The following are examples of incidental contaminants that may be chemical hazards

<table>
<thead>
<tr>
<th>Source</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agricultural chemicals</td>
<td>Can be acutely toxic if present in the food at high levels and may cause health risks with long-term exposure.</td>
</tr>
<tr>
<td>(e.g., pesticides, herbicides)</td>
<td></td>
</tr>
<tr>
<td>Cleaning chemicals</td>
<td>Can cause chemical burns if present in the food at high levels.</td>
</tr>
<tr>
<td>(e.g., acids, caustics)</td>
<td></td>
</tr>
<tr>
<td>Maintenance chemicals</td>
<td>Chemicals that are not approved for food use and may be toxic.</td>
</tr>
<tr>
<td>(e.g., lubricants, paint)</td>
<td></td>
</tr>
</tbody>
</table>

Metal poisoning: chemicals from containers or food contact surfaces of inferior metal that are misused and inferior-metal poisoning.
2.3.1 Cleaning Chemicals

Cleaning chemicals are perhaps the most common potential chemical contaminants used at the facility level in any food preparation or production operation. Cleaning residues may remain on utensils or within pipework and equipment and be transferred directly onto foods, or they may be splashed onto food during the cleaning of adjacent items.

It is therefore vitally important that HACCP team members consider the implications of the cleaning procedures in their operation. Problems can be prevented by the use of nontoxic “food grade” cleaning chemicals and through the design and management of appropriate cleaning procedures. This will include adequate training of staff and may involve post-cleaning equipment inspections and audits of chemicals in use on site.

2.3.2 Pesticides

In agriculture, pesticides are used during production to protect crops and improve yields, and after harvest, they are again used to protect the crops in storage. However, not all pesticides are safe for use in food production and even those that are safe for food use may leave residues that could be harmful in high concentrations. To overcome these problems most countries have very strict control of the pesticides that can be used and on the residue limits that are acceptable. These are set through expert toxicological studies and are normally laid down in legislation. From the food safety point of view, you need to understand any pesticide risks from raw materials at any stage in their preparation. You also need to know which pesticides are permitted for use and what the maximum safe residue limits are in each case. Control can be built into your HACCP system to ensure that the safe levels are never exceeded in your products.

In addition to raw materials that have direct pesticide contact, you must also consider the possibility of cross-contamination with pesticides at any stage in food production. This could be cross-contamination of your raw materials or it could happen on your site, e.g., from rodenticides.

2.3.3 Toxic Metals (also known as heavy metals)

Metals can enter food from a number of sources and can be of concern at high levels. The most significant sources of toxic metals to the food chain are:

- Environmental pollution.
- The soil in which food stuffs are grown.
• Equipment, utensils, and containers for cooking, processing, and storage.

• Food-processing water.

• Chemicals applied to agricultural land.

Particular metals of concern are tin (from tin containers), mercury in fish, cadmium and lead, both from environmental pollution. Also significant are arsenic, aluminum, copper, zinc, antimony, and bismuth, and these have been the subject of research studies. Just as for any other chemical hazard, you need to understand the particular risk of toxic metals to your products, and this is likely to be associated with the raw materials, metal equipment, and finished-product packaging. Control can be built in as part of your HACCP system, product and process design, and prerequisite programs.

2.3.4 Dioxins and Furans

Neither of these two groups are manufactured directly but they are created as byproducts in the processes used to manufacture pesticides, preservatives and disinfectants, and in paper processing. They can also be formed when materials such as plastic, paper, and wood are burned at low temperatures. There are several hundred dioxins and furans, some of which are nontoxic, some only slightly toxic and a small number are amongst the most toxic substances known. Dioxins are ubiquitous environmental contaminants and are generally present in very low concentrations in all foods.

There have been several high profile contamination incidents involving dioxins. These include Belgian animal feed in 1999 resulting in contaminated meat, poultry, and dairy products; Irish pork products in 2008 and German eggs in 2010, both of which were also associated with contaminated animal feed.

2.3.5 Plasticizers and Packaging Migration

Certain plasticizers and other plastics additives are toxic and are of concern if they are able to migrate into food. Migration depends on the constituents present and also on the type of food, for example, fatty foods promote migration more than some other foodstuffs.

The constituents of food-contact plastics and packaging are normally strictly governed by legislation, along with the maximum permitted migration limits in a number of food models. The HACCP team should be aware of current issues for both food packaging and plastic utensils and should build control into the HACCP and product design systems. This might mean the requirement for checks on migration at the packaging concept stage.
2.3.6 Veterinary Residues

Hormones, growth regulators, and antibiotics used in animal treatment can pass into food. Hormones and growth regulators have been banned from food production in many countries, and the use of antibiotics and other medicines are normally tightly controlled. Carry-over of antibiotics can cause major problems due to the potential for serious allergic responses in susceptible individuals. Similarly, hormones and growth regulators can potentially cause health issues when consumed by humans, and it has also been suggested that overuse of antibiotics in agriculture can make antibiotics less effective in human disease. The HACCP team should consider the risks of contamination in their raw materials and product so that appropriate control and monitoring can be instigated. This will include control at the primary producer and may also involve monitoring at the incoming raw material stage.

Control of chemical hazards

The control measures applied for chemical hazards depend on the specific hazard. It is important to research fully valid methods of control as a part of your HACCP planning process.

Some examples of control measures include:

- Good Agricultural Practice (GAP) during growing, harvesting and storage.
- Transport and storage control including temperature control, moisture control, separation, etc.
- Hygiene control.
- Inspection and release programs.
- Heat treatments.
- Supplier Quality Assurance (SQA) procedures.
Table 2.3 Examples of practical hazard control options - chemical hazards

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Control measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>All types of chemical hazards</td>
<td>• Prerequisite programs/support systems, e.g., SQA, GMP/GAP, cleaning, handling, and storage systems.</td>
</tr>
<tr>
<td></td>
<td>• Effective trace and recall procedures.</td>
</tr>
<tr>
<td>Mycotoxins</td>
<td>• SQA control of harvesting and storage to prevent mold growth and mycotoxin formation in cereals, groundnuts, dried fruit.</td>
</tr>
<tr>
<td></td>
<td>• Heat treatment during process to destroy mold and prevent growth in product.</td>
</tr>
<tr>
<td></td>
<td>• Controlled dry storage.</td>
</tr>
<tr>
<td></td>
<td>• Intrinsic factors to reduce $a_w$ to &lt;0.7.</td>
</tr>
<tr>
<td>Cleaning chemicals</td>
<td>• Use of nontoxic, food-compatible cleaning compounds.</td>
</tr>
<tr>
<td></td>
<td>• Safe operating practices and written cleaning instructions.</td>
</tr>
<tr>
<td></td>
<td>• Separate storage for cleaning reagents.</td>
</tr>
<tr>
<td></td>
<td>• Covered designated labeled containers for all chemicals.</td>
</tr>
<tr>
<td>Pesticides, veterinary residues, and plasticizers in packaging</td>
<td>• Specification to include suppliers’ compliance with maximum legal usage levels.</td>
</tr>
<tr>
<td></td>
<td>• Verification of supplier records.</td>
</tr>
<tr>
<td></td>
<td>• Annual surveillance program of selected raw materials.</td>
</tr>
<tr>
<td>Toxic metals/PCBs/dioxins and furans</td>
<td>• Specifications and surveillance where appropriate.</td>
</tr>
<tr>
<td>Nitrates, nitrites, and nitrosamines and other chemical additives</td>
<td><strong>As contaminants:</strong></td>
</tr>
<tr>
<td></td>
<td>• Specifications and surveillance where appropriate.</td>
</tr>
<tr>
<td></td>
<td><strong>As additives:</strong></td>
</tr>
<tr>
<td></td>
<td>• Safe operating practices and written additive instructions.</td>
</tr>
<tr>
<td></td>
<td>• Special storage in covered, designated labeled containers.</td>
</tr>
<tr>
<td></td>
<td>• Validation of levels through usage rates, sampling, and testing.</td>
</tr>
<tr>
<td>Allergens</td>
<td>• Awareness of the potential allergenic properties of certain ingredients. Special consideration given to adequate labeling, production scheduling and cleaning, segregation or cross-contamination controls, rinse water testing, dedicated equipment, and to the control of rework.</td>
</tr>
</tbody>
</table>

**Note:** These control options are not necessarily effective on their own and will often be used in combination to control specific hazards. Some of the suggestion options will be more appropriate to prerequisite programs than to inclusion in the HACCP plan.
2.4. Allergenic Hazards

In recent years, the problem of food allergy has been growing in importance for the food industry as the number of people, particularly children, affected by allergy symptoms has increased. Food manufacturers have been encouraged to respond to this development, particularly in terms of **labelling foods clearly**. Along with clear allergen labelling comes a responsibility to ensure that such labels are accurate. When foods are labelled as not containing specific allergens, it is extremely important that they do not become contaminated with those allergens during production.

**What is Food Allergy?**

Food allergy can be defined as an adverse, immune-mediated reaction to food. Often, people will refer to any adverse reaction to food as an “allergy.” However, it is important to remember that true food allergies involve the **immune system** and are almost invariably mediated through immunoglobulin E (IgE).

The majority of food allergies are caused by **proteins**, which sensitize and then elicit an **allergic reaction** in sensitive individuals. Food allergy needs to be differentiated from food intolerance, a condition that has no immune-system involvement and includes reactions to certain food components, such as lactose, amines and histamine. Adverse reactions that lack an immunological mechanism are sometimes referred to as non-allergic food hypersensitivity reactions.

Food intolerances can sometimes be controlled by limiting the amount of a particular food eaten, but with food allergies, much stricter avoidance of the food is necessary. Symptoms of an allergic reaction can range in severity from a skin rash or slight itching of the mouth, to migraine headaches, to anaphylactic shock and death. The type and severity of an allergic response is determined by many factors, including dosage, route of administration, a frequency of exposure, and genetic factors. This is not to be confused with a food intolerance, which is an abnormal physiological response to a specific food. Symptoms of food intolerance may include cramps, diarrhea and bloating.

**Anaphylactic shock** is the most severe adverse reaction to food and can be **fatal** if left untreated. It generally occurs within minutes of consumption, but occasionally the reaction may be delayed, with symptoms appearing several hours after the initial exposure. Initial symptoms of an IgE mediated allergic reaction are characterized by itching, hives, and/or swelling of the lips, palate, tongue, and throat. Once the food enters the stomach and intestine, symptoms may include cramping, nausea, pain, and diarrhea. Subsequent systemic symptoms
generally affect the pulmonary and cardiovascular system. The most dangerous symptoms include breathing difficulties and a drop in blood pressure or shock.

**Common allergens of concern include:**

- Peanuts (groundnuts)
- Tree nuts
- Eggs
- Milk products
- Shellfish
- Fish
- Soy/soya
- Wheat

The above list is often described as the “big 8” allergens due to commonality of occurrence. Allergens are normally considered under the heading of chemical hazards since it is a chemical, usually protein, component of the food product that causes the response in susceptible individuals. This is clearly an issue for concern with respect to protecting the health of a specific sector of the population. In fact, the population levels affected are considered to be approximately 2% of adults and 7% of children; however, up to 20-30% of adults believe that they are affected by some sort of allergy or adverse reaction to food.

The control options open to the food processor manufacturing products with allergenic components are raw material control, effective pack labeling, control of rework, and effective cleaning of equipment. The label must describe the product contents accurately, highlighting any potentially allergenic components. A manufacturer or caterer who produces several different products must also consider the chance of cross-contamination of allergenic components into the wrong product where they will not be labelled. This is particularly important in the case of recycling loops and rework of product, and these issues should be considered as part of the HACCP Study. The possibility of mislabeling through using misprinted or incorrect packaging, e.g., packing a ready meal product into the wrong sleeve, should also be evaluated.

Strict adherence to good manufacturing practices (GMP), Hazard Analysis Critical Control Points (HACCP), and allergen prevention plans will reduce the likelihood of cross-contamination.
3. 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 eating, and the source of the hazard is often easy to identify.

A physical hazard can enter a food product at any stage of production, Hard or sharp objects are potential physical hazards and can cause:

- Cuts to the mouth or throat.
- Damage to the intestine.
- Damage to teeth or gums.

**What are some common, physical hazards?**

The main types of physical hazards in food include:

- **Glass**: common sources found in food processing facilities are light bulbs, glass containers and glass food containers.

- **Metal**: common sources of metal include metal from equipment such as splinters, blades, broken needles, fragments from worn utensils, staples; etc.

- **Plastics**: common sources of soft and hard plastics include material used for packaging, gloves worn by food handlers.

- **Stones**: field crops, such as peas and beans, are most likely to contain small stones picked up during harvesting. Concrete structures and floors in food processing facilities can also be a source of small stones.

- **Wood**: common sources of wood come from wood structures and wooden pallets used to store or transport ingredients.

**How can common physical hazards be prevented?**

There are many ways food processors can prevent physical hazards in food products, including:

- **Inspect raw materials** and food ingredients for field contaminants (ex: stones in cereals) that were not found during the initial receiving process.
• Follow **good storage practices** and evaluate potential risks in storage areas (ex: sources of breakable glass such as light bulbs, staples from cartons, etc.) and use protective acrylic bulbs or lamp covers.

• **Develop specifications and controls for all ingredients and components**, including raw materials and packaging materials: Specifications should contain standards for evaluating the acceptability of ingredients or packaging materials (ex: recycled cardboard used for packaging sometimes contains traces of metals that can be detected by metal detectors.

• Set up an **effective detection** and elimination system for physical hazards in your facility such as metal detectors or magnets to detect metal fragments in the production line, filters or screens to remove foreign objects at the receiving point).

• Properly and regularly maintain the equipment in your facility to avoid sources of physical hazards such as foreign material that can come from worn out equipment.

• **Periodic employee training** on shipping, receiving, storing, handling, equipment maintenance and calibration will also help prevent physical hazards from being introduced into food products.
Table 2.4. Examples of practical hazard control options—physical hazards

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Control measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>All types of physical hazards (including intrinsic to the product, i.e., fruit stalks, stones, nut shells)</td>
<td>Prerequisite programs/support systems, e.g., Supplier QA, cleaning.</td>
</tr>
<tr>
<td></td>
<td>• Effective trace and recall procedures.</td>
</tr>
<tr>
<td></td>
<td>• Detection systems, e.g., vision sorters, X-ray.</td>
</tr>
<tr>
<td>Specific extrinsic physical cross-contaminants such as:</td>
<td></td>
</tr>
<tr>
<td>Glass</td>
<td>• Elimination of all glass except lighting which must be covered—light breakage procedure.</td>
</tr>
<tr>
<td></td>
<td>• Glass-packed products—glass breakage procedures, inversion/washing/blowing of glass packaging before use.</td>
</tr>
<tr>
<td>Wood</td>
<td>• Exclusion of all wooden materials such as pallets, brushes, pencils, tools from exposed product areas.</td>
</tr>
<tr>
<td></td>
<td>• Segregation of all packaging materials.</td>
</tr>
<tr>
<td>Metal</td>
<td>• Equipment design—preventative maintenance</td>
</tr>
<tr>
<td></td>
<td>• Avoidance of all loose metal items—jewelry, drawing pins, nuts and bolts, small tools</td>
</tr>
<tr>
<td></td>
<td>• Metal detection—sensitivity appropriate for the product, calibrated (3-monthly) and checked (hourly).</td>
</tr>
<tr>
<td>Plastic</td>
<td>• Avoidance of all loose plastic items—pen tops, buttons on overalls, jewelry</td>
</tr>
<tr>
<td></td>
<td>• Breakage procedures in place where hard brittle plastic is used</td>
</tr>
<tr>
<td>Building fabric</td>
<td>• Design and maintenance</td>
</tr>
</tbody>
</table>
### Table 2.5 Effects of food processing on food safety hazards.

<table>
<thead>
<tr>
<th>Processing operation</th>
<th>Intended effect on food safety hazards</th>
<th>Example food types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning</td>
<td>Removal of foreign material and dust</td>
<td>Grain crops</td>
</tr>
<tr>
<td>Wet</td>
<td>Reduction in level of microorganisms and foreign material</td>
<td>Raw foods, e.g. vegetables, fruit, dried fruit</td>
</tr>
<tr>
<td>Antimicrobial dipping/spraying</td>
<td>Reduction in levels of microorganisms</td>
<td>Fruit and vegetables</td>
</tr>
<tr>
<td>Fumigation</td>
<td>Destruction of certain microorganisms and pests</td>
<td>Nuts, dried fruit, cocoa beans</td>
</tr>
<tr>
<td>Pasteurization / cooking</td>
<td>Destroys vegetative pathogens, e.g. <em>Salmonella spp.</em>, <em>Listeria monocytogenes</em></td>
<td>Milk products, meat, fish, ready meals</td>
</tr>
<tr>
<td>Thermal processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilization: UHT/aseptic</td>
<td>Destroys pathogens and prevents recontamination in packaging system</td>
<td>UHT milk, fruit juices</td>
</tr>
<tr>
<td>Sterilization: cans/pouches</td>
<td>Destroys pathogens</td>
<td>Canned meats, soups, pet food, etc.</td>
</tr>
<tr>
<td>Evaporation/dehydration</td>
<td>Halts growth of pathogenic bacteria at aw 0.84, all microorganisms at aw 0.60</td>
<td>Various foodstuffs, e.g. dried fruit, milk powder, cake mixes</td>
</tr>
<tr>
<td>Salt preserving</td>
<td>Halts growth of pathogenic bacteria at aw 0.84, all microorganisms at aw 0.60; growth of many microorganisms halted at ca. 10% salt</td>
<td>Fish, meats, vegetables</td>
</tr>
<tr>
<td>Sugar preserving</td>
<td>Halts growth of pathogenic bacteria at aw 0.84, all microorganisms at aw 0.60</td>
<td>Jam, fruits, syrups, jellies, Confectionery</td>
</tr>
<tr>
<td>Chilling (&lt; 5 °C)</td>
<td>Slows or prevents growth of most pathogens</td>
<td>Cooked meats, dairy products, fruit juices</td>
</tr>
<tr>
<td>Freezing (at least -10 °C)</td>
<td>Prevents growth of all microorganisms. Destroys some parasites</td>
<td>Many foodstuffs, e.g. fruit, vegetables, meat, fish, ice cream, etc.</td>
</tr>
<tr>
<td>Fermentation/acidification</td>
<td>Halts growth of pathogens; destroys some organisms, depending on pH/acid used</td>
<td>Cheese, yogurt, vegetables, fruit, etc.</td>
</tr>
<tr>
<td>Separation (e.g. filtration)</td>
<td>Removes physical hazards and/or pathogens (depending on filter pore size), adjusts chemical concentration (e.g. reverse osmosis)</td>
<td>Various foodstuffs, e.g. sugar, grains, water, etc.</td>
</tr>
</tbody>
</table>
Chapter 3
General Principles of Food Hygiene

Objectives

After reading this chapter, you should be able to:

- Define the terms related to food hygiene.
- Explain hygiene rules for the handling of foods.
- Define the general requirements for hygienic layout of food factory.
- Define and explain Procedures, Practices and conditions are essential to food safety.
- Understand the responsibility for hygienic work.

1. Codex Alimentarius Commission

The Codex Alimentarius Commission is an intergovernmental body with over 180 members, within the framework of the Joint Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), with the purpose of protecting the health of consumers and ensuring fair practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

The Codex General Principles of food hygiene:

- Identify the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption.
- Recommend a HACCP-based approach as a means to enhance food safety.
- Indicate how to implement those principles.
- Provide a guidance for specific codes, which may be needed for - sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas.
2. Prerequisite Programmes (PRP) / Good Manufacturing Practice (GMP)

Prerequisite programmes or ‘Good Manufacturing Practice’ (GMP) provide the hygienic foundations for any food operation. The terms ‘prerequisite programmes’ and ‘Good Manufacturing Practice’ are used interchangeably in different parts of the world but have the same general meaning. Several groups have suggested definitions for the term prerequisites and the most commonly used are reproduced here. **Prerequisite programmes are:**

- Practices and conditions needed prior to and during the implementation of HACCP and which are essential to food safety (World Health Organization WHO).
- Universal steps or procedures that control the operating conditions within a food establishment, allowing for environmental conditions that are favorable for the production of safe food (Canadian Food Inspection Agency).
- Procedures, including GMP, that address operational conditions, providing the foundation for the HACCP system (USA National Advisory Committee for Microbiological Criteria for Foods).

3. Definitions

**Food hygiene** all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

**food chain** sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption.

![Fig. 3.1. Communicating within the food supply chain (taken from ISO 22000)](image-url)
Cleaning removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant any biological or chemical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

Contamination introduction or occurrence of a contaminant in food or food environment.

Establishment any building or area in which food is handled and the surroundings under the control of the same management.

Materials general term used to indicate raw materials, packaging materials, ingredients, process aids, cleaning materials and lubricants.

Product contact all surfaces that are in contact with the product or the primary package during normal operation.

Food grade lubricants and heat transfer fluids formulated to be suitable for use in food processes where there may be incidental contact between the lubricant and the food.

Disinfection reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment to a level that does not compromise food safety or suitability.

Cleaning in place (CIP) system that cleans solely by circulating and/or flowing chemical detergent solutions and water rinses by mechanical means onto and over surfaces to be cleaned.

Cleaning out of place (COP) system where equipment is disassembled and cleaned in a tank or in an automatic washer by circulating a cleaning solution and maintaining a minimum temperature throughout the cleaning cycle.

Sanitation all actions dealing with cleaning or maintaining hygienic conditions in an establishment, ranging from cleaning and/or sanitizing of specific equipment to periodic cleaning activities throughout the establishment (including building, structural, and grounds cleaning activities).

Material/product specification detailed documented description or enumeration of parameters, including permissible variations and tolerances, which are required to achieve a defined level of acceptability or quality.

First Expired First Out (FEFO) stock rotation based on the principle of dispatching earliest expiration dates first.

First In First Out (FIFO) stock rotation based on the principle of dispatching earliest received products first.

Food handler any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.
Food suitability assurance that food is acceptable for human consumption according to its intended use.

Primary production those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

Label printed matter that is part of the finished product package conveying specific information about the contents of the package, the food ingredients and any storage and preparation requirements.

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

Product recall removal of a non-conforming product from the market, trade and warehouses, distribution centers and/or customer warehouses because it does not meet specified standards.

HACCP a system that identifies, evaluates and controls hazards that are significant for food safety.

Note: These definitions adapted from Codex (2009) and PAS 220:2008

3. Primary Production

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- Avoiding the use of areas where the environment poses a threat to the safety of food.
- Controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety.
- Adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

3.1 Environmental hygiene

Consideration shall be given to potential sources of contamination from the local environment.

Note: Food production should not be carried out in areas where potentially harmful substances could enter the product.

3.2 Hygienic production of food sources

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 a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the taking of such measures - see “Hazard Analysis and Critical Control Point (HACCP) system in chapter 4.
Producers 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 fecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately.

3.3 Handling, storage and transport

Procedures should be in place to:

▪ Sort food and food ingredients to segregate material that is evidently unfit for human consumption.

▪ Dispose of any rejected material in a hygienic manner.

▪ Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures, which may include controlling temperature, humidity, and/or other controls.

4. Establishment: construction and layout of buildings

4.1 General requirements

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 disinfection and minimize airborne 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.

▪ Suitable facilities are available for temperature, humidity and other controls and effective protection against pest access.
Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

4.2 Location of establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

- Environmentally polluted areas
- Industrial activities that might present a risk of contamination (for example chemical production).
- Areas subject to flooding unless sufficient safeguards are provided.
- Areas prone to infestations of pests.
- Areas where wastes, either solid or liquid, cannot be removed effectively.

Poorly designed and constructed buildings and equipment are potential sources of physical, chemical and microbiological hazards. Such hazards could cause illness or injury to consumers and so must be prevented or minimized.

Fig. 3.2 Bad outside areas

5. Establishment: layout of premises and workspace

5.1 General requirements

Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices. The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.
5.2 Internal design, layout and traffic patterns

- The internal design and layout of food establishments should permit good food hygiene practices, including providing adequate space, with a logical flow of materials, products and personnel, and physical separation of raw from processed areas.

**Note:** examples of physical separation may include walls, barriers or partitions, or sufficient distance to minimize risk (Figure 3.3)

- Openings intended for transfer of materials shall be designed to minimize the entry of foreign matter and pests.

![Diagram showing physical separation between raw materials receiving areas and ready to eat areas (RTE)](image)

**Fig. 3.3** physical separation between raw materials receiving areas and ready to eat areas (RTE)
5.3 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:

- Process area walls and floors shall be washable or cleanable, as appropriate for the process or product hazard. Materials shall be resistant to the cleaning system applied.
- Walls and partitions should have a smooth surface up to a height appropriate to the operation.
- Wall floor junctions and corners shall be designed to facilitate cleaning.
  
  **Note:** It is recommended that wall floor junctions are rounded in processing areas (Figure 3.4).
- Floors shall be designed to avoid standing water.

![Fig. 3.4 Wall floor junctions](image)

- In wet process areas, floors shall be sealed and drained. Drains shall be trapped and covered.
- Ceilings and overhead fixtures shall be designed to minimize buildup of dirt and condensation.
Floors shall be made from suitable materials that are impervious, non-absorbent, washable and non-toxic, such as epoxy resin. Wood is not a suitable flooring material in food handling areas.

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

Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect. External opening doors shall be closed.

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, that will not contaminate food.

5.4 Location of equipment

- Equipment shall be designed and located to facilitate good hygiene practices and monitoring.
- Equipment shall be located to permit access for operation, cleaning and maintenance.

5.5 Storage of food, packaging materials, ingredients and non-food chemicals

- Facilities used to store ingredients, packaging and products shall provide protection from dust, condensation drains, waste and other sources of contamination.
- Storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where specified.
- Storage areas shall be designed or arranged to allow separation of raw materials and finished products.
- All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.
The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

- Shelving must be constructed in an easily cleanable design of smooth metal or plastic.
- Shelves should be a minimum of 2.5 cm away from the wall. Bottom shelves must be at least 15 cm above the floor.
- A separate, secure (locked or otherwise access controlled) storage area shall be provided for cleaning materials, chemicals and other hazardous substances.

### 6. Facilities

#### 6.1 General requirements

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. "Utilities" quality shall be monitored to minimize product contamination risk.

#### 6.2 Water supply

- 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.

**Note:** Potable water should conform to the World Health Organization’s Guidelines for drinking-water quality.
- Water used as a product ingredient, including as ice or steam (including culinary steam), or in contact with products or product surfaces shall meet specified quality and microbiological requirements relevant to the product.

**Note:** It is recommended that water that can come into contact with the product should flow through pipes that can be disinfected.

### Table 3.1 Examples demonstrating the importance of design and facilities

<table>
<thead>
<tr>
<th>Problem</th>
<th>Effect</th>
<th>Potential hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishment in inappropriate locations</td>
<td>Prone to flooding, near to a business using toxic chemicals or producing a lot of dust</td>
<td>Food becomes contaminated</td>
</tr>
<tr>
<td>Badly designed buildings and equipment</td>
<td>Difficult premises to clean and maintain</td>
<td>A source of microbiological contamination</td>
</tr>
<tr>
<td>Poorly constructed buildings and equipment</td>
<td>Pest entry, water leaks, condensation, poor drainage</td>
<td>Food becomes contaminated</td>
</tr>
<tr>
<td>Inappropriate construction materials</td>
<td>Surfaces: difficult to clean, deteriorate and shed dirt, dust or other particles onto food</td>
<td>Food becomes contaminated</td>
</tr>
<tr>
<td>Poor layout</td>
<td>Inadequate separation between clean and dirty areas, or inappropriate flow lines for food, waste, and people</td>
<td>Increase chance of microbiological cross contamination of food products by food poisoning bacteria</td>
</tr>
<tr>
<td>Insufficient space</td>
<td>Causes problems for the operations being carried out, unable to handle large quantities of food</td>
<td>Cramped conditions could cause cross contamination</td>
</tr>
<tr>
<td>Inadequate hygiene facilities (toilets and personal hygiene procedures hand washing basins)</td>
<td>Staff are unable to follow personal hygiene procedures</td>
<td>Product contamination</td>
</tr>
</tbody>
</table>

### 6.3 Cleaning

- Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.
Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.

6.4 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- Minimize airborne contamination of food, for example, from aerosols and condensation droplets.
- Control ambient temperatures.
- Control odors that might affect the suitability of food.
- Control humidity, where necessary, to ensure the safety and suitability of food.
- Ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odors, and to facilitate drying after wet cleaning.
- Ventilation systems shall be designed and constructed such that air does not flow from contaminated or raw areas to clean areas. Specified air pressure differentials shall be maintained (High Control GMP area, positive pressure air). Systems shall be accessible for cleaning, filter changing and maintenance.
- Toilets are adequately ventilated to remove odors.

6.5 Compressed air and other gases

- Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.
- Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.
- Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade.

**Note:** Use of oil-free compressors is recommended.

6.6 Lighting

- The lighting provided (natural or artificial) shall allow personnel to operate in a hygienic manner.

**Note:** The intensity of the lighting should be appropriate to the nature of the operation.
- Light fixtures shall be protected with shatterproof and waterproof covers to minimize the risk of contamination of food by glass fragments if there are breakages and for ease of cleaning.

![Light fitting with cover](image)

**Fig. 3.9 Light fitting with cover**

### 7. Waste disposal

All liquid waste, including sewage, generated by a food establishment shall be disposed of in an approved manner into either a public sewer system or to an approved on-site sewage disposal system.

#### 7.1 General requirements

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

#### 7.2 Containers for waste and inedible or hazardous substances

Containers for waste and inedible or hazardous substances shall be:

A) Clearly identified for their intended purpose.

B) Located in a designated area.

C) Constructed of an impervious material which can be readily cleaned and sanitized.

D) Closed when not in immediate use.

E) Locked where the waste may pose a risk to the product.
7.3 Waste management and removal

- Provision shall be made for the segregation, storage and removal of waste.
- Accumulation of waste shall not be allowed in food handling or storage areas. Removal frequencies shall be managed to avoid accumulations.
- Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused. Removal and destruction shall be carried out by approved disposal contractors. The organization shall retain records of destruction.

7.4 Drains and drainage

- Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided. Drains shall have a capacity sufficient to remove expected flow loads.
- Lay floors so that waste water and effluent is directed down slopes into drains to minimize pooling.
- Fit open drainage channels with removable gratings for easy cleaning and maintenance. open or partly open drain channels are to flow away from the product flow so that they don't carry waste from dirty to clean areas.

Fig. 3.10 Different type of drains
8. Equipment suitability, cleaning and maintenance

8.1 General requirements

- Equipment and containers coming into contact with food should be designed and constructed to ensure that, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.

- Contact surfaces shall not affect, or be affected by, the intended product or cleaning system. Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

- Equipment and containers should be made of materials with no toxic effect such as stainless steel, or food grade plastics.

8.2 Hygienic design

- Equipment shall be able to meet established principles of hygienic design, including:
  
a) Smooth, accessible, cleanable surfaces, self-draining in wet process areas.
  
b) Use of materials compatible with intended products and cleaning or flushing agents.
  
c) Framework not penetrated by holes or nuts and bolts (Physical hazards).

- Piping and ductwork shall be cleanable, drainable, and with no dead ends.

- 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.

- Rounding off corners within equipment to aid cleaning and monitoring internal voids that cannot be cleaned and where food material can accumulate.

- Equipment shall be designed to minimize contact between the operator’s hands and the products.

8.3 Product contact surfaces

Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust or corrosion free.

8.4 Temperature control and monitoring equipment

- Equipment used for thermal processes shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.

- Equipment shall provide for the monitoring and control of the temperature.
8.5 Cleaning utensils and equipment

- Wet and dry cleaning programmes shall be documented to ensure that all utensils and equipment are cleaned at defined frequencies.

- The programmes shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning (e.g. CIP/COP), the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning.

8.6 Preventive and corrective maintenance

What different between Preventive and corrective maintenance?

Preventative Maintenance: A proactive approach to lessening the likelihood of a piece of equipment or the entire system failing is to perform maintenance while the component is still functioning. A schedule is set up to regularly monitor the system and reports are analyzed to see if and where assistance is needed. While this approach is more complicated to carry out than corrective maintenance because of the scheduling aspect, it is more cost-effective in the long run on new equipment.

Corrective Maintenance: This type of maintenance is also known as reactive and is what needs to be done when the system or a component has already failed. The goal is to have the system back to working order in as short amount of time as possible.

- A preventive maintenance programme shall be in place.

- The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards.

  Note: Examples of such devices include screens and filters (including air filters), magnets, metal detectors and X-ray detectors.

- Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

- Maintenance requests which impact product safety shall be given priority.

- Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.

- The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.
9. Management of purchased materials

9.1 General requirements

Purchasing of materials, which affect food safety, shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements.

The conformance of incoming materials to specified purchase requirements shall be verified.

9.2 Selection and management of suppliers

There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include:

a) Assessment of the supplier’s ability to meet quality and food safety expectations, requirements and specifications.

b) Description of how suppliers are assessed.

Note: Examples of a description of how suppliers are assessed include:

a) Audit of the supplying site prior to accepting materials for production.

b) Monitoring the performance of the supplier to assure continued approval status.

9.3 Incoming material requirements (raw/ingredients/packaging)

- Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. seals are intact, free from infestation, temperature records exist).

- Materials shall be inspected, tested or covered by COA to verify conformance to specified requirements prior to acceptance or use. The method of verification shall be documented.

Certificate of Analysis (COA): document provided by the supplier which indicates results of specific tests/analysis, including test methodology, performed on a defined lot of the supplier’s product.
10. Personnel hygiene and employee facilities

Objectives:
To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:
- maintaining an appropriate degree of personal cleanliness.
- behaving and operating in an appropriate manner.

Rationale:
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.

10.1 Personnel hygiene facilities and toilets
Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

Establishments shall:
(A) Provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer).
(B) Have sinks designated for hand washing, separate from sinks for food use and equipment cleaning stations.
(C) Provide an adequate number of toilets of appropriate hygienic design, each with hand washing, drying and, where required, sanitizing facilities.
(D) Have employee hygiene facilities do not open directly onto production, packing or storage areas.

10.2 Staff changing facilities
- Provide an area that is separate from food handling areas and from the toilets, with sufficient lockers so that staff can store outdoor clothing.
- Staff changing facilities could be located outside in a separate building from the main building, provided adequate level of hygiene measures are maintained by staff.

10.3 Staff canteens and designated eating areas
- Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross-contamination of production areas is minimized.
• Staff canteens shall be managed to ensure the hygienic storage of ingredients and preparation and serving of prepared foods. Storage conditions, cooking and holding temperatures and time limitations, shall be specified.

10.4 Health status

• People known, or suspected, to be suffering from, or to be a carrier of, a disease or illness 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. Any person so affected should immediately report illness or symptoms of illness to the management.

• Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

• Workers who return to work after the interruption due to the disease must obtain a medical report that will fully recover from the disease in addition to their suitability to work and their handling of food.

10.5 Illness and injuries

• Conditions that should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered include:
  - Diarrhea
  - Vomiting
  - Fever
  - sore throat with fever
  - Visibly infected skin lesions (boils, cuts, etc.)
  - Discharges from the ear, eye or nose

• People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food or food contact materials.
- In food handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately.

10.6 Work wear and protective clothing

- Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition.

- Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.

- Work wear shall not have buttons. Work wear shall not have outside pockets above waist level.

- Outdoor clothing should be housed in lockers and should not come into contact with protective clothing used in the factory.

- Whilst a plain ring (covered with a detectable dressing) may be worn on the hand all other jewelry including stoned rings, bangles, necklaces and pendants must be removed before entering the processing area.

Fig. 3.11 Work wear shall not have outside pockets
▪ Work wear shall be laundered to standards and at intervals suitable for the intended use of the garments.

▪ All employees of the food establishment and visitors must wear the protective cover of hair covering all hair before entering the food preparation halls.

Fig. 3.12 Protective cover of hair
▪ Where gloves are used for product contact, they shall be clean and in good condition.

**Note:** Use of latex gloves should be avoided where possible.

▪ Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.

▪ Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

### 10.7 Personal cleanliness

▪ Personnel in food production areas shall be required to wash and, where required, sanitize hands:

  (A) Before starting any food handling activities.

  (B) Immediately after using the toilet.

  (C) Immediately after handling raw food or any potentially contaminated material.

  (D) After sneezing, coughing and using tissue paper.

  (E) After smoking, eating and drinking.

  (F) After use of cleaning and disinfection chemicals.

  (G) After disposal of waste and fouling.

▪ Fingernails shall be kept clean and trimmed.

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**Fig. 3.13 Total bacterial count of hand swaps**
10.8 Proper hand washing practices

**Hand Wash Steps**

1. Wet hands using warm water 38-40°C
2. Use soap
3. Rub hands palm to palm
4. Rub back of hand with palm of other hand, fingers interlaced
5. Rub palm-to-palm fingers interlaced
6. Rub back of fingers with hands clasped
7. Rub thumbs
8. Rub tips of fingers into palms
9. Rub wrists
10. Wash soap away
11. Dry the hands using paper towels or hot air dryer
12. Use hand disinfectant

*Fig. 3.14 Proper hand washing method*
10.9 Personal behavior

A documented policy shall describe the behaviors required of personnel in processing, packing and storage areas. The policy shall at a minimum cover:

(A) Permissibility of smoking, eating, chewing in designated areas only.

(B) Control measures to minimize hazards presented by permitted jewelry.

(C) Prohibition of the use of nail polish, false nails and false eyelashes.

(D) Prohibition of carrying of writing implements behind the ears.

(E) Maintenance of personal lockers so that they are kept free from rubbish and soiled clothing.

(F) Prohibition of storage of product contact tools and equipment in personal lockers.
11. Cleaning and sanitizing

11.1 General requirements
Cleaning and sanitizing programmes shall be established to ensure that the food processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

11.2 Cleaning and sanitizing agents and tools
- Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer’s instructions.
- Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter.

11.3 Color-code clean tools
Food manufacturing sites use a variety of containers and tools during food production and sanitation of processing equipment and production environment. From scrapers to squeegees—a well-designed color coding system is an important component of a food company’s internal hygiene control.

Clearly defined color-coding tools for different areas of the food manufacturing site can help eliminate the most fundamental causes of bacterial and/or allergen cross-contamination when managed correctly. A color-based system can also support an effective, simplified cleaning procedure that are particularly relevant for employees who do not share the same first language.

To build an effective and practical color-coding program, you need to know your facility, equipment, and processes very well, and the potential cross-contamination risks. Start with dividing your production areas into visually separated zones based on the risk to the product (i.e.: Ready-To-Eat (RTE), high hygiene, low care, and include allergen separation where necessary). Assign each area(zone its own color for production and sanitation tools. This in turn will aid in controlling the risks of cross contamination. An example may include (but are not limited to):

- Containers for raw ingredients and/or rework should be a different color than containers for RTE ingredients or rework.
- Containers for ingredients and re-work should be a totally different color than waste containers.
▪ The sanitation brush for scrubbing product contact surfaces in raw should be a different color than the sanitation brush for scrubbing product contact surface in RTE or high hygiene.

▪ The sanitation brush for scrubbing walls should be a different color than the brush used for scrubbing a floor.

Fig. 3.17 Color-code clean tools

Standard operating procedures (SOP’s) should be developed for the container and tools on specific uses, cleaning, inspection, and sanitation using a sequencing approach. For example, product-contact tools and containers should always be cleaned first, followed by non-product contact tools and containers to prevent cross contamination.

Standard operating procedures (SOP's): Procedures and work instructions for cleaning and disinfection.

11.4 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve:

▪ Pre-clean: Removing debris from surfaces.

▪ Rinse using water at 60 °C

▪ Applying a detergent: Method of applying detergent is by foaming it on the equipment and allowing it to work for a few minutes prior to the next step of rinsing.
▪ After applying detergent by high-pressure spray, or foaming, rinse the equipment with water to remove residues of detergent.

▪ Disinfection with subsequent rinsing unless the manufacturers’ instructions indicate on scientific basis that rinsing is not required.

![Image of manual cleaning with foam]

Fig. 3.18. Manual cleaning with foam. Allow several minutes for detergent action.

If manual cleaning (see Figure 3.18) is still required as is probable in certain areas, the following checks must be implemented:

▪ The operator is properly trained in the use of chemicals and the safety precautions required.

▪ The operator is sufficiently covered by protective clothing, e.g. boots and waterproof garments.

▪ A constant supply of hot and cold running water is nearby.

▪ The detergents used must be accurately dosed. Overuse of chemicals will not improve the cleaning action.

▪ The least harmful detergent must be used for the cleaning operation.
Wash, rinse, and sanitize food contact surfaces of sinks, tables, utensils, thermometers, carts, and equipment:

- Before each use.
- Between uses when preparing different types of raw animal foods, such as eggs, fish, meat, and poultry.
- Between uses when preparing ready-to-eat foods and raw animal foods, such as eggs, fish, meat, and poultry.
- Any time contamination occurs or is suspected.

**Sanitize**

There are several general classes of sanitizers. These include:

A. Halogens — chlorine, iodine, and bromine
B. Phenols
C. Quaternary Ammonium Compounds

Consider the following items when selecting a sanitizer for your particular operation:

1. The length of time the sanitizer will be in contact with the surface to be sanitized.
2. The temperature at which the sanitizer will be used. For example, in the case of chlorine, as the temperature is increased, chlorine is less effective.
3. The amount of organic material (fats, proteins, vegetable materials, etc.) present in or on the equipment to be sanitized.
4. The cost of the sanitizer.
5. The sanitizer’s pH. It is important to know the pH of the solution in which the sanitizer will be expected to act. Again, using chlorine as an example, we find that the lower the pH, the more effective chlorine is as a sanitizing agent.

11.5 Cleaning and sanitizing programmes

- Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.

- Cleaning and/or sanitizing programmes shall specify at a minimum:
  (A) Areas, items of equipment and utensils to be cleaned and/or sanitized.
  (B) Responsibility for the tasks specified.
  (C) cleaning/sanitizing method and frequency.
  (D) Monitoring and verification arrangements.
In addition, a Master Sanitation Schedule (MSS) must be established for all areas outside the regular equipment and process area cleaning. It should include overheads and light fixtures, walls and ceilings, coolers and freezers, and the external yard and perimeter; this could also be incorporated into a Master Cleaning Schedule designated to indicate tasks which are daily, weekly, monthly, quarterly, or annual.

11.6 Cleaning in place (CIP) systems

- CIP systems shall be separated from active product lines.
- Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

Note: Caustic alkaline or acidic cleaners may be effective in removing food debris, but they can also be corrosive to softer metals such as aluminum, copper, or lower grades of steel. Stress cracking and clouding can also occur when hard plastics are exposed to corrosive cleaning agents for prolonged periods of time. Higher grades of stainless steel are likely to be more resistant to corrosion over time, which is why it is a preferred material for handling foods that are acidic, salty, or high in fat or water.

11.7 Chemicals

- All chemicals used must be suitable for food use and approved by the appropriate authorities.
- A Material Safety Data Sheet (MSDS), sometimes called a hazard data sheet, must be retained on file along with a supplier continuing guarantee. All chemicals must be properly labeled and never decanted and stored in old or new food containers.
- Chemicals must be stored securely and in accordance with the manufacturer’s recommendations. This is best done by having a locked area within the facility.

11.8 Biofilms and detergents

Biofilms: Sometimes, no matter what you do to clean, some types of bacteria can produce a substance that protects them from their environment and helps them to stick to food contact surfaces. These bacterial communities are known as biofilms. If a biofilm develops on a food contact surface, it cannot be easily seen or detected, and it is very difficult to remove. Biofilm layers are often thin and can contain dangerous pathogens such as, Listeria, E. coli and Salmonella.
However, the only way to definitively confirm the presence of biofilm is to conduct biofilm testing through methods such as:

1. **Adenosine triphosphate (ATP) bioluminescence**—ATP is the energy molecule stored in all microorganisms. By analyzing ATP levels, you can reveal the presence of living bacteria on equipment surfaces. However, this is a broad test, and often only detects biofilms in the early stages of formation when bacteria are actively searching for nutrients.

2. **UV light detection**—UV light clearly reveals the presence of organic sediment otherwise invisible to the naked eye.

3. **Total organic carbon (TOC) measurement**—TOC measurement in food processing settings is most often used to test rinse water after it’s been used to clean equipment or piping. A low TOC measurement helps validate cleaning efficacy.

**Note:** Biofilm can form on any type of surface, including stainless steel, concrete, glass and plastic. However, biofilm is most likely to form on rough, penetrable surfaces or on equipment that has scratches, cracks or dents because they provide a viable niche for bacterial growth and are especially difficult to sanitize. Biofilm also tends to form in hard-to-reach places that are not cleaned regularly, such as the underside of conveyor belts.

![ATP measure device](image)

**Fig. 3.19.** ATP measure device

**How do you remove biofilm?**

Removing biofilm from surfaces is much more difficult than preventing it from forming. Food processors should develop and maintain a thorough sanitation regimen to help prevent a conditioning layer from attaching to equipment surfaces.
Five steps for removal of biofilm:

1. **Dry clean**: Before using chemicals, remove as much visible soil as possible by scrubbing, brushing and sweeping the affected surface. However, be careful not to clean so rigorously as to scratch or etch the surface, as this will only create an environment prone to biofilm growth.

2. **Rinse**: Rinse equipment, using water at 60°C.

3. **Apply chemical treatment**: The proper chemical to use for biofilm removal will depend on the type of food materials used in the food plant. Studies have shown that the most effective chemicals include sodium hypochlorite, iodine and peracetic acid. Allow an extended exposure time (usually at least five minutes) for the chemicals to dissolve the biofilm effectively. Then, scrub and brush the equipment to completely remove all layers of bacteria.

4. **Apply a final rinse**: Rinse the equipment once more, following the same temperature (60°C).

5. **Inspect the equipment**: Use one of the detection methods mentioned above to confirm you have successfully eliminated the biofilm.

11.9 Monitoring sanitation effectiveness

Cleaning and sanitation programmes shall be monitored at frequencies specified by the organization to ensure their continuing suitability and effectiveness.

12. Pest Control

The purpose of discussing pest control is to know the major pests that can contaminate the food supply and how the presence of these unwanted guests can be controlled. That pests can cost the food industry billions of dollars every year. During the past century, an estimated 10 million people died from rodent-borne diseases.

12.1 General requirements

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 likelihood of infestation and thereby limit the need for pesticides.

12.2 Pest control programmes

- The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.
• Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements.

• Programmes shall include a list of chemicals that are approved for use in specified areas of the establishment.

12.3 Integrated Pest Management (IPM)
IPM is based on the identification of pests, accurate measurement of pest populations, assessment of damage levels, and knowledge of available pest management strategies or tactics that enable the specialist to make intelligent decisions about control. IPM offers the possibility of improving the effectiveness of pest control programs while reducing some of the negative effects. Many successful IPM programs have reduced pesticide use and increased protection of the environment.

IPM is a systematic approach to pest management, which comprises:
• Building, machinery and materials design.
• Building maintenance and exclusion practices.
• Inspections and monitoring.
• Physical control methods.
• Chemical control methods.
• Environmental management.

Early detection of pest activity is essential if the impact of corrective control measures is to be optimized. A combination of thorough regular inspections and on-going monitoring using a variety of detectors will provide the information upon which to build control strategies. IPM can prevent infestation before pesticides are even considered. In practice, IPM is an ongoing cycle of seven critical steps:

Step 1: Inspection
The cornerstone of an effective IPM program is a schedule of regular inspections. For food processors, weekly inspections are common, and some plants inspect even more frequently. These routine inspections should focus on areas where pests are most likely to appear such as receiving docks, storage areas, employee break rooms, etc. and identify any potential entry points, food and water sources, or harborage zones that might encourage pest problems.

Step 2: Preventive Action
As regular inspections reveal vulnerabilities in your pest management program, take steps to address them before they cause a real problem. One of the most effective prevention measures is exclusion, i.e., performing structural maintenance to close potential entry points...
revealed during an inspection. By physically keeping pests out, you can reduce the need for chemical countermeasures.

- Buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed. External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

- Eliminate cracks, crevices, and ledges for ease of cleaning and elimination of potential pest harborages.

- Locate equipment off the floor and away from walls or seal equipment to walls and floors.

Step 3: Identification
Different pests have different behaviors. By identifying the problematic species, pests can be eliminated more efficiently and with the least risk of harm to other organisms. Professional pest management always starts with the correct identification of the pest in question. Make sure your pest control provider undergoes rigorous training in pest identification and behavior.

Step 4: Analysis
Once you have properly identified the pest, you need to figure out why the pest is in your facility. Is there food debris or moisture accumulation that may be attracting it? What about
odors? How are the pests finding their way in - perhaps through the floors or walls? Could incoming shipments be infested? The answers to these questions will lead to the best choice of control techniques.

**Step 5: Treatment Selection**

IPM stresses the use of non-chemical control methods, such as exclusion or trapping, before chemical options. When other control methods have failed or are inappropriate for the situation, chemicals may be used in least volatile formulations in targeted areas to treat the specific pest. In other words, use the right treatments in the right places, and only as much as you need to get the job done. Often, the “right treatment” will consist of a combination of responses, from chemical treatments to baiting to trapping. But by focusing on non-chemical options first, you can ensure that your pest management program is effectively eliminating pests at the least risk to your food safety program, non-target organisms, and the environment.

**Step 6: Monitoring**

Since pest management is an ongoing process, constantly monitoring the facility for pest activity and facility and operational changes can protect against infestation and help eliminate existing ones. Since pest management professional most likely visits the facility on a bi-weekly, food staff needs to be the daily eyes and ears of the IPM program. Employees should be cognizant of sanitation issues that affect the program and should report any signs of pest activity.

Pest monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

Detectors and traps shall be of robust, tamper resistant construction. They shall be appropriate for the target pest.

The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analyzed to identify trends.

**Step 7: Documentation**

Up-to-date pest control documentation is one of the first signs that the facility takes pest control seriously. Important documents include pest activity reports, service reports, corrective action reports, trap layout maps, lists of approved pesticides. Records of pesticide use shall be
maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.

12.4 Resistance methods of insects

12.4.1 Mechanical methods

Flying insect control requires removal of breeding sites, such as the roof puddles, and food sources. Garbage is a prime source for both food and breeding sites; therefore, dumpsters must be placed away from open doors. All standing water should be eliminated from processing and distribution areas. Keeping flying insects from entering buildings is difficult but essential. Resistance procedures include air curtains and strip doors.

Indoor flying insect control can be achieved with electrocutes, sticky traps or baited flytraps but must be maintained correctly and cleaned periodically. Bulbs must be changed regularly, as most lose their effectiveness after 6 months. Cleaning is essential, as auditors upon insect fragments and consider them proof that insects exist within facilities.
12.4.2 Biological control

Use of biological control is frequently incorporated into integrated pest management programs.

Pheromone Traps

A pheromone is a chemical attractant released by an insect to affect the behavior of the same species of insect. Sex pheromones are used to facilitate mate location and mating. There are several commercially available sex pheromones for use to attractant insects into sticky traps where they become permanently trapped and die.

12.5 Control of rodents

Control of rodents, especially rats, is difficult because of their ability to adapt to the environment. The most effective method of rodent control is *proper sanitation*. Without an entrance to shelter and the presence of debris, which can nourish rodents, these pests cannot survive and will migrate to other locations. Without effective sanitation practices, poisons and traps will provide only a temporary reduction in a rodent population.

Prevention of entry: See step 2 of IPM steps

- Bait stations must be tampering resistant, secured to the location, and locked. You should only use poison bait in areas external to the plant—brining poison into food processing areas is not recommended or legal in many parts of the world.

- Mechanical traps can be used in areas around entryways and regularly inspected and maintained.
Internal traps (or sticky boards if used) should be positioned around the building according to risk, i.e., areas of frequent catches might require a higher number of traps. Usually, they will be about 25 ft apart. All traps and bait stations will be numbered and marked on the plant schematic.

You will want to track rodent activity to enable identification of hot spots around the premises and to see whether there is seasonal variation. For monitoring purposes, non-toxic bait stations may be used which enables targeted and minimal use of poison. In terms of frequency of routine monitoring, a typical schedule might be weekly for internal and external traps and monthly for external bait stations as a minimum.

**Poisoning:** Examples of rodenticides are the anticoagulants, such as 3-(α acetonylfurfuryl)-4-hydroxycoumarin (fumarin), 3-(α-Aacetonylbenzyl)-4-hydroxycoumarin (warfarin), 2-pivaloyl-1,3-indandione (pival), brodifacoum, bromadiolone, and chlorophacinone.

- Any pesticides used on site should be recorded by name, % active ingredient, target organism, method and rate of application, area treated, license number and name of applicator, date, and signature.
- The effectiveness of the overall pest control program must be routinely (at least annually) reviewed and adjustments made.

### 13. Control of operation

To produce food that is safe and suitable for human consumption by:
- Formulating design requirements with respect to raw materials, composition, processing, distribution and consumer use to be met in the manufacture and handling of specific food items.
- Designing, implementing, monitoring and reviewing effective control systems.

#### 13.1 General requirements

Programmes shall be in place to prevent, control and detect contamination. Measures to prevent physical, allergen and microbiological contamination shall be included.

#### 13.2 Control of food hazards

Food business operators should control food hazards through the use of systems such as HACCP. They should:
- Identify any steps in their operations that are critical to the safety of food.
- Implement effective control procedures at those steps.
- Monitor control procedures to ensure their continuing effectiveness.
Review control procedures periodically, and whenever the operations change. These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation, calibrating equipment or correctly loading refrigerated display units. In some cases, a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is described in “Hazard Analysis and Critical Control Point (HACCP) system.

13.3 Key aspects of hygiene control systems

13.3.1 Microbiological cross contamination

- Areas where a potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation plan implemented. A hazard assessment shall be carried out to determine potential contamination sources, the susceptibility of the product and control measures suitable for these areas as follows:
  (A) Separation of raw from finished or ready to eat (RTE) products.
  (B) Structural segregation - physical barriers/walls/ separate buildings.
  (C) Access controls with requirements to change into required work wear.
  (D) Traffic patterns or equipment segregation - people, materials, equipment and tools.
  (E) Air pressure differentials.

- Purchasing foods: especially high-risk foods (from reputable suppliers that should have good controls to prevent contamination).

- Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and, where necessary, disinfected after raw food, particularly meat and poultry, has been handled or processed.

- Good standards of personal hygiene: particularly with regard to hand washing minimizing food handling wherever possible and using disposable gloves or clean utensils to handle, where appropriate.

13.3.2 Allergen management

- Allergens present in the product, either by design or by potential manufacturing cross contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.
Products shall be protected from unintended allergen cross contact by cleaning and line change over practices and/or product sequencing.

- **Manufacturing cross-contact may arise from either:**
  
  (a) Traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations.
  
  (b) When contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

- **Rework containing allergen(s) shall be used only:**
  
  (a) In products which contain the same allergen(s) by design.
  
  (b) Through a process which is demonstrated to remove or destroy the allergenic material.

  **Note:** Food handling employees should receive specific training in allergen awareness and associated manufacturing practices.

13.3.3 Physical contamination

- Where glass and/or brittle material are used, **periodic inspection requirements** and defined procedures in case of breakage shall be put in place.

  **Note:** Glass and brittle material (such as hard plastic components in equipment) should be avoided where possible.

- Glass breakage records shall be maintained.

- Based on **hazard assessment**, measures shall be put in place to prevent, control or detect potential contamination.

- Controlling the entry of non-food handlers to food preparation and storage areas.

  **Examples of such measures include:**
  
  a) Adequate covers over equipment or containers for exposed materials or products.
  
  b) Use of screens, magnets, sieves or filters.
  
  c) Use of detection/rejection devices such as metal detectors or X-ray.

  **Note:** Sources of potential contamination include wooden pallets and tools, rubber seals, personal protective clothing and equipment, etc.
13.3.4 Chemical contamination

Chemical materials should be:

- Properly stored in appropriate containers.
- Kept in locked cupboards away from food storage and preparation areas.
- Used in accordance with given instructions.
- Disposed carefully and safely after use.

13.3.5 Time and temperature control

Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

- Temperature control systems should consider:
  - Nature of the food, e.g. its water activity, pH, and likely initial level and types of microorganisms.
  - Intended shelf life of the product.
  - Method of packaging and processing.
  - How the product is intended to be used, e.g. further cooking/processing or ready-to-eat.
- Such systems should also specify tolerable limits for time and temperature variations.
- Temperature recording devices should be checked at regular intervals and tested for accuracy.

13.4 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 not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

13.5 Water

13.5.1 In contact with food

Only potable water should be used in food handling and processing, with the following exceptions:
for steam production, fire control and other similar purposes not connected with food.

- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean seawater).

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water that has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

13.5.2 As an ingredient
Potable water should be used wherever necessary to avoid food contamination.

13.5.3 Ice and steam
Ice should be made from potable water. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

13.6 Management and supervision
The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

13.7 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.

13.8 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. Where a product has been withdrawn because of an immediate health hazard, other products that 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.

### 14. Transportation

Measures should be taken where necessary to:

- protect food from potential sources of contamination.
- protect food from damage likely to render the food unsuitable for consumption.
- provide an environment that effectively controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food.

Food may become contaminated or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

#### 14.1 General

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

#### 14.2 Requirements

- Where necessary, conveyances and bulk containers should be designed and constructed so that they:
  
  - Do not contaminate foods or packaging.
  - Can be effectively cleaned and, where necessary, disinfected.
  - Permit effective separation of different foods or foods from non-food items during transport.
  - Provide effective protection from contamination, including dust and fumes.
  - Can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption.
  - Allow any necessary temperature, humidity and other conditions to be checked.
14.3 Use and maintenance

- Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

- Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

15. Product information / consumer awareness

**Products should bear appropriate information to ensure that:**

- Adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly.

- The lot or batch can be easily identified and recalled if necessary.

**Consumers should have enough knowledge of food hygiene to enable them to:**

- Understand the importance of product information.

- Make informed choices appropriate to the individual.

- Prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

**Information for industry or trade users** should be clearly distinguishable from consumer information, particularly on food labels.

15.1 General

Insufficient product information and/or inadequate knowledge of general food hygiene can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

15.2 Product information

Information shall be presented to consumers in such a way as to enable them to understand its importance and make informed choices.

**Note:** Information may be provided by labelling or other means, such as company websites and advertisements, and include storage, preparation and serving instructions applicable to the product.
15.3 Labelling of pre-packaged foods
Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely.

15.4 Consumer education
Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information, follow any instructions accompanying products, and make informed choices. In particular, consumers should be informed of the relationship between time/temperature control and foodborne illness.

16. Rework
What is food rework?
The US Code of Federal Regulation defines food rework as being “clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing, re-blending or reformatted into the finished product, that is suitable for use as food”.

This process is to assist businesses in their daily workflow operations by providing guidance in monitoring how to rework effectively and safely to eliminate the risk of “Product Contamination”. This includes the reasonable expected handling of the product where all facilities are considered, and all risks are identified.

16.1 General requirements
Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained.

16.2 Storage, identification and traceability
▪ Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
▪ Segregation requirements for rework (e.g. allergen) shall be documented and met.
▪ Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained.
▪ The rework classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, a line of origin, shelf life).
16.3 Rework usage

▪ Where rework is incorporated into a product as an “in-process” step, the acceptable quantity, type and conditions of rework use shall be specified. The process step and method of addition, including any necessary pre-processing stages, shall be defined.

▪ Where rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

17. Training

Training is fundamentally important to any food hygiene system. Inadequate hygiene training and/or instruction and supervision of all people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

17.1 Training programmes

Factors to consider in assessing the level of training required include:

▪ The nature of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms.

▪ 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.

▪ The expected length of time before consumption.

17.2 Periodic training

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.
Chapter 4

Hazard Analysis and Critical Control Point (HACCP)

Objectives

- After reading this chapter, you should be able to:
  - List and explain the importance of the principles of HACCP.
  - Assess health hazards and their significance for the food product.
  - Identify critical control points, including critical limits to ensure their control.
  - Explain control measures that prevent, reduce, or minimize hazards associated with foods.
  - Describe the steps of design, implement, and manage appropriate programs for verification and maintenance of HACCP systems.

1. What is HACCP?

HACCP is an abbreviation for the Hazard Analysis and Critical Control Point system, which is synonymous with food safety management. The HACCP system, which is science-based and systematic, identifies specific hazards and evaluates for their control to ensure the safety of food. 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 is not the only method in ensuring that safe food products are manufactured. The plan will be successful when other procedures are in place such as sanitation standard operating procedures (SSOP’s) and by using good manufacturing practices (GMP’s). These programs are fundamental in the development of a successful HACCP plan.

HACCP can be applied throughout the food chain from primary production to final consumption 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. The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a multidisciplinary approach; this multidisciplinary approach should include, where appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. 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.

In brief, HACCP is applied by taking a number of straightforward steps:
• Understand your product—what is making it safe?
• Look at your production process from start to finish—understand your operating environment and process activities.
• Identify potential hazards and decide where they could occur in the process.
• Put in preventative control measures with defined safety limits.
• Monitor the controls.
• Write it all down and keep records as evidence that you have done it.
• Ensure that it continues to work effectively.

HACCP should not be:
• An academic exercise
• Put on a shelf

HACCP should be:
• Science based with validated controls
• Continuously evolving and maintained
• Kept simple.

The HACCP system and guidelines for its application were developed by the Codex Committee for Food Hygiene on the Codex Alimentarius Commission, a joint Food Standards Programme of the Food and Agriculture Organization (FAO) of the United Nations, and the World Health Organization (WHO). The HACCP system and guidelines were published in 1993 and revised in 1997.
2. Where did HACCP come from?

- HACCP originated in 1959 as part of the U.S. manned space program.
- The Pillsbury Co. worked with NASA and U.S. Army laboratories.
- It recognized that traditional quality control methods (inspection and testing) did not give enough assurance of product safety.
- A preventative approach was needed.
- It is based on the engineering system failure Mode and Effect Analysis (FMEA).
- It was shared with the food industry and regulatory agencies in 1971 in the United States.
- It was adopted and developed by several companies and progressed around the world.
- HACCP is now incorporated into legislation in some countries.

3. What are the benefits?

- Food safety is not negotiable with customers. HACCP provides a system for managing food safety controls.
- Preventative-Provides structure for objective assessment of "what can go wrong" and requires controls being put in place to prevent problems.
- Systematic-It is a logical approach, ensuring a comprehensive study of defined scope.
- Increased confidence-Because it's a step-by-step approach, it is less likely that hazards will be missed. This offers increased confidence to both the food business and its customers than could be achieved by a traditional sampling and testing-based approach.
- Effective use of resources-These are very expensive so focus on critical food safety areas. It is cost effective through prevention of food safety-related waste/incident costs.
- Help demonstrate due diligence-HACCP approach is a foundation for the defense under the Food Safety Act (1990) UK. HACCP also enables UK and European companies to meet the regulatory requirements for a HACCP approach.
- HACCP helps with prioritization in making informed judgments on food safety matters and removes bias, ensuring that the right personnel with the right training and experience are making the decisions.
HACCP will also help to demonstrate effective food safety management through documented evidence which can be used in the event of litigation.

HACCP enables food companies to meet their legal obligations to produce safe, wholesome food.

The disciplines of applying HACCP are such that there is almost always going to be an improvement in product quality. This is primarily due to the increased awareness of hazards in general and the participation of people from all areas of the operation.

4. Is HACCP applicable to everyone?

Yes, absolutely, HACCP is logical in its systematic assessment of all aspects of food safety from raw material sourcing through processing and distribution to final use by the consumer. Various terms are used to describe the scope of the HACCP system. “Farm to fork” illustrate the fact that food safety control must encompass the entire food chain if you don’t want to be in a “crop to court” situation! If we consider a simple supply chain model (Figure 4.1), we can see that there are various sectors within the food industry. HACCP is applied to the whole of the supply chain.

A sizeable lobby thinks HACCP is not applicable to small businesses. Of course, this perception is rejected. The key is flexibility in application and appropriateness of documentation, i.e., measuring and recording information that adds value as evidence of food safety control. The HACCP technique itself is a straightforward and logical system of control, based on the prevention of problems—a common sense approach to food safety management. HACCP is a key element of all company product safety management systems and, with good training and education, everyone ought to be able to at least understand the concept.

Fig. 4.1 Simplified supply chain model
In brief, HACCP is suitable for use in various food processing and handling facilities because the same HACCP principles apply whatever the location or food process.

**Primary Producers**

These are the fish producers and the land farmers, either raising livestock for the meat industry or the growers of the crops and vegetables that will be used by the processors in their conversion into finished products or sent directly to retail or food service. The individual steps within the on-farm process can be **assessed systematically for the potential for hazards to occur**, just as with any other area of the food processing industry. **Control measures can then be identified**, and the control points that are **critical** to food safety established. **Critical limits** may be harder to identify, but here the farmer is often helped by **legislative limits**, for example, in the case of herbicide and pesticide application.

For primary producers, there may be added difficulty in understanding the impact of their actions further down the supply chain. Yet for the processors it is almost impossible to anticipate what potential new hazards may arise at their stage in the chain if they do not know what has occurred earlier on during primary production.

An issue that may not appear to be a hazard on the farm may well have an impact further down the chain and require control measures to be implemented at the stage of the earlier primary process. For example, presenting animals for slaughter in an unfit state may increase the likelihood of *E. coli* contamination of the meat. Application of **hazard analysis** at the primary-producer stage is useful to identify likely hazards and how they will be controlled either through **prerequisite hygiene programs** or through **specific control measures**. This is probably best done by use of a team approach. This could involve both the primary producers themselves, but also their customers (i.e., the processors, retailers, and caterers).

**Food Service and Catering Operations**

Food service and catering operators, large and small, usually have a vast number of raw materials and menu items, and a high turnover of staff. The principles of HACCP remain very relevant to this environment; however, the implementation may differ somewhat from a large food-processing establishment. Small and/or less-developed businesses do not always have the resources and the necessary expertise on-site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and regulatory authorities.

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills. Therefore, **ongoing training** is necessary for all levels of employees and managers, as appropriate.
Retailers

As seen with the food service and catering example, retailers should also be able to adopt HACCP to ensure that they sell safe food, which the primary producers and processors have endeavored to ensure, reaches them in good condition. Purchasing from reputable suppliers, correct temperature control, and prevention of cross-contamination will be essential control measures in both large and small premises. However, the HACCP principles, if truly understood and linked to good hygiene practices, should help to improve food safety control and hence significantly reduce risk. Effective training in both of these sectors is essential.

Consumers

This is a difficult area, as consumers do not necessarily have access to reliable sources of education and training in food safety. HACCP techniques can be applied very successfully in the home environment and to some extent; there is much similarity between a domestic kitchen and that of the small caterer. It is important that consumers should take responsibility for storing, preparing, and cooking foods properly, rather than expecting all products to be completely free of microorganisms at the point of purchase.

Food hygiene education of the consumer is a vital element in the prevention of foodborne illness. Education should include the principles of good consumer practices (GCPs), i.e., good hygiene practice in the home, how to prevent cross-contamination, the importance of temperature in controlling microbiological food safety and of reading labels. Some governments are starting to work with industry and trade organizations in acknowledgement that improved understanding and consumer ownership of preventative control measures will result in a decrease in the number of food poisoning outbreaks.

5. What causes the limitations or failure of HACCP?

- Lack of knowledge may arise due to improperly trained or untrained personnel or when there are not enough people on the HACCP Team or where HACCP is done at the corporate level with little or no input from the processing facility.

- Incomplete/inadequate implementation, e.g., paper HACCP Plan is not implemented, leads to a false sense of security.

- Lack of maintenance means the system is not up-to-date and new/emerging hazards may be missed.

- Poor records / too much paperwork.

- The system sits in the manager’s office.

- Too many critical control points.
6. Definitions

Control (a) to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan. (b) The state wherein correct procedures are being followed and criteria are being met.

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

Food safety hazard: A biological, chemical or physical agent in food, 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.

Prerequisite programme: Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption. Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

Operational prerequisite programme (OPRP): PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

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 criterion that separates acceptability from unacceptability. A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

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

Deviation: Failure to meet a critical limit.

Corrective action: Procedures followed when a deviation occurs to eliminate the cause of a detected nonconformity or other undesirable situation.

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

Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.
**HACCP plan**: The written document which is based upon the principles of HACCP and which delineates the procedures to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

**HACCP system**: The result of the implementation of the HACCP Plan procedures to be followed.

**HACCP team**: The group of people who are responsible for developing, implementing and maintaining the HACCP system.

**Validation**: Obtaining evidence that the control measures managed by the HACCP plan and by the operational PRPs are capable of being effective.

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

### 7. HACCP Principles

#### 7.1 The Key Stages of HACCP
- You cannot just “jump” in and use HACCP principles without preparation and planning.
- Development of a HACCP system through the application of HACCP principles follows four key stages. (Figure 4.2)

---

**Fig. 4.2 The key stages of HACCP**
In brief, this involves the following steps:

- **Plan** - what needs to be done to maintain food safety and write it down.
- **Do** - what you planned to do to maintain food safety.
- **Check** - that you are doing what you planned to do to maintain food safety and write down what was checked and when.
- **Act** - to correct any food safety problems and write down what has been done about the problem and when.

  - Key Stage 1 = The **Planning** stage (for HACCP and PRP requirements)
  - Key Stage 2 = The **Doing** Stage (both for HACCP program development and PRP upgrades)
  - Key Stage 3 = **Checking** that the HACCP plan is valid before implementation
  - Key Stage 4 = **Act** to monitor and maintain the HACCP, PRP, and overall Food safety program.

### 7.2 Management Commitment

- Management commitment is key to a successful food safety system.

- Management commitment ensures that a food safety system is as much a part of daily business as maintaining sales and reducing costs.

- Even if management only plays a supporting role in the food safety system, management commitment must be visible to all employees.

- Management commitment can be shown by:
  - Promoting HACCP activities at internal meetings.
  - Posting signs indicating in-house HACCP policies.
  - Posting a sign indicating management commitment to HACCP.
  - Supplying adequate resources for HACCP development, implementation and food safety training.
  - Regular review of HACCP materials and progress reports.
  - Regular attendance by management at HACCP training sessions.
  - Standardizing and enforcing disciplinary actions for employees who do not meet their HACCP responsibilities.
### Table 4.1. Logic sequence for application of the Codex HACCP principles (Codex)

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Assemble HACCP team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Describe Product</td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify Intended Use</td>
</tr>
<tr>
<td>Step 4</td>
<td>Construct Flow Diagram</td>
</tr>
<tr>
<td>Step 5</td>
<td>On-site Confirmation of Flow Diagram</td>
</tr>
<tr>
<td>Step 6</td>
<td>List all Potential Hazards, conduct a Hazard Analysis, and Consider Control Measures</td>
</tr>
<tr>
<td>Step 7</td>
<td>Determine Critical Control Points (CCPs)</td>
</tr>
<tr>
<td>Step 8</td>
<td>Establish Critical Limits for each CCP</td>
</tr>
<tr>
<td>Step 9</td>
<td>Establish a Monitoring System for each CCP</td>
</tr>
<tr>
<td>Step 10</td>
<td>Establish Corrective Actions</td>
</tr>
<tr>
<td>Step 11</td>
<td>Establish Verification Procedures</td>
</tr>
<tr>
<td>Step 12</td>
<td>Establish Documentation and Record Keeping</td>
</tr>
</tbody>
</table>

#### 7.3 Preliminary steps of HACCP

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. The five preliminary tasks are given in Figure 4.3

![Fig. 4.3 Preliminary steps of HACCP](image-url)
Step 1: Assemble the HACCP team

It is important that HACCP is not carried out by one person alone but is the result of a multidisciplinary team effort—the HACCP team. The HACCP team consists of experts ("expert" meaning having knowledge and experience) from the following areas:

1. **Quality Assurance/Technical**—providing expertise in microbiological, chemical, and physical hazards, an understanding of risk and hazard significance assessment, and knowledge of measures that can be taken to control the hazards.

2. **Operations or Production**—has responsibility for and has detailed knowledge of the day-to-day operational activities required in order to produce the product.

3. **Engineering**—able to provide a working knowledge of process equipment and environment with respect to hygienic design and process capability.

4. **Additional expertise**—may be provided both from within the company and from external consultancies. The following areas should be considered:
   - **Supplier Quality Assurance**—essential in providing details of supplier activities and in an assessment of hazard and risk associated with raw materials. The person responsible for auditing and approving suppliers will have a broad knowledge of best practices gained through observing a wide range of manufacturing operations. They will also need to know how the raw materials are used in your company.
   - **Research and Development (R&D)**—if the company is one where new products and process development is a continuous activity, then input from this area will be essential.
   - **Storage and Distribution**—for expert knowledge of storage and handling throughout the distribution chain. This is particularly important if distribution conditions, e.g., strict temperature control, are essential to product safety.
   - **Procurement**—participation of purchasing personnel will mean that they are made fully aware of the risks associated with particular products or raw materials and can assist with communication of any proposed change in suppliers. They will also be a partner for communication of your specifications and expectations.
   - **Microbiologist**—if the company has its own microbiologists, then their expert knowledge is absolutely needed on the HACCP team. Many smaller companies do not have this option and, where microbiological hazards require consideration, they should identify a source of expert help from outside, i.e., a food research association, a university, a reputable consultancy, or analytical laboratory.
   - **Statistical process control (SPC)**—This would be useful when setting up sampling plans or for a more detailed assessment of process control data.
• **HACCP experts**—it may be appropriate initially to co-opt an external HACCP specialist onto the HACCP team. This may be useful in helping the company team to keep on the right track and become familiar with the HACCP approach. It could also be extremely important in helping the company to determine whether they have got the right expertise on the team and as an early assessment of whether the initial HACCP studies are correct.

• **Other**—facilitation skills are extremely useful and often can be found within Human Resource or training departments if available. Also, needed is a person who can prepare all the documents during and in between meetings.

We have now considered the disciplines required within the team and, in summary, it should be emphasized that expert judgment is essential in assessment of **hazards and risks**. What else is important with respect to the type of people involved in the team? Personal attributes will include:

1. Being able to evaluate data in a logical manner using expertise within the team and perhaps using published data for comparison.
2. Being able to analyze problems effectively and solve them permanently, treating the root cause not the symptom of the problem.
3. Being creative by looking outside the team, the company, and the country for information and ideas.
4. Communication skills. The HACCP team will need to be able to communicate effectively both internally within the team and externally, across all levels of the company.
5. Leadership abilities. Leadership skills of some degree will be useful in all members of the team. After all, they are leading the company in its HACCP approach to food safety management. It is recommended that one member of the team is appointed to **HACCP team leader**. This is often the quality assurance (QA) Manager but consider carefully what the leadership of a team entails. You are Personnel or Human Resources department may be helpful in identifying suitable courses for development of these skills if they are not already sufficient.

**The HACCP team leader** will have a key role in the success of the HACCP system and he or she is likely to become the company HACCP expert and be regarded as such. In the leadership role, the team leader will be responsible for ensuring that:

• The team members have sufficient breadth of knowledge and expertise.
• Their individual skills and attributes are considered.
• Individual training and development needs are recognized.
• The team and work tasks are organized adequately.
• Time is made available for reviewing progress on an ongoing basis.
• All skills, resources, knowledge, and information needed for the HACCP system are available either from within the company or through identifying useful external contacts.

The behavior within the team must be supportive, encouraging all members to participate. With all team members fully committed to producing and maintaining an effective HACCP system.

Within the HACCP team itself, consider the range of disciplines required. In smaller companies, the same person may be responsible for both Quality Assurance (QA) and Operations. In terms of ideal team size, four to six people is a good range. This is small enough for communication not to be a problem but large enough to be able to designate specific tasks.

In large companies, the “experts” and senior people in the three main disciplines of QA, Production, and Engineering may not be close enough to the operation. It may then be more effective to have a series of smaller departmental teams, still made up of the three main disciplines but at a less senior level. This ensures that the true working knowledge of activities is captured and subsequently reviewed by appropriate experts in each area. An example of this could be represented diagrammatically, as in Figure 4.4.

![Figure 4.4 Example of HACCP team structure in a large organization](image-url)
HACCP Team Responsibilities:

- Develops the HACCP Plan.
- Completes study and generates HACCP documentation.
- Ensures verification of the HACCP Plan.
- Communicates and trains.
- Reviews deviations from CCPs.
- Reviews HACCP activities in response to change.
- Schedules and conducts internal audits.

Fig. 4.5 Planning and preparation of HACCP
Baseline Audit and Gap Analysis

It is important to evaluate the resources and systems in place and compare these against the requirements to manage HACCP effectively, before putting together a Project Plan for the HACCP initiative. This will include a review of your facility environment as well as an assessment of the current systems and personnel resources.

In order to plan the pathway to an effective HACCP system and food safety program, it is important to consider two basic questions:

1. What resources and systems (including PRPs) need to be in place for HACCP to work?
2. What resources and systems do I currently have?

The differences between 1 and 2 are the gaps that will need to be filled. A third question (How will I get there?)

The most effective way of identifying the gaps is to carry out a baseline audit of current control measures for food safety and quality management, using auditors with expert knowledge (ideally include a reputable independent expert who is external to the company or at least the facility) of the standards and systems required to support HACCP.

An example of the types of questions that might be considered for the initial gap analysis assessment follows in Table 4.2

Fig. 4.6 The HACCP support network
## Table 4.2 Prerequisite program and management status gap analysis checklist

<table>
<thead>
<tr>
<th>Prerequisite program area</th>
<th>Questions</th>
<th>Status: in place (Yes/ No)</th>
<th>Auditor notes (HACCP Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Environment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>Are your buildings, grounds, and equipment in good repair?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Does process flow logical?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>Do you have a layout that enables the control of cross-contamination? Consider:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Traffic patterns—people, equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>• Air and drain flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>• Personnel hygiene facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>▪ Captive uniforms and shoes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>▪ Hand washing stations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>▪ Rest room and cafeteria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Facility design</td>
<td>Do storage and distribution practices present a food safety risk?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Equipment</td>
<td>Is it of sanitary design?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Equipment</td>
<td>• Suitable for cleaning, maintenance, and preventative maintenance?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Equipment</td>
<td>Is it capable of control as specified in your program?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Equipment</td>
<td>Is there a calibration program?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Utilities/services</td>
<td>Are utilities such as air, water, energy effectively controlled for food safety?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Utilities/services</td>
<td>Lighting—is it adequate for inspection and observation of cleaning needs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2. Programs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>Do you have an approved supplier list detailing the source (manufacturing location) of all raw materials?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>Do you understand the safety criteria governing your raw materials?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>Does the raw material need to be handled in a specific manner when it arrives at your location (for safety)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>Do suppliers provide analytical information and is it valid?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>• Are any tests carried out and is the lab certified/approved?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>Are approved specifications held for all raw materials?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Supplier quality assurance</td>
<td>• Has the supplier signed their agreement to comply?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4.2 Continued

<table>
<thead>
<tr>
<th>Prerequisite program area</th>
<th>Questions</th>
<th>Status: in place (Yes/No)</th>
<th>Auditor notes (HACCP Team)</th>
</tr>
</thead>
</table>
| **b) Cleaning and Disinfection (sanitation)** | Have all suppliers been audited? (and against which criteria?)  
- What training and calibration do your internal supplier approval auditors receive?  
- For the suppliers that were not audited, was a desktop review and approval undertaken? | | |
| (c) Allergen control | Are risk-based sanitation schedules in place?  
Are cleaning procedures being complete including reference to the:  
- Equipment to be cleaned  
- Method of cleaning and materials used  
- Responsibilities for implementation  
- Validations and verification procedures  
Are records complete and signed by responsible person? | | |
| (d) Pest control | Are allergens clearly identified in raw material specifications?  
Are allergen production scheduling matrices up to date?  
Have allergen cleans been validated?  
Is the label verification program adequate? | | |
| (e) Good laboratory practice | Is the building adequately proofed and protected against pest ingress or harborage?  
Do you have a third-party contract with a licensed provider?  
Is there someone on staff who has expertise and oversight of the program?  
Are monitoring and corrective action procedures in place?  
Has there been significant activity in recent or past history?  
- Was corrective and preventative action been taken in a timely manner? | | |
| (e) Good laboratory practice | Does the laboratory (internal/external) operate to a good practice system?  
Are controls built into the sample testing procedures? | | |
### Table 4.2 Continued

<table>
<thead>
<tr>
<th>Prerequisite program area</th>
<th>Questions</th>
<th>Status: in place (Yes/No)</th>
<th>Auditor notes (HACCP Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(f) Preventative maintenance</strong></td>
<td>Is analyst performance monitored?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are all laboratory staff routinely trained?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is sampling carried out in a hygienic manner?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>(g) Trace, recall, and Incident management</strong></td>
<td>Does a preventative maintenance schedule exist?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Does it cover all key equipment for food safety?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Would traceability systems ensure that all of the correct material could be identified and withdrawn/recalled in a timely manner?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have lot traceability recall procedures been tested?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there a designated Incident Management team?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are personnel trained in incident management and media handling?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(h) Quality management systems</strong></td>
<td>Is there a senior level supported Quality Policy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there a Quality Management System in place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is it based on an accepted framework, e.g., ISO benchmarked scheme?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Does it cover all parts of the operation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there a well-established Corrective and Preventative Action (CAPA) program in place?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3. People

| **(a) Personal hygiene** | Is there a program for restriction of jewelry, finger nail polish, hair, etc.? |                           |                           |
|                         | Is there a captive uniform and shoe program?                          |                           |                           |
|                         | Is there an employee ill health monitoring and reporting program? Does it apply to visitors and contractors? |                           |                           |
| **(b) Personal behavior** | Are rules in place?                                                   |                           |                           |
|                         | Are they clearly communicated?                                        |                           |                           |
Table 4.2 Continued

<table>
<thead>
<tr>
<th>Prerequisite program area</th>
<th>Questions</th>
<th>Status: in place (Yes/No)</th>
<th>Auditor notes (HACCP Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) Training and education</td>
<td>Are employees trained commensurate with working activities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is training validated?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Are records in place to confirm this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is training verified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Are records in place to confirm this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>How are training needs established?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are job descriptions in place which include food safety roles and responsibilities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are employees engaged and knowledgeable about their food safety role?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is action taken when irregularities/noncompliance's are observed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Step 2: Describe Product

It is important for all members of the HACCP team to understand the background to the product/process that they are about to study. This is achieved by constructing a product description (also known as a process description). The product description is not simply a specification for the product, but rather contains information important to making safety judgments.

The following criteria are normally included:

- Hazard types to be considered.
- Main ingredient groups to be used in the product/process line.
- Main processing technologies (e.g. heating, freezing, drying, cooling, etc.)
- Key control measures.
- Intrinsic (recipe) factors.
- Storage and distribution conditions.
- Packaging system (e.g. vacuum, modified atmosphere).

The task of constructing a product description helps to familiarize all HACCP team members with the product/process under study. It is normal practice to document the product description and include it with the HACCP plan paperwork. The document is also useful at later stages as a
familiarization tool for HACCP system auditors or any personnel who need to gain an understanding of the HACCP plan.

Fig. 4.7 HACCP Key stage 2—HACCP studies and HACCP plan development
Example: describe ice cream product

- These are frozen, ready-to-eat products containing both pasteurized and unpasteurized components. The cream, sugar, powders, heat-stable liquids, and water are subject to pasteurization, while the flavoring and particulates are added without further heat processing. Air is also whipped into the product at freezing.

- The products will be consumed, without further processing, by the general population, including high-risk groups (e.g., children and elderly).

- The products are packed in containers of 1.0 liter, 500 ml, and 100 ml single-serve sizes.

- Products included:
  - Plain Ice cream (Vanilla)
  - chocolate, strawberry

- Key process technologies:
  - Blending
  - Homogenization
  - Pasteurization
  - Freezing

- Principal raw material types:
  - Dry powders, e.g., skimmed milk powder, cocoa, granulated sugar
  - Semi moist particulates, e.g., cookie dough, flaked coconut
  - Bulk liquids, e.g., cream, liquid sugar
  - Dry particulates, e.g., chocolate chips, shortcake cookie pieces, walnut pieces
  - Frozen fruit pulps, and concentrates
  - Ambient liquids and pastes, e.g., flavorings, lethicin
  - Packaging, e.g., plastic tubs, lids, labels

- Key hazards for consideration:
  A. Microbiological
    - Pathogens in raw materials added post-pasteurization
    - Spore outgrowth at aging stage

  Physical
    - Fruit stalks
    - Nut shells
    - Metal
Chemical

- Allergens: dairy, nuts, wheat gluten (in shortcake and cookie dough), lecithin (in chocolate).
- Packaging chemical migration issues.
- Antibiotics in cream and skimmed milk powder.
- Aflatoxin in flour (cookie dough) and nuts.
- Adulterants (Melamine in dairy components).

Key control measures:
- Supplier quality assurance activities (specifications, supplier approval)
- Process control steps
- Cross-contamination prevention
- Temperature control
- Labeling

Step 3: Identify Intended Use
It is necessary to identify the intended use of the product, including the intended consumer target group, because different uses may involve different hazard considerations and different consumer groups may have varying susceptibilities to the potential hazards. This information is usually included as part of the product description (Step 2).

Step 4. Construct Flow Diagram
A process flow diagram, outlining all the process activities in the operation being studied, needs to be constructed. The purpose of the process flow diagram is to document the process and provide a foundation for the hazard analysis (Step 6). It should be carefully constructed by members of the team as an accurate representation of the process and should cover all stages from raw materials to end product or the end of the process module, as defined in the HACCP study terms of reference. The following types of data should be included:

- Details of all raw materials and product packaging, including format on receipt and necessary storage conditions.
- Details of all process activities, including sampling and any other routine manual interventions and the potential for any delay stages. It is important that this lists all the individual activities rather than becoming a list of process equipment.
- Temperature and time profile for all stages. This will be particularly important when analyzing microbiological hazards as it is vital to assess the potential for any pathogens present to grow to hazardous levels.
- Details of any product reworking or recycling loops.
- Storage conditions, including location, time, and temperature.
• Distribution/customer issues (if included in your terms of reference).

A simple example of a process flow diagram is shown in Figure 4.8. This shows a process of ice cream production.

![Flow diagram of ice cream processing](image_url)

Fig. 4.8 Flow diagram of ice cream processing
Step 5. On Site Confirmation of Flow Diagram

Since the process flow diagram is used as a tool to structure the hazard analysis, it is important to check and confirm that it is correct. This is done by walking the line and comparing the documented diagram with the actual process activities, noting any changes necessary. This exercise is normally done by members of the HACCP team but could also be done by process line operators. The completed process flow diagram should be signed off as valid by a responsible member of staff, e.g. the HACCP team leader.

Step 6. List all Potential Hazards; Conduct a Hazard Analysis and Consider Control Measures

When the Process Flow Diagram has been completed and verified, the team can move on to the next stage of the HACCP study, the hazard analysis, as described by HACCP principle 1. The team must ensure that all potential hazards are identified and considered.

Hazard analysis involves the collection and evaluation of information on hazards and conditions leading to their presence, in order to decide which are significant for food safety and therefore should be addressed in the HACCP plan. Several resources and techniques are available to the team to assist in this task. However, before starting out on the hazard analysis, all team members must be clear on the meaning of the word “hazard.” Remember, a “hazard” is normally considered to be a factor that may cause a food to be unsafe for consumption. Hazards can be of biological, chemical, or physical nature (review chap. 2).

Control Measure: an action or activity that can be used to prevent, eliminate or reduce a hazard to an acceptable level.

A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish three objectives:

- Those hazards and associated control measures are identified.
- The analysis may identify needed modifications to a process or product so that product safety is further assured or improved.
- The analysis provides a basis for determining CCPs in Principle 2.

The process of conducting a hazard analysis involves two stages: The first, hazard identification, can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the
intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards which may be introduced, increased, or controlled at each step in the production process. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation.

After the list of potential hazards is assembled, stage two, the hazard evaluation, is conducted. In stage two of the hazard analysis, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard adverse effect and its likely occurrence in the type of operation being studied. This may be done using judgement and experience or using a structured ‘risk assessment’ method, where different degrees of likelihood and severity are weighted to help with the significance decision. Effective control measures then need to be identified for each significant hazard. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard. However, there may be differences of opinion, even among experts, as to the likely occurrence and severity of a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

Hazard analysis chart is shown in table 4.3. It is also extremely important to document the source or cause of each hazard, as this helps in identifying the most appropriate effective control measure. The documentation produced is then used as the basis for the hazard analysis and discussion of control measures. The use of such documentation helps to structure the thinking and discussions of the team, and therefore helps to ensure that all potential hazards are included. At each stage in the process flow diagram, the specific hazards and their causes or sources should be identified

Table 4.3 Hazard Analysis Chart

<table>
<thead>
<tr>
<th>Process steps</th>
<th>Hazard and source/cause</th>
<th>Likelihood</th>
<th>Severity</th>
<th>Significant Hazard</th>
<th>Control measure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Questions to Be Considered

The following includes some questions to help with hazard identification based on those put together by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients
1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
2. Are potable water, ice and steam used in formulating or in handling the food?
3. What are the sources (e.g., geographical region, specific supplier)?

B. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.
1. What hazards may result if the food composition is not controlled?
2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

C. Procedures used for processing
1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?

D. Microbial content of the food
1. What is the normal microbial content of the food?
2. Does the microbial population change during the normal time the food is stored prior to consumption?
3. Does the subsequent change in microbial population alter the safety of the food?
4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?

E. Facility design
1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design and use
1. Will the equipment provide the time-temperature control that is necessary for safe food?
2. Is the equipment properly sized for the volume of food that will be processed?
3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
4. Is the equipment reliable or is it prone to frequent breakdowns?
5. Is the equipment designed so that it can be easily cleaned and sanitized?
6. Is there a chance for product contamination with hazardous substances; e.g., glass?
7. What product safety devices are used to enhance consumer safety?
8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
9. Are allergen protocols needed in using equipment for different products?

G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled “Keep Refrigerated” if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?
8. Are potential allergens in the ingredients included in the list of ingredients on the label?

H. Sanitation
1. Can sanitation have an impact upon the safety of the food that is being processed?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education
1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of food?

J. Conditions of storage between packaging and the end user
1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use
1. Will the food be heated by the consumer?
2. Will there likely be leftovers?

L. Intended consumer
1. Is the food intended for the general public?
2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, and immunocompromised individuals)?
3. Is the food to be used for institutional feeding or the home?

Severity and Hazard Significance

Hazard and Risk

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

**Risk:** the combination of the probability of occurrence of harm and the severity of that harm. The term “hazard” is not to be confused with the term “risk” which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization, absence from work, etc.) when exposed to a specified hazard.
Within the HACCP study we need to take a logical, practical approach to **risk evaluation**. At the end of the hazard identification step, the team will have a list of potential hazards that might occur in the raw materials and during the process. Risk evaluation involves the evaluation of the potential hazards on this list, to establish the realistic significant hazards that the HACCP system must control.

**Significant Hazard:**
Hazards that are of such a nature that their elimination or reduction to an acceptable level is essential to the production of safe foods.

Significant hazards are determined by evaluating their likelihood of occurrence and the severity of the potential effect if they should occur. This is a risk-based judgment performed by the HACCP team and many teams find it helpful to divide “likelihood” and “severity” up into smaller risk evaluation categories to assist in determining significance (Figure 4.9).

![Figure 4.9 Determination of hazard significance](image)

<table>
<thead>
<tr>
<th>Likelihood of occurrence</th>
<th>Hazard severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>Life threatening or long-term chronic illness (e.g., infection, intoxication), or death.</td>
</tr>
<tr>
<td>Medium</td>
<td>Medium</td>
<td>Injury or intolerance. Not usually life threatening.</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>Minor effect. Short duration.</td>
</tr>
<tr>
<td>High</td>
<td>High</td>
<td>Highly probable. Known history in the sector.</td>
</tr>
<tr>
<td>Medium</td>
<td>Medium</td>
<td>Could occur. Minimal history within the sector but has happened.</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>Unlikely to occur. No known examples.</td>
</tr>
</tbody>
</table>

In the scheme illustrated in Fig. 4.9, those hazards with a medium or high likelihood of occurrence and a medium to high severity of effect are considered as being significant.
Table 4.4 risk evaluation chart

<table>
<thead>
<tr>
<th>Hazard/source</th>
<th>Likelihood of occurrence</th>
<th>Severity of outcome</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Medium Low</td>
<td>High Medium Low</td>
<td></td>
</tr>
<tr>
<td>For example, presence of <em>Salmonella</em> in raw chicken</td>
<td>✓</td>
<td>✓</td>
<td>Severe outcome if not controlled by the cooking process</td>
</tr>
</tbody>
</table>

It is also helpful to use a structured approach to be documenting the significance evaluation, thus providing a documented commentary on the evaluation of high, medium, or low risk. This could be incorporated into the Hazards analysis chart shown in (Table 4.3) to form a hazard analysis and risk evaluation chart or table. An example of this is shown in Table 4.4.

**Risk Matrix**

It lets the facility assess food safety by ranking risks on how severe they are. This assessment model offers a simple method that processors can use to look into food safety concerns.

**Identifying Control Measures**

When all potential hazards have been identified and analyzed, the team should go on to list the associated control measures (also sometimes known as preventative measures or controls). This is particularly important for the significant hazards, but it is useful to consider control...
measure options for all hazards identified. The control mechanisms for each significant hazard and are normally defined as those factors that are required in order to prevent, eliminate, or reduce the occurrence of hazards to an acceptable level for food safety. Control measures must always relate to the hazard that they are there to control. They must also be validated as being capable of control at all times.

After that, can complete the hazard analysis table of ice cream?

Table 4.5 Hazard Analysis Chart for some raw materials

<table>
<thead>
<tr>
<th>Raw materials</th>
<th>Hazard and source</th>
<th>Likelihood of occurrence</th>
<th>Severity of effect</th>
<th>Significance Y/N</th>
<th>Control measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw milk</td>
<td>Biological:</td>
<td>M</td>
<td>H</td>
<td>Y</td>
<td>Pasteurization</td>
</tr>
<tr>
<td></td>
<td>Pathogenic bacteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chemical:</td>
<td>M</td>
<td>H</td>
<td>Y</td>
<td>Supplier Quality Assurance (SQA) procedures. Certificate of Analysis (COA).</td>
</tr>
<tr>
<td></td>
<td>Antibiotics residues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical:</td>
<td>M</td>
<td>L</td>
<td>N</td>
<td>Filtration</td>
</tr>
<tr>
<td></td>
<td>Impurities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skim milk Powder (SMP)</td>
<td>Salmonella from supplier cross contamination</td>
<td>M</td>
<td>H</td>
<td>Y</td>
<td>Pasteurization and post-process control.</td>
</tr>
<tr>
<td>Lecithin</td>
<td>Allergen</td>
<td>H</td>
<td>H</td>
<td>Y</td>
<td>Labelling</td>
</tr>
<tr>
<td>Packaging—plastic tubes and film</td>
<td>Chemical and plasticizer additives</td>
<td>M</td>
<td>M</td>
<td>N</td>
<td>SQA specifications.</td>
</tr>
<tr>
<td>Process steps</td>
<td>Hazard and source</td>
<td>Likelihood of occurrence</td>
<td>Severity of effect</td>
<td>Significance Y/N</td>
<td>Control measure</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------------------------------------------</td>
<td>--------------------------</td>
<td>--------------------</td>
<td>------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Filtration</td>
<td>Carry-through of foreign material due to filter malfunction</td>
<td>L</td>
<td>M</td>
<td>N</td>
<td>Planned preventative maintained - filter in place and intact</td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Survival of vegetative pathogens through not achieving correct heat process (time and/or temperature)</td>
<td>H</td>
<td>H</td>
<td>Y</td>
<td>Correct heat process achieved</td>
</tr>
<tr>
<td>Aging</td>
<td>Outgrowth of spore-forming pathogens due to temperature abuse</td>
<td>L</td>
<td>H</td>
<td>N</td>
<td>Temperature maintenance (4 °C) Maximum storage 4 hours</td>
</tr>
<tr>
<td>Fill tubs/cartons</td>
<td>Hazardous foreign material ingress from environment or filling heads</td>
<td>L</td>
<td>M</td>
<td>N</td>
<td>Planned Preventative maintenance and redesign. Later metal detector</td>
</tr>
<tr>
<td>Label</td>
<td>Allergen hazard not identified</td>
<td>H</td>
<td>H</td>
<td>Y</td>
<td>Nuts, eggs, dairy and gluten, etc. all need to be labeled. Bar code scanner in place.</td>
</tr>
<tr>
<td>Metal detect</td>
<td>Metal contamination not identified due to equipment malfunction</td>
<td>H</td>
<td>M</td>
<td>Y</td>
<td>Effective metal detection—calibrated metal detector suitable for product dimensions. Planned Preventative maintance.</td>
</tr>
</tbody>
</table>

Remember that more than one control measure may be required to control a hazard that occurs at different stages of the process. For example, the potential for contamination with *Listeria monocytogenes* before and after cooking in a ready-to-eat product. For contamination before cooking the heat process might be the control measure, while environmental hygiene controls
would be required to prevent contamination after cooking. Similarly, more than one hazard might be effectively controlled by one control measure, e.g., two microbiological pathogens by a heat process, or physical hazards such as glass and metal through use of sifting.

Step 7. Determine Critical Control Points (CCPs) (Principle 2)
A CCP is a point, step, or procedure where a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

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 (Codex 2009).

CCPs can be found by using your thorough knowledge of the process and all the possible hazards and measures for their control. The information established during the hazard analysis should allow the identification of CCPs through the expert judgment of the team and specialist advisers.

Too many points as CCPs, rather than correctly identifying the real CCPs, may mean that you lose credibility and commitment as there will always be some points where you are prepared to negotiate a deviation. For example, if a metal detector failed at a raw material stage, you could switch it off and rely on the one at the end of the line, which, as long as the sensitivity is appropriate, would lead to potential increase in the amount of substandard product that is later rejected but with minimal compromise on food safety.

On the other hand, too few CCPs would be even more disastrous and could cause the sale of unsafe food. It is important that control is focused where it is essential for food safety and so care should be employed to ensure that the CCPs are correctly identified.

It is important to identify the correct points as CCPs so that resource can be focused on their management during processing. CCPs can be identified using HACCP team knowledge and experience or by using tools such as the Codex CCP decision tree (see Fig. 4.11). Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels.

Examples of CCPs may include thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration
of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation could also be CCPs. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs. This can be due to differences in each facility’s layout, equipment, selection of ingredients, processes employed, etc.

Simplified decision tree

“If I lose control is it likely that food poisoning/injury/harm will result?”

YES

Will a subsequent step eliminate or reduce the hazard to an acceptable level?

YES

Critical Control Point (CCP).

NO

Not CCP

Fig. 4.10 Simplified decision tree
Codex CCP decision tree

Q1: Do control preventive measure(s) exist?
   - YES: Modify step, process or product
   - NO: Is control at this step necessary for safety?
     - NO: Not a CCP
     - YES: Proceed with next question

Q2: Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?
   - NO: Stop
   - YES: Proceed with next question

Q3: Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?
   - YES: Proceed with next question
   - NO: Not a CCP

Q4: Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to an acceptable level?
   - YES: Critical Control Point
   - NO: Stop

*Fig. 4.11 Codex CCP decision tree*
Operational PRPs

The OPRP concept provides that OPRPs can be considered as an essential program for managing significant hazards and are, in a way, the missing link between the day-to-day good hygienic operating conditions and CCPs. CCPs manage hazards at a process step whereas OPRPs are programs that are designed to manage hazards across multiple process steps since they are about control of people and/or the process environment. Let us refer to the either relevant definitions that are in Codex, 2009 or ISO 22000: 2005 which are the primary international references:

PRP

Food safety basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling, and provision of safe end products and safe food for human consumption (ISO 22000: 2005)

OPRP

PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the process environment (ISO 22000: 2005).

These definitions are quite different, and it might be helpful to liken these two definitions with those related to specific control measures and CCPs in HACCP:

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex, 2009).

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 (Codex, 2009).

PRPs are to OPRPs what control measures are to the CCPs. In other words, OPRPs, like CCPs, are essential for food safety, i.e., you would not run the plant without assurance that they were in place and operating effectively. PRPs are about basic good hygienic operating conditions aimed at preventing the introduction of hazards or conditions which would allow their proliferation. With an OPRP we think about a process or program being used to control introduction of contamination via a direct product vector where subsequent steps will not eliminate or reduce the hazard to an acceptable level. This is usually after the pathogen reduction step in the case of microbiological hazards. Hazard analysis should be used to identify likely sources and vectors of microbiological hazards throughout the process—not only at the process steps but also through general process areas and which may arise through routine and non-routine activities, e.g., product sampling interventions or unclogging a blocked pipe. For any area that you may want to define “GMP” as a control measure for a hazard, try to be more
specific—this can be done during the Hazard Analysis stage. At every process step, consider the sources and vectors of environmental contamination (this can also be done for some chemical hazards such as allergens).

Some examples of OPRPs might be the requirement for HEPA filtration and positive air pressure in a high-risk (post-pathogen reduction) production area or the allergen sequencing (production scheduling) program in a plant that has multiple allergens. OPRPs require a higher degree of scrutiny than PRPs. If there was a failure in the PRP for a period of time, the likelihood of an immediate food safety event would be low, however, with an OPRP, a failure would be highly likely to result in a food safety event i.e., the plant would not be prepared to run without these programs.

Step 8. Establish Critical Limits for each CCP (Principle 3)

When you have identified all the CCPs in your process, the next step is to decide on their safety boundaries. This is HACCP principle 3. You must establish the criteria that indicate the difference between safe and unsafe product being produced so that the process can be managed within safe levels. The absolute tolerance at a CCP, i.e., the division between safe and potentially unsafe, is known as the critical limit. If the critical limits are exceeded, then the CCP is out of control and there is a high probability that a hazard will exist.

Critical limits are expressed as absolute values (never a range) and often involve criteria such as temperature and time, pH and acidity, moisture, etc. For example, critical limit for pasteurizing ice cream mixture is 83° C / 30 sec.

<table>
<thead>
<tr>
<th>Process step</th>
<th>Hazard</th>
<th>CCP</th>
<th>Critical limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasteurization of Mixture</td>
<td>Survival of vegetative Pathogens</td>
<td>Yes</td>
<td>83° C / 30 sec</td>
</tr>
<tr>
<td>Metal detecting</td>
<td>Metal not detected</td>
<td>Yes</td>
<td>All product passes through a working metal detector</td>
</tr>
<tr>
<td>Labeling</td>
<td>Allergens not identified</td>
<td>Yes</td>
<td>All product passes through a working bar code scanner</td>
</tr>
</tbody>
</table>

Validating Your Critical Limits

It is impossible to discuss critical limits and CCPs without reference to validation. Validation is mentioned in Codex (2009) as being part of verification (principle 6). However, the team needs to consider validation along the way and in particular as they determine CCPs and define the critical limit.
There are several important tasks to complete before implementing the HACCP plan. Firstly, the HACCP plan elements need to be validated to establish if the control mechanisms you have specified are actually suitable for control of the specific significant hazards that are likely to occur in the process. This is validation, defined by Codex (2009) as “obtaining evidence that the elements of the HACCP plan are effective.” This step is designed to ensure that both the controls will work and that all relevant significant hazards have been identified and addressed. The critical limits can be validated by reference to literature (confirming that, for example, 79.4 °C for 15 seconds is effective to control Salmonella) and also through laboratory collaborative studies and capability studies in the plant. Great care must be taken here, and it is advisable to use a subject matter expert who can determine whether literature information applies to the specific product/process in question at your facility.

In terms of whether your process is capable of operating to the critical limits, it is at this point that many companies will carry out process capability studies as part of their validation procedures.

**Step 9. Establish a Monitoring System for each CCP (Principle 4)**

Monitoring is the measurement or observation at a CCP that the process is operating within the critical limits. This is HACCP principle 4. It is one of the most important parts of the HACCP system once it is implemented, ensuring that the product is manufactured safely from day to day.

**Monitoring**

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (Codex, 2009).

The specific monitoring procedure for each individual CCP will depend on the critical limits, and also on the capabilities of the monitoring device or method. It is essential that the chosen monitoring procedure must be able to detect loss of control at the CCP (i.e., where the CCP has deviated from its critical limits), as it is on the basis of monitoring results that decisions are made and action is taken.

**Monitoring serves three main purposes:**

**First,**

It tells you when there’s a problem at a CCP, and control has been temporarily lost. (This allows you to take corrective actions right away.)

**Second,**

It tracks the system’s operation and can help identify dangerous trends that could lead to a loss of control. (This allows you to take preventive action to bring the process back into control before it goes beyond the critical limits.)
Third,
It provides written documentation of your compliance with the HACCP regulation. (This information can be used to confirm that your HACCP plan is in place and working right.)

**Monitoring Requires Precision**

Monitoring a CCP is a big responsibility. Employees must be properly trained and need to understand the reasons for careful monitoring procedures.

Specify in your monitoring procedures, every important detail about...

- **Who** will do the monitoring
- **What** is being monitored
- **When** it is done, and
- **How** it is done

For example, when taking the temperature of a piece of meat, be specific as to where you took the temperature. Remember that all records and documents associated with a CCP’s monitoring should be dated and signed or initialed by the person doing the monitoring and the results recorded.

For example, monitoring procedure of pasteurization step:

<table>
<thead>
<tr>
<th>CCPs</th>
<th>Hazard</th>
<th>Control measure</th>
<th>Critical limit</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pasteurization</td>
<td>Survival of Vegetative pathogens</td>
<td>Correct heat process, Operational Limit 83°C / 30 seconds</td>
<td>83°C / 30 sec</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Production Operator</td>
<td>Temperature and holding time</td>
<td>Thermometer and calculate time of holding</td>
</tr>
</tbody>
</table>

- **Tools for monitoring**
  - Thermometers: thermocouples, bi-metallic
  - Time temperature logs and other forms
  - Food Flow diagrams
  - Graphs
  - Clocks, timers, clipboards

![THERMOCOUPLES](image-url)
Staff training for monitoring CCPs

- Knowledge of HACCP
- Knowledge of importance of CCPs and monitoring
- Knowledge of monitoring frequency
- Knowledge of target levels/critical limits
- Competency to monitor and record
- Competency to take corrective action

Step 10. Establish Corrective Actions (Principle 5)

Monitoring shows that there is a deviation from a defined critical limit. Corrective actions will deal with the material produced while the process is out of control and will also bring the process back under control.

Corrective action: any action to be taken when the results of monitoring at the CCP indicate a loss of control; Codex [2009].

This is typified by in-line continuous monitoring systems that automatically adjust the process, e.g., automatic divert valves in milk pasteurization that open when the temperature falls below the operational limit, sending milk back to the unpasteurized side.

The best way to handle deviations is to have a plan of action already in place. In general, corrective action plans are used for:
1. Determining the disposition of non-complying product.
2. Correcting the cause of the non-compliance to prevent a recurrence.
3. Demonstrating that the CCP is once again under control (this means examining the process or product again at the CCP and getting results that are within the critical limits).

The factors that are often adjusted to maintain control include temperature and/or time, pH/acidity, ingredient concentrations, and flow rates. Some examples are as follows:
- Continue to cook for longer to achieve the correct center temperature.
- Add more acid to achieve the correct pH.
- Chill rapidly to correct storage temperature.
- Add more salt to the recipe.

Note: When adjusting the process to maintain control, you must ensure that you can do so without causing or increasing the hazard. For example, if the product temperature had risen above 5 °C and you implement rapid chilling to bring it back down, then you must know that the temperature has not risen high enough for long enough to allow the growth of any microbiological hazards that might be present.
Following a deviation, it is important to act quickly. You will need to take two types of action and it is vital that detailed records are kept.

A. Adjust the process to bring it back under control.
This may involve stopping and restarting the line if it is not possible to return the process to its normal operating level during production. Possibly a corrective action will involve the provision of a short-term repair so that production can restart quickly with no more deviations, while the permanent corrective action takes a longer period of time, e.g., the provision of temporary off-line metal detection until the in-line metal detector is repaired.

B. Deal with the material that was produced during the deviation period.
In order to handle non-complying materials effectively you will need to implement a series of further actions:
1. Place all suspect product on hold.
2. Assess the situation, seeking advice from the team, facility management, and other relevant experts. Here it is important to consider the likelihood of the hazard being present in the product.
3. Conduct further tests, where appropriate.

When you have obtained sufficient information, the decision about what should happen to the product can be taken. This would probably be to:
1. Destroy the nonconforming product.
2. Rework into new products.
3. Direct nonconforming product into less sensitive products such as animal feed (with appropriate hazard analysis to determine fitness for purpose).
4. Release product following statistically based sampling and testing.

Example of corrective action procedures:

<table>
<thead>
<tr>
<th>CCPs</th>
<th>Critical limit</th>
<th>Corrective actions</th>
<th>Procedure</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasteurizing</td>
<td>83° C / 30 sec</td>
<td>Report to Manager Contact QA and discuss. Ensure divert working correctly. Repair thermograph Hold product until correct heat</td>
<td>QA and Production Managers, Engineers</td>
<td></td>
</tr>
<tr>
<td>Metal detecting</td>
<td>All product passes through a working metal detector</td>
<td>Repair/recalibrate metal detector. Quarantine and recheck product back to previous good check.</td>
<td>Production Operator QA Supervisor, Engineers</td>
<td></td>
</tr>
</tbody>
</table>
Step 11. Establish Verification Procedures (Principle 6)
What difference between term Validation and Verification?

When you have completed your HACCP control chart and highlighted all CCPs and OPRPs on your Process Flow Diagram then the HACCP plan is complete. You have already validated the critical limits but, before going on to implement the plan it is important to know that it is correct and valid—a final check that you have got it right. This should be carried out soon after the plan is completed so that implementation can follow without delay.

Validation and verification are important elements of HACCP implementation and maintenance, so it is useful to remind ourselves of the definitions of these key terms here (Table 4.7).

Table 4.7. Defining validation and verification (adapted from Wallace et al., 2011)

<table>
<thead>
<tr>
<th>Term</th>
<th>Codex definition (Codex, 2009)</th>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation</td>
<td>Obtaining evidence that the elements of the HACCP plan are effective</td>
<td>• Is the HACCP plan capable of controlling all relevant hazards if correctly implemented? OR • Will it work?</td>
</tr>
<tr>
<td>Verification</td>
<td>The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.</td>
<td>Is there compliance with food safety requirements defined in the HACCP plan OR • Is it working in practice?</td>
</tr>
</tbody>
</table>
The purpose of initial validation of the HACCP plan is to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to validate the HACCP plan often include (1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations. For example, validation of the cooking process for beef patties should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

Subsequent validations are performed and documented by a HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized.

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures.

These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system.

Ongoing verification activities include, but are not limited to:

- The calibration of process-monitoring instruments.
- Direct observations of monitoring activities and corrective actions.
- The review of records.

One aspect of verification is evaluating whether the facility’s HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is resulting in the control of the hazards. If the results of the comprehensive verification identify deficiencies, the HACCP
team modifies the HACCP plan as necessary.

**Step 12. Establish Documentation and Record Keeping (Principle 7)**

It is important to document the HACCP system and to keep adequate records. The HACCP plan will form a key part of the documentation, outlining the CCPs and their management procedures (critical limits, monitoring, and corrective action). It is also necessary to keep documentation describing how the HACCP plan was developed, i.e. the hazard analysis, CCP determination and critical limit identification processes. When the HACCP plan is implemented in the operation, records will be kept on an ongoing basis. **Essential records include:**

- Food flow diagrams
- Recipes
- Time and temperature logs
- Training records
- CCP monitoring records
- Records of corrective actions associated with critical limit deviation.
- Records of modifications to processes and the HACCP plans.

The following table is an example of a HACCP plan summary.
### Table 4.8. HACCP plan summary

<table>
<thead>
<tr>
<th>CCPs Steps</th>
<th>Hazard</th>
<th>Control Measure</th>
<th>Critical limit</th>
<th>Monitoring</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Who</td>
<td>What</td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Survival of vegetative pathogens</td>
<td>Correct heat process, Operational Limit 83 °C/30 seconds</td>
<td>83 °C/30 seconds</td>
<td>Production Operator</td>
<td>Temperature and holding time</td>
</tr>
<tr>
<td>Metal detecting</td>
<td>Metal not detected</td>
<td>Effective metal detection</td>
<td>All product passes through a working metal detector.</td>
<td>Production Operator</td>
<td>Check metal detector is working at start-up and throughout the run</td>
</tr>
<tr>
<td>Labeling</td>
<td>Allergens not identified</td>
<td>Bar code scanner.</td>
<td>All product passes through a working bar code scanner.</td>
<td>Maintenance Operator</td>
<td>Check bar code scanner is working at start-up and throughout the run</td>
</tr>
</tbody>
</table>
The following chart illustrates manufacturing steps of cooked sausage product:

1. **Receive raw meat**
2. **Storage of meat**
3. **Recipe Review**
4. **Preparing meat (Weight / grind meat)**
5. **Weight out Cure Mix/Blend meats, seasonings and nitrates**
6. **Cook/Smoke**
7. **Mix and /or weight out seasonings**
8. **Chill/Storage**
9. **Packaging and labelling**
10. **Metal detecting**
11. **Storage/ Transport**

**Fig. 4.13 Flow diagram of cooked sausage**
## Table 4.9 Hazard Analysis Chart for some process steps

<table>
<thead>
<tr>
<th>Process steps</th>
<th>Hazard and source</th>
<th>Significance</th>
<th>Control measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving meat</td>
<td>B- Pathogens</td>
<td>Y</td>
<td>Cook step will eliminate pathogens. Visual inspection and verify products are received at 5°C or less and/or frozen products received frozen. Certificated supplier (SQA)</td>
</tr>
<tr>
<td></td>
<td><em>E. coli spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Salmonella spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Listeria monocytogenes</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C. None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P. None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receive Non-meat ingredients, packaging material</td>
<td>No hazard identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage of meat</td>
<td>B-Bacteria- Pathogens</td>
<td>Y</td>
<td>Cook step will eliminate pathogens. Perishable products are refrigerated at 4°C or less and frozen products are maintained frozen.</td>
</tr>
<tr>
<td></td>
<td><em>E. coli spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Salmonella spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Listeria monocytogenes</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C - None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P - None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage of Non-meat ingredients, packaging material</td>
<td>No hazard identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparing meat</td>
<td>Bacteria- Pathogens</td>
<td>Y</td>
<td>Cook step will eliminate pathogens.</td>
</tr>
<tr>
<td></td>
<td><em>E. coli spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Salmonella spp.</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Listeria monocytogenes</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C - None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P- Metal</td>
<td>Y</td>
<td>Metal detector</td>
</tr>
<tr>
<td>Weight out Cure Mix/Blend meats, seasonings and nitrates (CCP1)</td>
<td>B - None</td>
<td>Y</td>
<td>Nitrites &lt;156 / &gt;120 PPM is necessary to safely prevent the chemical hazard associated with curing foods. (9 CFR 318.7*).</td>
</tr>
<tr>
<td></td>
<td>C - Nitrites</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P- None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoke/Cook (CCP 2)</td>
<td>B- Pathogens</td>
<td>Y</td>
<td>Cook to proper internal temperature to eliminate pathogens (Minimum of 70°C C / 15 sec for beef.</td>
</tr>
<tr>
<td></td>
<td><em>Listeria monocytogenes</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Salmonella spp</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>E. coli</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C - None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P - None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process steps</td>
<td>Hazard and source</td>
<td>Significance Y/N</td>
<td>Control measure</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Chilling** (CCP3) | **B - Pathogens**
**C. perfringens spores**
**C - None**
**P - None** |                  | **Rapid cooling from 70 °C to 4 °C within 2 hours maximum.**                      |
| **Packaging**   | **P-Hazardous foreign material ingress from environment** | **N**            | **Planned Preventative maintenance. Later metal detector.**                    |
| **Labelling** (CCP4) | **Allergen hazard not identified** | **Y**            | **All ingredients and seasonings need to label**
**Bar code scanner in place**                                           |
| **Metal detecting** (CCP5) | **Metal contamination not identified due to equipment malfunction** | **Y**            | **Effective metal detection—calibrated metal detector suitable for product dimensions. Planned preventative maintance.** |
| **Storage/transport** | **B - Pathogens** | **Yes**          | **SOPs**                                                                      |

*Food Safety and Inspection Serv. (Meat, Poultry), USDA

**SOP- Standard Operation Procedure
<table>
<thead>
<tr>
<th>CCPs Steps</th>
<th>Hazard</th>
<th>Control Measure</th>
<th>Critical limit</th>
<th>Monitoring</th>
<th>Critical limit</th>
<th>Monitoring</th>
<th>Corrective action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weight out Cure Mix/Blend meats, seasonings and nitrates</strong></td>
<td>C-Nitrite</td>
<td>Adjust the ratio to &lt;156 ppm nitrite in final product</td>
<td>&lt;156 ppm nitrite in final product</td>
<td>Trained Staff</td>
<td>Weight of cure added to mixture</td>
<td>Weigh cure out using calibrated digital scale</td>
<td>Each batch</td>
<td>Report to Manager</td>
<td>QA and Production Managers, Review batch report</td>
</tr>
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<tr>
<td><strong>Smoke/Cook</strong></td>
<td>Survival of vegetative pathogens</td>
<td>Correct heat operational limit 70°C / 15 sec for beef.</td>
<td>70°C / 15 sec</td>
<td>Production operator</td>
<td>Internal temperature of largest piece of meat</td>
<td>Calibrated digital thermometer</td>
<td>Each batch</td>
<td>Hold product until correct heat</td>
<td>QA and Production Managers, Review temp record</td>
</tr>
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<tr>
<td><strong>Chilling</strong></td>
<td>Growth of pathogens bacteria</td>
<td>Rapid cooling from 70°C to 4°C within 2 hours</td>
<td>Decrease cooking temperature to 4°C within 2 hours</td>
<td>Production operator</td>
<td>Internal temperature of largest piece of meat</td>
<td>Calibrated digital thermometer</td>
<td>Each batch</td>
<td>Reheat to 70°C and try another method to rapidly cool product or discard batch.</td>
<td>QA and Production Managers, Review temp record</td>
</tr>
</tbody>
</table>

**Note:** CCP 4 and CCP 5 back to table 4.8.
Activity (1): You are auditor

While you are auditing a kitchen for a fast food restaurant, that is preparing an egg burger and sausage meals. Perform the following tasks:

A. Categorize the ingredients of this meal to identify Potentially Hazardous Foods.
B. Numerous sources of cross contamination have been observed. Note some of these sources.
C. Design checklist for auditing / Provide the most important points to be inspected to ensure the safety of final product.

Activity (2): Customer Complaint Letter

Each group will be given a representative consumer complaint letter received by a food processing company. The group must identify if the complaint involves a food quality or food safety problem and respond accordingly. If the complaint involves a food quality problem, the participant should ascertain the cause of the quality defect and identify a possible solution. If the complaint letter describes a food safety problem, the participant should determine whether the problem is biological, chemical or physical in nature and its root causes and identify the control measures.

Examples for customer complaint

1. Hair in ice cream product
2. Dark potato in potato chips
3. Skin rash and itching after eating chocolate with nuts
4. Swollen canned vegetables
5. Yogurt packages with a defect of water layer separation (syneresis)
6. Soft sticky texture of bread
7. Impurities in a bottle of mineralized water
Activity (3): Supermarket

Spend 5 or 10 minutes observing customers at a supermarket display of various food items.

1. Record the location of various food items, time of purchase including your opinion about level of customer’s awareness regarding following the food safety rolls.
2. What is the meaning of “major 4°C areas,” in a supermarket?
3. Design checklist for auditing.

Activity (4): Meat processing

Bacteria, viruses and parasites can pose a serious risk to public health if strict food hygiene procedures are not followed. Well-known examples include illnesses linked to salmonella in poultry; listeria in dairy, meat and fishery products.

1. Visit meat processing plant or store.
2. Spend 30 minutes observing building and personal.
3. Check that proper and effective measures are taken to detect and to control Salmonella and other pathogenic bacteria at all relevant stages of the processing chain.
4. Check if they apply prerequisite programmes.
5. Write a short report on which steps recognize as critical control point and which are not.

Activity (5): Inspection of storage area

When you inspect a cheese factory store, write a short report that includes the following points:

1. Record your feedback on ventilation
2. Temperature and humidity are controlled - what to check?
3. Explain stock rotation
4. Found during inspection of some rat droppings - What are the root causes and what are the preventive measures to be followed?
5. How to check the cleaning and sanitation program?
Activity (6): Comment on these photos:

1. 
2. 
3. 
4. 
5. 
6.
Activity (7): As a member of the HACCP team at a pasteurized milk production plant. Flow diagram of steps as follow:

1. Receiving of milk
2. Filtration
3. Pasteurization (72°C/ 15 sec)
4. Cold Storage (4°C)
5. Packaging
6. Metal detecting
7. Homogenization
8. Storage in silo tanks (4°C)
9. Distribution

A. Identify which are steps CCPs?
B. Describe the hazard analysis table
C. Create HACCP plan summary

Activity (8): Supplier control

You are the person responsible for auditing and approving suppliers in a factory producing ice cream with nuts.

A. Explain the most important criteria for the receipt of raw materials in terms of quality and safety.
B. Create the hazard analysis table for all incoming materials
C. What are the most important tests that must be included in the certificate of analysis?

Activity (9): Catering supervisor

You are assigned to supervise the preparation of salmon broccoli casserole meal. Preparation is for 100 persons (the general public) attending a banquet.

**Ingredients:** Onions / Cooking oil / cans of mushroom / broccoli / rice / cans of salmon / eggs / cream sauce / cheddar cheese / milk.
A. What ingredients are known PHF

B. Processing steps as follows:

1. Receive ingredients
2. Store ingredients
3. Prepare ingredients
4. Cook onions and mushrooms
5. Combine other ingredients and mix
6. final cooking
7. Cool casserole
8. Store in cooler
9. Reheat casserole in oven
10. Hold casserole hot on steam table
11. Serve

C. Complete the table

<table>
<thead>
<tr>
<th>Process step</th>
<th>Potential Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare ingredients</td>
<td>Contamination from people, raw foods, environment, utensils, equipment, wastewater, chemicals and foreign objects. Growth of bacteria during prep.</td>
</tr>
<tr>
<td>Cook mushrooms and onions</td>
<td></td>
</tr>
<tr>
<td>Combine and mix ingredients</td>
<td></td>
</tr>
<tr>
<td>Final cooking</td>
<td>Survival of Salmonella in eggs, other bacteria from pre-prepared rice and cream sauce handling. Survival of spores; survival of toxins. Contamination by chemicals. Contamination by foreign objects.</td>
</tr>
<tr>
<td>Cool</td>
<td></td>
</tr>
<tr>
<td>Cold storage</td>
<td></td>
</tr>
<tr>
<td>Reheat</td>
<td></td>
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<tr>
<td>Hold</td>
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</tbody>
</table>

D. In your view, any of the above steps is a critical control point?

E. Create HACCP plan summary
References and Recommended Reading


