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सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
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FICSI
Food Industry Capacity and Skill Initiative

Participant Handbook

Sector
Food Processing

Sub-Sector
Food Processing

Occupation
Quality Analysis

Reference ID: **FIC/Q7603, Version 3.0**
NSQF level: 6

Food Microbiologist

Published by

First Edition, Jan 2020

Printed in India at

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This book is sponsored by FICSI - Food Industry Capacity and Skill Initiative

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Disclaimer

> Skilling is building a better India. If we have to move India towards development then Skill Development should be our mission.

Shri Narendra Modi
Prime Minister of India

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Certificate

COMPLIANCE TO QUALIFICATION PACK – NATIONAL OCCUPATIONAL STANDARDS

is hereby issued by the

FOOD INDUSTRY CAPACITY AND SKILL INITIATIVE SECTOR SKILL COUNCIL

for

SKILLING CONTENT - PARTICIPANT HANDBOOK

Complying to National Occupational Standards of

Job Role/ Qualification Pack: **'Food Microbiologist'** QP No. **'FIC/Q7603, NSQF Level 6'**

Date of Issuance: December 30th, 2021

Valid up to: December 30th, 2024

**Valid up to the next review date of the Qualification Pack or the 'Valid up to' date mentioned above (whichever is earlier)*

Authorised Signatory
(Food Industry Capacity and Skill Initiative Sector SkillCouncil)

Acknowledgements

FICSI is thankful to all organizations and individuals who have helped us in preparation of this practical guide.

We extend our special thanks to Ministry of Food Processing Industries (MoFPI) for providing their unequivocal support for developing and reviewing the content through National Institute of Food Technology Entrepreneurship and Management (NIFTEM).

We also wish to extend our gratitude to all authors who reviewed the content and provided valuable inputs for improving the quality, coherence, and content presentation in chapters.

The preparation of this participant Handbook would not have been possible without the support of the Food Processing Industries. The Industry feedback has been extremely encouraging from inception to conclusion & it is with their inputs that we have tried to bridge the skill gaps existing today in the Industry.

This participant handbook is dedicated to all the aspiring youth who desire to achieve special skills which would be a lifelong asset for their future endeavors and help them make a bright career in the Food Processing Sector.

About this book

This Participant Handbook is designed to enable training for the specific Qualification Pack(QP). Each National Occupational Standards(NOS) is covered across Unit/s.

Key Learning Objectives for the specific NOS mark the beginning of the Unit/s for that NOS. The symbols used in this book are described below.

This reference book has been developed for use Participant Handbook of the skill development course for a Food Microbiologist being implemented by FICSI through its affiliated training service providers. The contents of this book are completely aligned to the Qualification Pack for the role of a Packing Machine Worker-Food Processing NSQF level 6 and has been divided into Units corresponding to each NOS (national Occupational Standard). The contents of the book have been developed by NIFTEM (National Institute of Food Technology, Entrepreneurship and management, Kundli with support of MOFPI, Government of India).

Symbols Used


Key Learning Outcomes


Unit Objectives


Exercise


Tips


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Activity


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1. Introduction to Training Programme and Overview of Food Processing Industry

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Key Learning Outcomes

At the end of this module, you will be able to:

1. Identify each other and build rapport with fellow participants and the trainer.
2. Describe the roles and responsibilities of food microbiologist.
3. Illustrate the food processing industry.
4. Identify and enumerate the sub-sectors.

UNIT 1.1: Introduction to the Training Program

Unit Objectives

At the end of this unit, you will be able to:

1. Outline the purpose and benefits of the program.
2. Identify the components of the skill card.
3. Discuss the outcomes of the program.

1.1.1 Training Program Outline

This training program is developed to impart specific knowledge and skills relevant to job role required to perform as a "Food Microbiologist", in the "Food Processing" Sector/Industry. The training program of Food Microbiologist processing is based on the Qualification Pack (QP) code FIC/Q7603. A QP consists of a set of National Occupational Standards (NOS). A NOS specifies a standard competency that an incumbent must possess while performing job duties. The following six NOS which are compulsory to QP Food Microbiologist are mentioned below:

1. FIC/N7609 Prepare and maintain work area and lab equipment
2. FIC/N7610 Carry out microbiological analysis of food products
3. FIC/N7611 Monitor food safety system
4. FIC/N7612 Complete documentation and record keeping related to microbiological analysis of food products
5. FIC/N9001 Ensure food safety, hygiene and sanitation for processing food products
6. FIC/N9004 Manage and lead a team

Occupational Standards are the set of competencies that an incumbent must be able to fulfill while at the workplace. On the other hand, knowledge elements consist of organizational and technical knowledge necessary to perform the desired set of competencies. Occupational Standards can be categorized into National and Global Occupational Standards. After successful completion of training and passing the assessment, participant will be issued a skill card (Figure 1.1.1)

Fig. 1.1.1: Skill Card

Skill Card is issued to Certified Trainers and Assessors, displays the following:

- Name
- Unique ID

- Certification Grade
- Validity of the Certification

The skill cards are awarded to the training beneficiaries after their successful completion of the training Programme. Skill Cards consists of quick response (QR) code. The purpose of the QR code is to make the employer understand the kind of skill training the person or the trainee has undergone. Not only employer, the skill card is beneficial for a trained job seeker too as the process of recruitment becomes hassle free and he/she will not have to carry bundles of certificates to apply for vacant positions. The card can also be converted into a smart card, with an embedded chip in the future.

1.1.2 Training Outcomes

After completing this program, participants will be able to:

1. Prepare and maintain work area and machineries
2. Carry out food microbiological analysis
3. Document and maintain records relate to food microbiology
4. Monitor food safety and hygiene system.
5. Manage and lead a team

The training on the Qualification Pack "Food microbiologist" will provide knowledge to the beneficiary on the science of microbiology which is the study of the occurrence, significance, analysis and several diseases caused by various microorganisms such as bacteria, fungi, protozoa and algae. These microbes are omnipresent and form part of food chain as well. In most cases the presence of these microbes in the food poses no adverse consequences. However, there are certain food borne illness which can occur due to consumption of contaminated food with pathogenic microorganisms like Clostridium perfringens and Bacillus cereus.

Fig. 1.1.2: Tomato Spoilage due to Clostridum spp.

Micro-organisms present in food can affect in one of several ways:

- They can cause spoilage;
- They can cause food borne illness;
- They can also enhance the nutritional properties of food in a beneficial way, such as the food fermentation.

Fig. 1.1.3: Effects of micro-organisms

In this training program trainer will cover the aspects of food Microbiology, explain the role of food microbiologist and current food safety system, food hygiene and sanitation, and demonstrate the specific microbial tests as per guidelines which will ultimately lead to safe food consumption.

The following table provides the modules to be discussed and their corresponding duration.

Module	Module No.	Theory Duration (hrs.: min)	Practical Duration (hrs.: min)
Introduction to the Training Program	1	1.00	0.00
Organizational Standards and Norms	2	4.00	2.00
Introduction to Food Microbiology	3	1.00	1.00
Prepare and Maintain Work Area and Lab Equipment	4	14.00	12.00
Microbiological Analysis	5	15.00	52.00
Monitoring of Food Safety System	6	10.00	17.00
Documentation and Record Keeping of Microbiological Analyses	7	4.00	14.00
Food Safety, Hygiene and Sanitation	8	8.00	22.00
Manage and lead a team	9	13.00	10.00
Professional and core skills	10	8.00	13.00
IT Orientation	11	10.00	10.00
Total		**88**	**152**

Table 1.1.1: Overview of Training Program

1.1.3 Program Overview

The Training Programme is based on the Qualification Pack (FIC/Q7603). It consists of eleven modules whose description is mentioned in the following pages.

In **Module-1** "Introduction to the Training Program" trainer will first Introduce trainees to each other and build rapport with fellow participants followed by providing overview to the training program; let understand the roles and responsibilities of food microbiologist; let understand the food processing sector and paraphrase the various sub sectors of food processing industry.

In **Module-2** "Organizational Standards and Norms" trainer will cover aspects like how to conduct oneself at the workplace; personal hygiene and sanitation guidelines and food safety hygiene standards to follow in a work environment.

In **Module-3** "Introduction to Food Microbiology" trainer will cover topics like listing the types of food microbes; causes of food spoilage; process of food spoilage and the criteria to check food spoilage.

In **Module-4** "Prepare and Maintain Work Area and Lab Equipment" trainer will cover the points like cleaning laminar air flow cabinet or lab bench using approved disinfectants and sanitizers; ensuring that the hygiene is maintained to keep it free from microbes to carry out microbiological analysis; destruction of microbes from used culture media following Standard Operating Procedure (SOP) and cleaning of equipment and glass wares.

In **Module-5** "Microbiological Analysis" trainer will cover aspects like weighing required chemicals, solvents in calibrated instruments, prepare liquid and solid culture media (nutrient broth and nutrient agar) following SOP; transferring prepared broth, culture media, solvent etc. in glass wares, plug with cotton plug, wrap with paper and prepare for sterilization using autoclave; sterilized items from autoclave and transfer to sterile area, cool and store at suitable temperature following SOP; preparing of solid culture media such as slopes/slants, plates from nutrient agar in sterile area; sampling requirement and procedure following SOP; taking swab test samples from employees' hand and cloth for evaluating personnel hygiene, on equipment and machineries in the production line, in the premises for evaluating sanitation and collect air samples and its labelling procedures following SOP; prepare the work space (Laminar Air Flow Cabinet) or lab bench by wiping with disinfectant, clean glass ware, tools and equipment dilute samples following SOP; compiling of results of microbiological tests and prepare microbiological data; analyzing microbiological data and compare with food safety standards of the organization, national and international regulations; implications of test results with respect to food safety standards and draw conclusions; inoculating samples aseptically in labelled liquid and solid culture media (through suitable techniques such as broth inoculation, pour plate, direct plating, streak plate, spread plate, membrane filtration, etc.), as applicable, following SOP; adjusting controls of all equipment; carrying out serial dilution of sample in sterile media and plating them in sterile condition for counting microbes, following SOP; counting the micro- organisms and colonies under the microscope and record counts; test to identify the type and characteristics of microbes from the colonies of microbes grown in the Petri plates plated through serial dilution; preserving of pure culture through refrigeration, paraffin method, freeze drying etc., maintaining the parameters like temperature, anaerobic condition, pressure etc., following SOP; compiling the results of microbiological tests and prepare microbiological data; analyzing of microbiological data and compare with food safety standards of the organization, national and international regulations

In **Module-6** "Monitoring of Food Safety System" trainer will cover the topics like maintaining the workplace in a clean and tidy order to meet workplace standards and waste disposal following industry standards; corrective action; carrying out internal audit on housekeeping to ensure safety and hygiene system are in place; food safety requirements in the food products production process based on microbial analysis results of production line, premises and food product; microbiological hazards in production process, and its critical control point to minimize or prevent those hazards; taking swab sample of work area, materials, equipment, products and personnel routinely for microbiological analysis and discussing of reports; procedures after audit like different findings, reanalyzing the preventive measures based on the audit findings, and arriving at additional preventive controls to address the hazards identified; monitoring premises of the food processing unit, processing machineries, drainage system to ensure it meets food hygiene standards of the processing unit; monitoring storage area for raw materials, packaging materials, finished goods to ensure quality standards are met and food products are fit for human consumption; monitoring of personnel hygiene and health condition of employees and PPE; and hygiene system of the organization.

In **Module-7** "Documentation and Record Keeping of Microbiological Analyses" trainer will cover the entire documentation system followed in the organization; the need for documenting and recording of purchase of: raw materials and packaging materials and machineries; and the method of documenting and recording the details of materials to final purchase to inventory management

In **Module-8** "Food Safety, Hygiene and Sanitation" trainer will cover the importance of safety, hygiene and sanitation in the food processing industry; industry standards to sustain a safe and hygiene workplace; Hazard Analysis and Critical Control Point (HACCP) principles to eliminate food safety hazards in the process and products and safety practices in the work area

The generic modules at number 09, 10 and 11 will majorly focus on the training of managing team; enhancing professional skills and IT skills.

By the end of this course, it is expected that each of the participants will be metamorphosed into an excellent Food Microbiologist. Happy learning!

UNIT 1.2: Role and Responsibilities of a Food Microbiologist

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the duties and profile of food microbiologist.
2. Describe the roles and responsibilities of a food microbiologist.
3. List the educational requirements, desired skills and competencies required for a food microbiologist.

1.2.1 Job Duties

Introduction

The importance of microbiology professionals for the food industry can be judged from the need to avoid food spoilage, ensuring the shelf life of raw materials and food safety, to standardize the microbial processes for foods (fermented foods), formulate new products. One of the main hurdles the Indian food industry may face is the availability of skilled man power. There is huge requirement of microbiology professionals to work in this industry. There are too many graduates and post graduates, who are not knowledgeable adequately to be able to perform a microbiologist's job properly.

Many developments and innovations have taken place in the food industry that requires well trained manpower including microbiologists. With the integrated food laws being promulgated in India under the Food Safety and Standard Act 2006, Indian food industry needs to make a note of the importance of microbiologists and hire them in key positions to ensure food safety and to meet the requirements of act.

A food microbiologist determines food safety through research, analysis and experimentation. The primary duties of a food microbiologist are to ensure that food safety and quality is maintained in the food laboratory or in quality control department of the company with adherence to FSSAI guidelines and international standard bodies. Food microbiologists play very important role and study presence of micro-organisms in food and are mainly concerned with the prevention of diseases born from food. Their main aim is to conduct research on food poisoning, spoilage, and safety, as well as providing their inputs in developing and implementing food regulations. Food microbiologists investigate food samples, checking them for Salmonella, Listeria, and other pathogenic microorganisms that cause food borne illness. The main role of food microbiologist is to conduct test of samples in the company producing food products and check the levels of microbes as per FSSAI standards. The main goal is to ensure safe and wholesome food through conduction of microbiological tests.

Fig. 1.2.1: A Food microbiologist at work

Food microbiologists working in the food production industry consider the factors of food storage that affects the processing and packaging of food products. They introduce measures to ensure food producers comply with government regulations on food health. Those employed as researchers in a laboratory, or as educators also work to raise public awareness of disease prevention. In broader view, a food microbiologist is supposed to:

- Develop new food products;
- Process design for the production of foods, packaging materials;
- Determine shelf life and
- Perform microbiological and chemical testing.

Fig. 1.2.2: A food microbiologist can work in food analysis laboratory or in food industry

A food microbiologist may function in various industries and in different environments. These include government and private laboratories, manufacturing units. List of the major food plants employing microbiologists are mentioned in Table No. 1.2.1

Company	Major Activity
Al Kabeer	Meat products
Hindustan Lever Ltd.	Health foods
Britannia	Biscuits, bakery products
ITC foods division	Packed foods
Balaji Foods & Feeds Ltd	Egg products
Ovobel Foods	Egg products
MTR Foods	Ready–to-eat & Ready-to-use foods
Eureka Forbes	Water purification systems
Parry's	Spirulina, sugar, specialized food products
Nutrine	Confectionery
Biocon	Food enzymes
Amul	Dairy products
Nestle	Health beverages
Mother Dairy	Dairy products
Godrej Foods	Fruit juices
United Breweries	Alcoholic beverages

Table 1.2.1: List of major food plants employing microbiologists

Food Microbiologist are responsible for knowing the most current methods of microbiological analysis ensuring their company complies with those standards.

In India, the profile of a Food Microbiologist includes, but not limited to:

- Proper understanding of Regulations linked to Food Safety and Standards Authority of India (FSSAI), Codex, United States Food and Drug Administration (USFDA), Flavor Extract Manufacturers Association (FEMA), Generally Recognized as Safe (GRAS) Substances, European Food Safety Authority (EFSA), Product Approval and Registrations, Food claims, Labeling, Nutrient profile, Food additives, Food safety and Import-export norms etc.;
- Performance-driven and Result-oriented;
- Well-developed Leadership qualities and proactive in taking initiatives;
- Ability to provide training to associates based on a good practical background;
- Aspiring, responsible, committed and adaptable;
- Strong ability to excel in a project team environment;
- Exceptional ability to organize and prioritize multiple projects;
- Good Communication & Interpersonal skills.

1.2.2 Role & Responsibilities

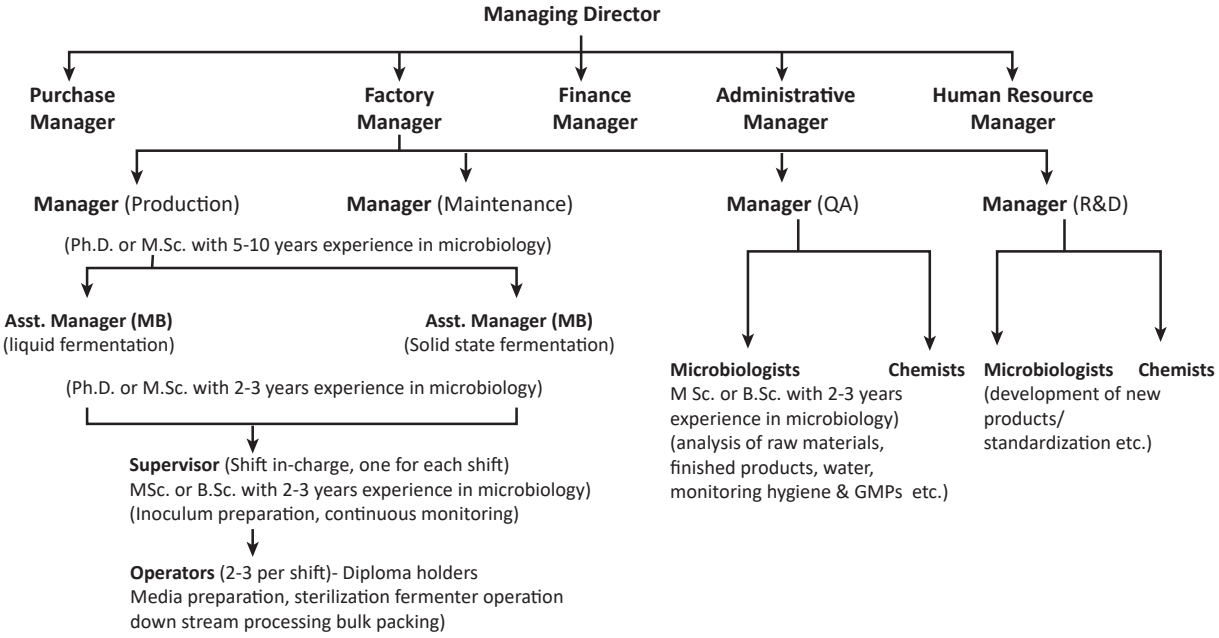
Food industry appoints microbiologists at various levels depending on the development stage of the industry. In general, fresh graduates or post graduate microbiologists are appointed either in quality assurance labs for analysis purpose or in production department depending on the type of foods being manufactured in the factory. Persons with doctoral degree in microbiology are taken at higher levels as assistant manager or manager based on the experience and they are accountable for complete monitoring of the food factory for implementation of hygiene and sanitation and for the production of microbiologically safe food products. They have a major role in execution the food safety systems like Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP) and HACCP, a comprehensive and science-based alternative for controlling food safety hazards. The microbiologists in R&D units are responsible for screening the cultures for better yields, manipulating the cultures using state-of-art molecular biological techniques, working on product economics, formulation of new products etc. Microbiologists also find appointments in production departments of various food industry where microbial enzymes are produced either by routine liquid fermentations or by solid state fermentation, in large scale mushroom producing plants, in production of food additive like microbial colors and polysaccharides, in alcoholic beverage industry etc.

A microbiologist in a fermentation-based industry, appointed as production and process manager, may have to integrate his microbiology knowledge with various other fields. Their major responsibilities may include production technologies; machinery required and used; implementation of food safety systems (GMP, GHP and HACCP); avoiding food safety hazards; knowledge on new products and processes; competitive technologies and their feasibility; regional resources; product economics and so on[1].

A microbiologist working in alcoholic industry or any fermentation-based food industry should be well experienced with maintenance of microbial cultures, fermenters and microbial growth, culture purity, starter characteristics, maintenance of constant performance of fermentation process, yields and their quality, microbial pathogens, biofilm formation and its control in water distribution systems, downstream process, using statistical models, computer-controlled technologies and so on . Hierarchical chart of various positions in a typical fermentation-based food plant is represented in figure 1.2.3.

[1] Vijayendra S.V.N. and Narasimha Rao P.R. (2012). Preparing Microbiology Professionals for Food Industries. Indian Food Industry. (https://www.researchgate.net/publication/216686557_Preparing_Microbiology_Professionals_for_Food_Industries)

However, depending on the type of food industry, microbiologist's job profile may differ to some extent. While a microbiologist working in canning industry may need to be well versed with thermal processing and its effect on microbial quality of foods, skills related to genetic manipulation of the microbial strains may have to be mastered by the microbiologists working in industry dealing with microbial enzymes or microbial mutants for novel products.



QA: Quality Assurance**, R&D: Research and development; MB: Microbiology**

Fig. 1.2.3 Hierarchical chart of various positions in a typical fermentation-based food plant

The job profile of microbiologists varies with the type of food industry where they get placement. The basic requirement for microbiologists is to check the microbial quality of the incoming raw materials, monitoring the in-process products and analyzing the finished products. This includes testing the products for total plate counts, yeasts & mold count, coliforms and for specific pathogens like Salmonella, Shigella, Listeria monocytogenes, Staphylococcus aureus, Campylobacter, Yersenia sp., Pseudomonas sp., E. coli, Bacillus cereus etc., based on the specifications of the given food product.

In addition to the analysis, they have to monitor the cleaning and sanitization of process equipment, food handlers' hygiene and microbial load in process area. It is the major responsibility of microbiologists to see that the products are prepared under strict hygienic conditions and the finished products leaving the factory are safe for consumption. Besides this, they also monitor the microbial quality of the process water at various locations such as water treatment plants, water distribution system in food industry. Preventing bio-film formation in water distribution system is essential to prevent contamination of the products through water. They should be aware of microbial specifications for various food products. Guiding the sanitarian for better maintain the process equipment's also becomes a part of microbiologist's role. In broader terms, all these job functions may be categorized into basic knowledge in microbiology, technical skills and industry related skills.

1.2.3 Required Education

A minimum of a bachelor's degree in food science, biology, microbiology, life sciences is required to take up this course 2-3 years of experience in a food processing unit handling microbiological analysis of food products would be preferable. The students may have 'core knowledge' in microbiology with high level integrative content of various related disciplines including chemistry, production engineering, genetics, biochemistry, molecular biology, immunology, pathology, marketing, ethics and law[2].

1.2.4 Required Skills

Food microbiologist requires main subject core skills as well as there is a need to integrate subject knowledge with non-subject based skills. These include general skills such as responsibility, hardworking, sound judgment, leadership, managing relationships and the like may be termed as non-subject based industry skills. General skills like basic math, communication, critical thinking, prioritizing tasks, problem solving, team work, organization skills etc.; industry related skills like microbe handling, aseptic technique, identifying irregular results, instrumentation, basic laboratory procedures, maintaining records, logs, protocols, troubleshooting ability etc.; attributes like willingness to ask for help, willingness to work around hazardous chemicals, tactfulness, thoroughness, working with many different people, scientific curiosity, safety consciousness, responsibility, reliability etc. are required.

1.2.5 Desired Competencies

In order to prepare graduates for the role of food it is necessary to instill competencies which can make them think like a professional. A professional can be defined as one who can recognize and adopt meaningful patterns to organize knowledge as per the context or requirement to retrieve and access appropriate information and use it in a flexible way. Further, Graduates coming out of universities and entering food industry require integration of science content as against the practice of focusing on a single sub discipline throughout their studies. They also need knowledge of the ethical, economic, and legal frame work in which the industry work. The eight competencies that are essential are:

1. competence in foresighted thinking;
2. competency in interdisciplinary work;
3. competency in cosmopolitan perception,
4. trans-cultural understanding and co-operation;
5. participatory skills;
6. competency in planning and implementation;
7. capacity for empathy, compassion and solidarity;
8. Competency in self-motivation and motivating others.

OECD's (Organization for Economic Co-operation and Development) list of competencies required for developing well-functioning organization (Table- 1.2.2) is a detailed account which may be of immense help in preparing the students professionally.

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[2] Vijayendra S.V.N. and Narasimha Rao P.R. (2012). Preparing Microbiology Professionals for Food Industries. Indian Food Industry. (https://www.researchgate.net/publication/216686557_Preparing_Microbiology_Professionals_for_Food_Industries)

[2] OECD (2005): Definition and selection of key competencies (DeSeCo). Project-executive summary of organization for economic co-operation and development.
(www.oecd.org/dataoecd/47/61/35070367.pdf)

Key Competencies are employed in different combinations in varying contexts

Competency Category 1: **Using Tools Interactively** (Cognitive, Socio-cultural and Physical tools)

Using tools interactively opens up new possibilities in the way individuals perceive and relate to the world

- **The ability to use language, symbols and text interactively – Communication competency**
  - Spoken & Written language skills
  - Computation and mathematical skills
- **The ability to use knowledge and information interactively – Information competency**
  - Recognise and determine what is not known
  - Identify, locate and access appropriate information sources
  - Evaluate the quality, appropriateness and value of information
  - Critical reflection on the nature of information – its technical infrastructure
  - Critical reflection on the nature of information – its social, cultural and ideological
  - context & impact
  - Organise knowledge and information
- **The ability to use technology interactively – Technological competency**
  - Awareness of new ways of technologies use in daily lives
  - Critical reflection on the nature of technology and its potential
  - Relate the possibilities embedded in technological tools to individuals own circumstances
  - and goals
  - Incorporate technologies into their common practices

Competency Category 2: **Interacting in Heterogeneous groups** (Social Capital)

One of the potential sources of inequity in the future could be differences in the competence of various groups to build and benefit from social capital (social competencies, social skills, intercultural competencies, soft skills

- **The ability to relate well to others**
  - Emotional intelligence and effective management of emotions
  - Respect and appreciate the values, beliefs, cultures and histories of others
  - Empathy – taking the role of another person
- **The ability to cooperate**
  - Work in teams and balance between commitment to the group and his or her own
  - priorities
  - The ability to present ideas and listen to those of others
  - The ability to construct tactical or sustainable alliances
  - The ability to negotiate
  - An understanding of the dynamics of debate and following an agenda
  - The capacity to make decisions that allow for different shades of opinion
- **The ability to manage and resolve conflicts**
  - Analyse the issues and interests at stake (e.g., power, recognitions of merit, division of
  - work, equity)
  - Identify areas of agreement and disagreement

○ Reframe the problem ○ Prioritize needs and goals
○ Competency Category 3: **Acting Autonomously**
Acting autonomously does not mean functioning in social isolation. On the contrary, it requires an awareness of one's environment, of social dynamics and of the roles one plays and wants to play. • **The ability to act within the big picture** ○ Understand patterns ○ Understand and consider wider context of one's actions and decisions ○ Understand the system in which they exist and its norms, values and social and economic institutions ○ Identify the direct and indirect consequences of their actions • **The ability to form and conduct life plans and personal projects** ○ Concept of project management to individuals ○ Define a project and set a goal ○ Identify and evaluate the resources they have access and they need (e.g., Time, money) ○ Prioritize and refine goals ○ Balance the resources needed to meet multiple goals ○ Learn from past action, projecting future outcomes ○ Monitor progress, making necessary adjustments as a project unfolds. • **The ability to assert rights, interests, limits and needs** ○ Understand one's own interests ○ Knowledge of written rules and principles on which to base a case ○ Construct arguments in order to have needs and rights recognized ○ Suggest arrangements or alternative solutions

Table 1.2.2: Competencies Required for Well-functioning Organization with applicability to the role of food microbiologist (Source: Narasimha Rao & Nair[4] , 2010)

[4] Narasimha Rao, B.P.R. and P.R.R. Nair (2010). Universities and corporate education, 21st century social responsibility of developing countries. SRRNet, Discussion papers in social responsibility, No.1002 (http://www.socialresponsibility.biz)

UNIT 1.3: Overview to the Food Processing Industry

Unit Objectives

At the end of this unit, you will be able to:

1. Describe the status of food processing industry in India as well as globally.
2. Discuss the SWOT analysis for food sector.

1.3.1 Food Processing Sector

Introduction

Agriculture accounts for about 1/4th of the Indian economy but employs about 2/3rd of its population. India has about 161 million hectares of arable land of which 55 million is irrigated. Considering these factors, it is clear that there is immense potential for the agriculture sector, and therefore the food sector. Food processing enhances shelf life and adds value even if agricultural produce is merely cleaned, sorted, and packaged. Further processing into high value-added products garners greater revenue for the producer. Food Processing is also employment intensive in that for every Rs. 1 million invested, 1.8 jobs and 6.4 indirect jobs are created[5].

The Processed Food Industry is divided into the following broad segments:

- Primary Processed Food – which includes products such as fruits and vegetables, packed milk, unbranded edible oil, milled rice, flour, tea, coffee, pulses, spices, and salt, sold in packed or non-packed forms.
- Value-added Processed Food – which includes products such as processed fruits and vegetables, juices, jams, pickles, squashes, concentrate, processed dairy products (ghee, paneer, cheese, butter), processed poultry, processed marine products, confectionary, chocolates, alcoholic beverages.

Fig. 1.3.1: A food processing unit

[5] NSDC Skill Gap Report Study. "Human Resource and Skill Requirements in the Food Processing Sector till 2022". Report Prepared by ICRA.

1. **Global Scenario:** The Global Processed Food Industry is valued at US $ 3.2 trillion and accounts for over 3/4th of global food sales. Despite the large size of the industry, only 6% of the processed food is traded around the world over as compared to bulk agricultural commodities where 16% of produce is traded. The USA is the single largest consumer of processed food and accounts for 31% of the global sales. This is because as countries develop, high quality and value-added processed food such as convenience food is preferred over staples, which are prevalent in less developed economies. Share of India in global food processed trade is only 1.6%.

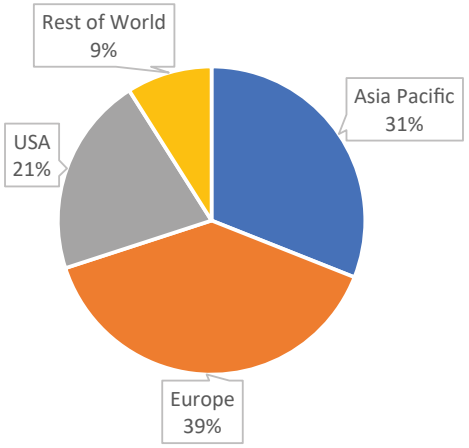


Fig. 1.3.2: Major Markets for sale of processed food (Source: FICCI Knowledge Paper)

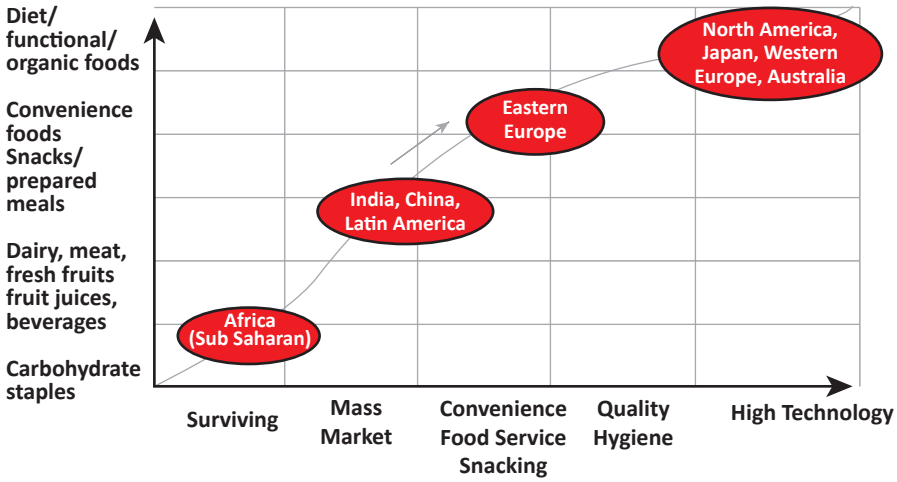


Fig. 1.3.3: Evolution of global food demand

2. **The Indian Scenario:** Food processing industry plays a very important role in the Indian economy. The Food Processing Industry (FPI) is one of India's largest industries with fifth position in terms of production, consumption, and exports. India is the second-largest food producer worldwide next to China. India has a production advantage in many agricultural products, with diverse agro-climatic conditions, with the ability to cultivate a wide range of agricultural raw materials needed by the food processing industry. The total food production in India is likely to double in the next ten years and there is a chance for large-scale investment in food processing, especially in canning, dairy processing, specialty processing, packaging, and frozen food. Major highlights of Indian food industry are depicted in the figure 1.3.4.

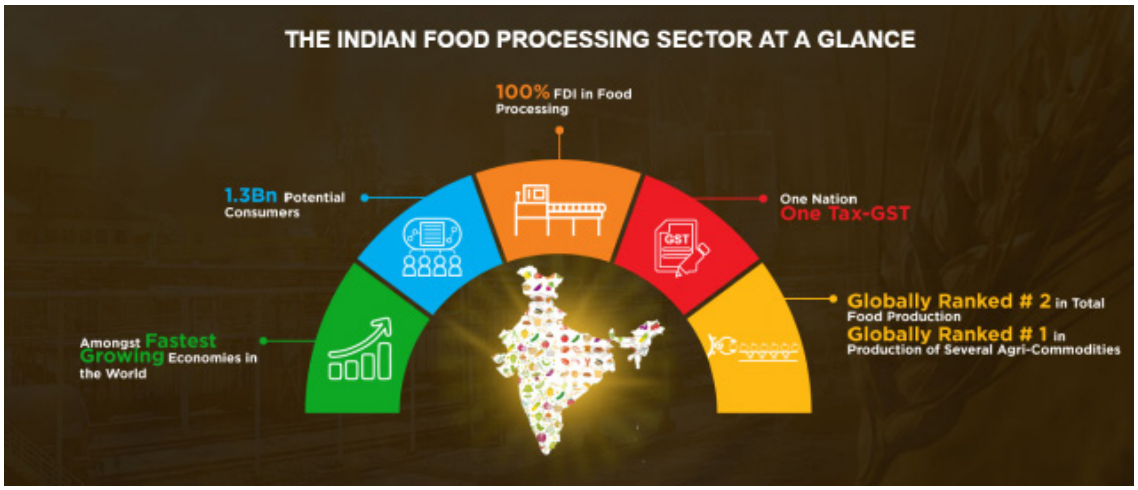


Fig. 1.3.4: A glance of the food processing industry in India (Source: MOFPI Investor Portal)

- **Food Industry Size-Key Highlights**

  Food Industry comprises various segments Fruits and Vegetables, Dairy, Edible Oils, Meat and Poultry, Non-alcoholic beverages, Grain-based products, Marine products, Sugar and sugar-based products, Alcoholic beverages, Pulses, Aerated beverages, Malted beverages, Spices, and Salt.

  Out of these segments, Dairy (16%), Grain-based Products (34%), Baker-based products (20%), and fish and meat products (14%) contribute to a major portion of industry revenues, apart from the manufacture of beverages.

  Importance of food industry can be assessed by looking at the figures mentioned below[6]:

  - The size of India's Food Processing Industry in 2008 was over Rs. 3,600 billion (US $ 72 billion)[7]. The overall consumption in food, as measured by PFCE, is about Rs. 19,000 billion (US $ 220 billion). The PFCE on food has registered a Compounded Annual Growth Rate (CAGR) of 9.8% between 2003 and 2008.
  - India is the second-largest producer of fruits and vegetables in the world, accounting for about 10 percent of the global production.
  - India ranks first in the world in production of milk. Milk and milk products account for a significant 17 percent of India's total expenditure on food.
  - The 'meat and marine products' market share is expected to increase from INR 25,200 crores in 2012 to INR 56,500 crores by 2017, witnessing a CAGR of 17 percent.
  - The Indian packaged food market, including confectionary, dairy, baked goods, sauces and household staples, such as packaged rice, was worth INR 1 lakh crores at the end of 2011.

  In spite of attractive key trends of the Indian food industry, the level of processing in India is low compared to international levels. Processing of agriculture produce is around 40% in China, 30% in Thailand, 70% in Brazil, 78% in the Philippines and 80% in Malaysia. The different levels of processing in key sub-sectors of food processing are depicted in figure 1.3.5. The highest level of processing is in milk and dairy sector and least is in fruits and vegetables sector, where as the major states in India where Food Processing is carried out are Andhra Pradesh (13.4% of

[6] NSDC Skill Gap Report Study. "Human Resource and Skill Requirements in the Food Processing Sector till 2022". Report Prepared by ICRA.

[7] NSDC Skill Gap Report on "Human Resource and Skill Requirements in the Food Processing Sector (2013-2017) (2017-2022)" Vol 10. Report prepared by KPMG advisory services Pvt. Ltd.

India's Food Processing industry, and a centre for fruits, vegetables, and grains), Gujarat (12.7%, and a centre for edible oils and Dairy), Maharashtra (14%, and a centre for fruit, vegetables, grains, and beverages), and Uttar Pradesh (12%, across almost all product categories).

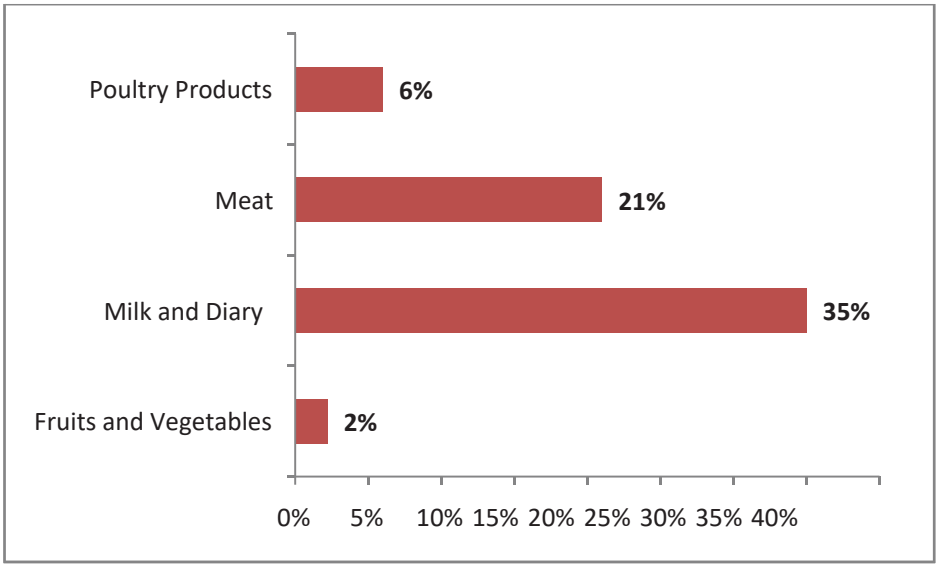


Fig. 1.3.5: Level of processing in India in select segments (Source: MOFPI and IMaCS analysis)

Indian agriculture and food processing sector have lot of potential to capture the opportunities present domestically as well as internationally. Learning about the strength, weakness, opportunities and threats of the sector will provide a clear picture of our food processing industry. Therefore, SWOT analysis is depicted in the next section in detail.

1.3.2 SWOT Analysis

Understanding of SWOT analysis of Indian Food Processing Sector is essential to understand the strengths, weaknesses, opportunities and threats prevailing in the sector. India is one of the world's largest producers as well as consumer of food products, with the sector playing an important job in contributing to the development of the economy. Food processing industry in India is increasingly seen as a budding source for driving the rural economy as it brings about synergy between the consumer, industry and agriculture. A well-developed food processing industry is expected to increase farm gate prices, reduce wastages, ensure value addition, encourage crop diversification, generate employment opportunities as well as export earnings. The challenges for the food processing sector are diverse and demanding, and need to be addressed on several fronts to gain maximum market benefits[8]. The major highlights of the SWOT analysis are mentioned below in the table 1.3.1

STRENGTH	• Abundant availability of raw material through India's diverse agro-climatic conditions and large population of livestock. For example, India is the highest producer of milk in the word and ranks first in the production of bananas, guavas, mangoes and cashew nuts. It also ranks second in the world for production of rice, wheat, groundnuts, onions, peas, and sugarcane.

[8] A Sarathe, R Gupta, A.L. Basediya and V Satish Kuchi. Recent Trends and SWOT Analysis of Food-Processing Industry Infrastructure in India: A Review. Bull. Env. Pharmacol. Life Sci., Vol 7 [6] May 2018: 107-116. (http://bepls.com/beplsmay2018/18.pdf)

	• Large population translating into a vast domestic market, with food consumption set to nearly double in the next 10 years. • Priority sector status for agro-processing given by the central government. • Low-entry costs and government incentives to promote food processing.
WEAKNESSES	• Storage warehouses are poorly equipped to handle the large food grains produce. • Cold chain facilities face erratic electricity supply. • Inadequately skilled workforce, especially in terms of technical skills and knowledge of operating and maintaining food machinery. • Lack of adequate training institutes, courses, R&D and testing facilities. Food testing laboratories are in the initial phase of setup all over the country by FSSAI. Most of them possess outdated infrastructure. • Lack of variety in offerings and high degree of commoditization, especially among small unorganized players that still employ a majority of workforce.
OPPORTUNITIES	• Increasing demand for secondary processing and packaged food items, such as RTE items and milk products. • Mandating contracts with organized retailers that may improve adherence to international quality standards, which could, in turn, encourage skill improvement for FP players, leading to improved access to domestic and export markets. • Growing role of regional FP players due to increased need for localization and customization of offerings by food companies to suit the Indian palate. • Extremely low processing levels especially in F&V sub-sector. • Gradual liberalization of the retail sector leading to improved backward linkages with processors
THREATS	• Lack of any incentives or skill development from the government on the packaging front may limit deeper penetration into small cities. • Delay in government initiatives — land acquisition and environmental hurdles in commissioning of mega food park projects. • Limited production and availability for processing variety of products, such as fruits and vegetables. • Lack of concerted efforts to integrate cooperatives (which are major players in the Food processing industry) in initiatives, such as food parks. • Limited growth in storage and warehousing capacity for other types of products may hamper the growth of the FP industry. Currently, a majority of cold-storage facilities are utilized for potatoes.

Table 1.3.1: SWOT Analysis of food processing industry

1.3.3 Promotion of Food Processing Industries through Government Initiatives

Food sector's weaknesses and threats can be alleviated with the support from the government and it is making every effort to promote investments in the sector through various schemes and policies. Recently launched Ministry of Food Processing's PMFME (Prime Minister Formalization of Micro Enterprises) scheme is to formalize the micro food processing industries and to create a sustainable growth for them with a vision to make them globally competitive. Government has also authorized joint venture (JV) plans, international partnerships, industrial licenses, and export-oriented units 100 per cent. Some measures taken by the Government of India to boost the food processing sector in India are as follows:

- Stimulating growth by leveraging reforms such as 100 percent Foreign Direct Investment (FDI) in food product marketing and provide incentives at the central and state levels;
- Making the supply chain network the priority;
- Creating an infra-fund for milk processing worth Rs 8,000 crore;
- Relaxing foreign direct investment (FDI) norms for the sector, allowing up to 100 per cent FDI in food product e-commerce through automatic route;
- Investing Rs 482 crore to improve India's food testing infrastructure through India's Food Safety and Standards Authority (FSSAI) by upgrading 59 well-known food testing laboratories and developing 62 new mobile testing laboratories across the country;
- Adopting international best practices for research in the fertilizer sector to allow farmers to obtain high-quality fertilizers at affordable rates, thereby achieving common man food security through the Indian Council for Fertilizer and Nutrient Research (ICFNR);
- The HRD (Human Resource Development) scheme is being introduced under the National Mission on Food Processing by State Governments. The scheme has the following four components:
    - [Entrepreneurship Development Program (EDP)]
    - [Entrepreneurship Development Program for Food Processing Training Centers (FPTC)]
    - [Entrepreneurship Development Program (EDP)]
    - [Entrepreneurship Training Centers (FPTC)] [Entrepreneurship Training Centers]

Over the years, some Indian states have taken independent initiatives to boost the development of agriculture and Agri- business industries through various policies and proposed measures. Such initiatives have helped these states attract considerable attention of investors. Baddi in Himachal Pradesh, for instance, has developed into a hub particularly for food processing industries.

The figure 1.3.6 provides a snapshot of policies across four key states in India i.e., Punjab, Haryana, Rajasthan, U. P[9] etc.

1.3.4 Current Challenges

Over 51 percent of our population is employed in the agriculture sector. Despite the steady decline, agriculture still contributes significantly to the Gross Domestic Product (GDP) and is an integral part of the economy. Food processing is closely interlinked with the two of our core industries — manufacturing and agriculture. Agricultural farm produce is the contributor to this sector while processing for value addition is enabled by the technology applied in a typical manufacturing setup.

[9] NSDC Skill Gap Report on "Human Resource and Skill Requirements in the Food Processing Sector (2013-2017) (2017-2022)" Vol 10. Report prepared by KPMG advisory services Pvt. Ltd.

Traditionally, every household has been involved in value addition to food at a very small scale. Few traditions have carried it forward and passed it on to generations spurning growth in small scale enterprises. These businesses are now at the cusp of transformation due to expansion and market opportunities. The food machinery in this sector is undergoing rapid modernization giving rise to employment to a large number of operational equipment professionals but still there are several challenges that are faced with food processing sector, these include:

Supply side bottleneck as dispersed marketable surplus because of low agricultural productivity, high seasonality, fragmented farmland holdings;

Product perishability is further enhanced by a lack of distribution;

Handiness of high-quality raw material impacting manufacturing and exports;

Inadequate logistics and cold chain infrastructure consequential in the loss of more than 30% of the production;

Inadequate transport facilities.

Punjab

- The Agro Industry Policy is incentivising the food processing sector.
- State nodal agencies, such as Punjab Agro Industries Corp Ltd. (PAIC), also work to infuse fast growth by encouraging more industrial partnerships.

Haryana

- The food processing sector is covered under the Government of Haryana's Industrial and Investment Policy 2011.
- Grain processing units will be a major beneficiary of this initiatives

Rajasthan

- Rajasthan's policy for the promotion of 'Agro-processing and Agribusiness 2010' will give focus to the areas in oilseeds processing and livestock.

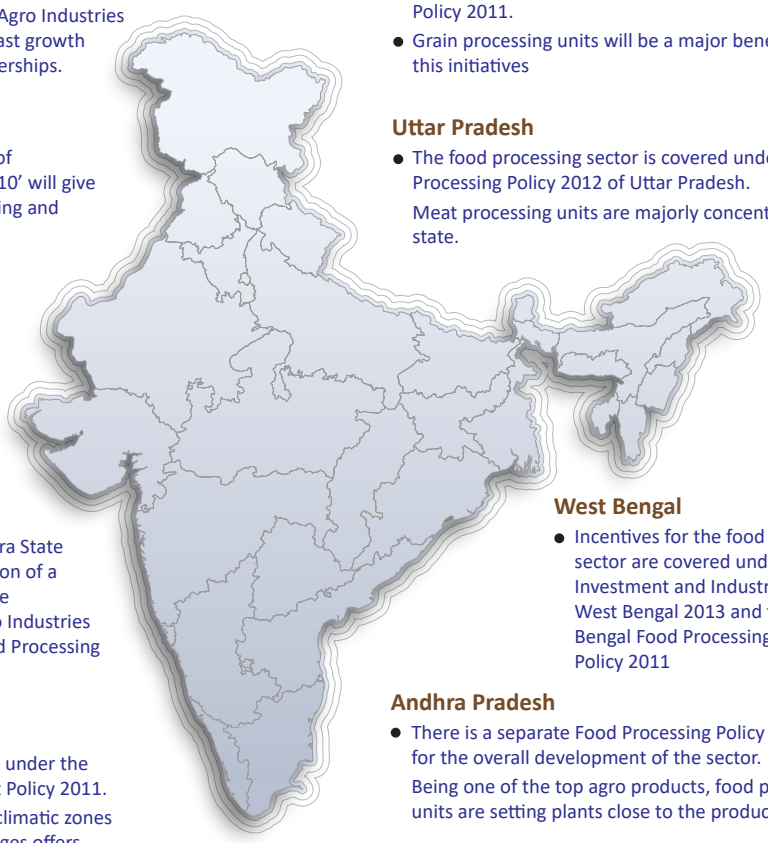
Uttar Pradesh

- The food processing sector is covered under the Food Processing Policy 2012 of Uttar Pradesh.

  Meat processing units are majorly concentrated in this state.

Gujarat

- The food processing sector gets coverage under the Agro Industrial Policy 2000.
- F&V processing units have set up their plants in this state due to industry friendly labour policies.



West Bengal

- Incentives for the food processing sector are covered under the Investment and Industrial Policy of West Bengal 2013 and the West Bengal Food Processing Industrial Policy 2011

Maharashtra

- Part 2010-15. Further, the Maharashtra State Food Processing Mission is an extension of a natural initiative managed by the state government by the Maharashtra Agro Industries Development Corporation of the Food Processing Policy

Andhra Pradesh

- There is a separate Food Processing Policy 2010-15 for the overall development of the sector.

  Being one of the top agro products, food processing units are setting plants close to the produce.

Karnataka

- The food processing sector is covered under the Integrated Agribusiness Development Policy 2011.

  Karnataka with its ten different agro-climatic zones and other bounteous natural advantages offers immense opportunities for high growth in agriculture and allied sectors.

Tamil Nadu

- The food processing sector is covered under the Tamil Nadu Agro and Agro Processing Policy 2008.

Fig. 1.3.6: State initiatives to boost food processing

1.3.5 Road Ahead

Given all of these obstacles, the food processing industry is evolving at a good rate with the hope of a better future attached to the mammoth business reach. Several key drivers of Indian food industry are as follows[10]:

- **Growth in organised retail:** Food retail is expected to grow well due to low penetration of organized retail and the potential market thereof.
- **Changing consumer preferences:** India has one of the largest consumer bases in the world with a young population (more open to trying out new food products), increasing income (marking a shift towards premium food products) and more time-starved consumers (leading to an increasing shift towards Ready-to-eat (RTE) and packaged foods).
- **Favourable government policies:** Direct support in the form of financial assistance for technology upgrade and setting up/modernization /expansion of food processing industries is being encouraged. 100 percent Foreign Domestic Investment (FDI) under the automatic route (except for alcohol, beer, and sectors reserved for small scale industries) is now permitted and this has spurred investment in India.
- **Supply of raw materials:** India ranks number one in the production of milk, bananas, guavas, mangoes, buffalo meat and cashew nuts. It ranks second in the world in the production of rice, wheat, groundnuts, onions, peas, and sugarcane. We have a climate that is suitable for year-round supply of agricultural products.
- **Availability of cheap labour:** India's comparatively cheaper workforce can be effectively utilized to set up large low-cost production bases for domestic and export markets.

Therefore, with the numerous advantages in the food manufacturing sector, the growth factor will rapidly increase in the coming few years bringing in bundle of opportunities for the entrepreneurs/ start-ups/food industries/MSME's (Micro, small and Medium Enterprises)

[10] NSDC Skill Gap Report on "Human Resource and Skill Requirements in the Food Processing Sector (2013-2017) (2017-2022)" Vol 10. Report prepared by KPMG advisory services Pvt. Ltd.

UNIT 1.4: Classification of Food and Agro-Processing Industry

Unit Objectives

At the end of this unit, you will be able to:

1. Explain food processing.
2. Identify various sub sectors of food processing industry.
3. Discuss the key trends food processing sub-sectors.
4. Diagram Value chain of food processing industry.

1.4.1 Introduction to Food Processing

The processing of food includes the processes and techniques used to turn raw materials into food for human consumption. The processing of food takes components which are washed, processed or slaughtered and butchered and uses them to produce marketable food items. The food can be made in several ways, a few are listed below:

- **One-off production:** This approach is used when consumers place an order to make it according to their own preferences, such as a wedding cake for example. It may take days to make one-off items, depending on how complex the concept is.
- **Batch production:** This approach is used when a company's market size is not evident and a product line has a variety. In order to make up a batch or run a certain amount of the same products must be made, for example a bakery will bake a limited number of cakes. This approach has to do with forecasting market demand.
- **Mass production:** This approach is used when a large number of similar items, such as candy bars, ready-made food and frozen food, have a mass market. The product moves along a production line from one manufacturing stage to the next.
- **Just-in-time (JIT) (production):** This manufacturing method is used primarily in restaurants. Many of the product's components are available in-house, and the consumer selects the product they want. This is then cooked in a kitchen, or in front of the customer such as sandwiches, pizzas, and sushi.

Food Processing Objectives

The objectives of food processing are multiple. For example, freezing or cooking provide both preservation and convenience. Heating or fermentation of soy is necessary both to achieve palatability and to remove the toxic substances (anti-nutritional substances).

Processing operations are conducted under controlled conditions to ensure that the process is completed in the most effective and competent manner. The resulting products include ingredients delivered to food manufacturers to be used in producing foods for consumers, as well as ingredients for consumers to use in food preparation. The development and implementation of new technologies enhances food quality and safety. New processing technologies enables food product innovation[11].

[11] A Sarathe, R Gupta, A.L. Basediya and V Satish Kuchi. Recent Trends and SWOT Analysis of Food-Processing Industry Infrastructure in India: A Review. Bull. Env. Pharmacol. Life Sci., Vol 7 [6] May 2018: 107-116. (http://bepls.com/beplsmay2018/18.pdf)

1.4.2 Food Industry Classification

Food processing industry is composed of various sub-segments. The major segments in the Food Processing sector comprise of Fruits and Vegetables, Dairy, Edible Oils, Meat and Poultry, Non-alcoholic beverages, Grain-based products, Marine products, Sugar and sugar-based products, Alcoholic beverages, Pulses, Aerated beverages, Malted beverages, Spices, and Salt.

Out of these segments share of Dairy (16%), Grain-based Products (34%), Bakery-based products (20%), and fish and meat products (14%) contribute to a major portion of industry revenues, apart from the manufacture of beverages.

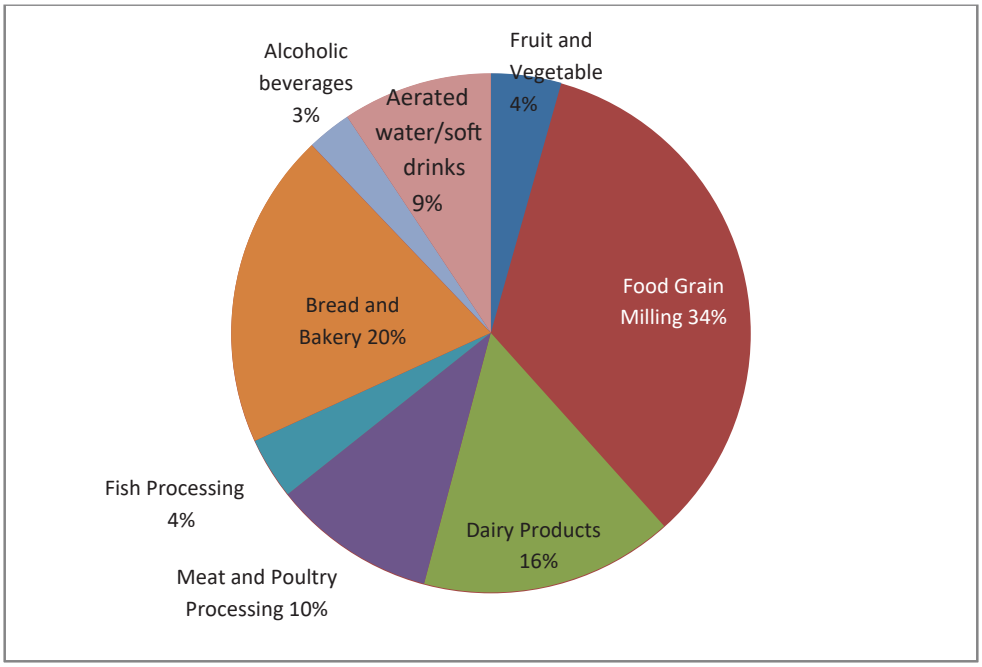


Fig. 1.4.1: Major segments in the food industry
(Source: Annual Survey of Industry (ASI), MOFPI and IMaCS analysis)

This handbook categorizes the sector/segments as per NIC (National Industrial (Activity) Classification lists. According to National Industrial Classification, different sub sectors are assigned specific codes and divided into different groups and sub-groups. The Central Statistical Organization (CSO) in the Ministry of Statistics and Programme Implementation is the nodal authority for bringing out the National Industrial Classification in India. It lists out economic activities and tasks with reference to industrial sectors in a systematic manner. The food processing sector is primarily classified in division X with five separate sub-groups representing sub-sectors, such as fruits and vegetables, milk and milk products, grain and oilseed, meat and marine processing and packaged foods. It also includes beverages as a separate sub-sector covering division XI from NIC.

	National Industrial Classification (NIC)	
Meat and marine Products	Section	C
	Division	10
	Group	101, 102
	Title	• Processing and preserving of meat • Processing and preserving of fish, crustaceans and mollusks and products

	National Industrial Classification (NIC)	
Fruits and Vegetables	Section	C
	Division	10
	Group	103
	Title	• Processing and preserving of fruit and vegetables
Grain and oilseed	Section	C
	Division	10
	Group	104, 106
	Title	• Manufacture of vegetable and animal oils • Manufacture of grain mill products, starches and starch products
Milk and milk Products	Section	C
	Division	10
	Group	105
	Title	• Manufacture of dairy products
Packaged foods	Section	C
	Division	10
	Group	107, 108
	Title	• Manufacture of other food products • Manufacture of prepared animal feeds
Beverages	Section	C
	Division	11
	Group	110
	Title	• Manufacture of beverages

Table 1.4.1 The codes and groups of various sub-sectors.

In the last five years, the growth of the Indian food processing (FP) sector has been faster than agricultural growth. The sector is poised for strong growth of about 15 percent till Financial year (FY) 2017, driven by growth in organized retail, changing consumer preferences and favorable government policies. By 2022, the food processing industry is expected to generate about 44.34 lakh new jobs, primarily entry-level and supervisory profiles. Several skill gaps exist in various stages of the food processing value chain that need to be addressed. This includes the food processing sector as well as ancillary industries, such as bottling and packaging. The growing quality consciousness by the consumers requires the workforce to be skilled in basic hygiene and sanitary practices. Processing units are also adopting mechanization and technology. There is a growing need to impart technical skills to more specialist personnel who are capable of working on imported machines in specific sub-segments especially dairy and fruit and vegetables. The outlook and brief description of various sub-sectors is presented in the table 1.4.2 which will throw more light on the potential of various sub-sectors in the food industry.

Sub-sector	Brief Description	Outlook
Fruits and vegetables	This includes fresh fruits and vegetables, dry fruits (raisins and cashew), processed and preserved fruits and vegetables (jams, jelly, pickle, sauce, food, paste, juice, concentrates, potato flour, canned fruit and vegetables).	Largely dominated by unorganized players, the industry has, over the years, witnessed rapid growth in ready-to- eat foods, frozen vegetables and processed mushrooms. The key challenge is the unavailability of infrastructure to store the produce. The cultural preference for fresh fruits and vegetables dominates over processed items.
Milk and milk products	This includes pasteurized milk, milk powder, ice cream powder, condensed milk, infant foods, cream, butter, cheese, ghee, khoya, ice cream, kulfi and other dairy products.	Growth in value-added dairy products is likely to increase rapidly. There has been a marked shift towards packaged milk particularly in urban areas and a decline in loose milk consumption. Packaged milk segment in India is projected to grow from INR 46560 crores to INR197400 crores by 2030, registering an annual growth of 8 percent.
Meat and marine products	Meat products include slaughtered, processed, preserved and canned mutton, beef, pork, poultry and others. Marine products segment includes sundried, artificially dehydrated, radiation preserved, processed, preserved and canned fish.	Dietary habits of people across the globe are changing fast and India with 25 percent of cattle population is gearing up to cater to the market. Indian seafood processing units are being encouraged to pursue value addition and export by the establishment of new units, capacity expansion and diversification of current activities.
Grain and oilseed	This includes milling of flour, rice, pulses, grain and other grains. It also includes processing and manufacturing of cereals (for breakfast), flour mixes and dough and other readymade powders (idli, dosa and gulab jamun).	India will continue to be one of the largest producers of cereals with more than 200 million tons of production annually. Growth in processing infrastructure in India may help the industry to optimally leverage its raw material advantage.
Packaged foods	This includes spices, snacks and savories, ready-to-eat (RTE) and ready-to-cook (RTC) food, beverages, chocolate and non-chocolate- based confectionery, biscuits and bakery items.	Packaged foods market is largely organized and has been witnessing strong growth across categories. Potato chips and potato-based products constitute about 85 percent share of the Indian snack market.
Beverages	This includes distilled alcoholic beverages, wines, beer, soft drinks, mineral water and other non-alcoholic beverages.	Consumption of non-alcoholic beverages in India is expected to increase by 16.5–19 percent over the next three years. Sales of alcoholic drinks are forecast to increase by CAGR of 8 percent by volume in 2012–17 period.

Table 1.4.2 Outlook of various sub-sectors of food sector (Source: Indian Food Industry)

1.4.3 Food Processing Value Chain

Key activities across value chain in various categories, such as dairy, poultry, fruits and vegetables, is broadly similar with the only difference being the production techniques and quality requirements. A considerable section of this value chain (production, logistics, processing and retailing) is unorganized with limited resources in training and development, which leads to significant skill gaps in key positions across the sector. For items, such as fruits, vegetables and other agricultural products (wheat, maize and rice), the produce typically passes through several intermediaries, such as commission agents (arthiyas and mashokars) and wholesalers, before reaching the food processing industry. This prevailing environment leads to a supply chain that has several intermediaries from the farm to the consumer. The unreasonably long supply chain results in steep escalation in the total cost to the consumer.

Another key difference between dairy and other segments is the degree of forward integration of processing companies, where a number of outlets selling milk and milk products are either owned or closely controlled by processors[12]. Similarly, even the larger grain and oilseed brands are acquiring or operating mills and manufacturing product(s) for their own labels. Key activities in food processing are depicted in figure no. 1.4.2.

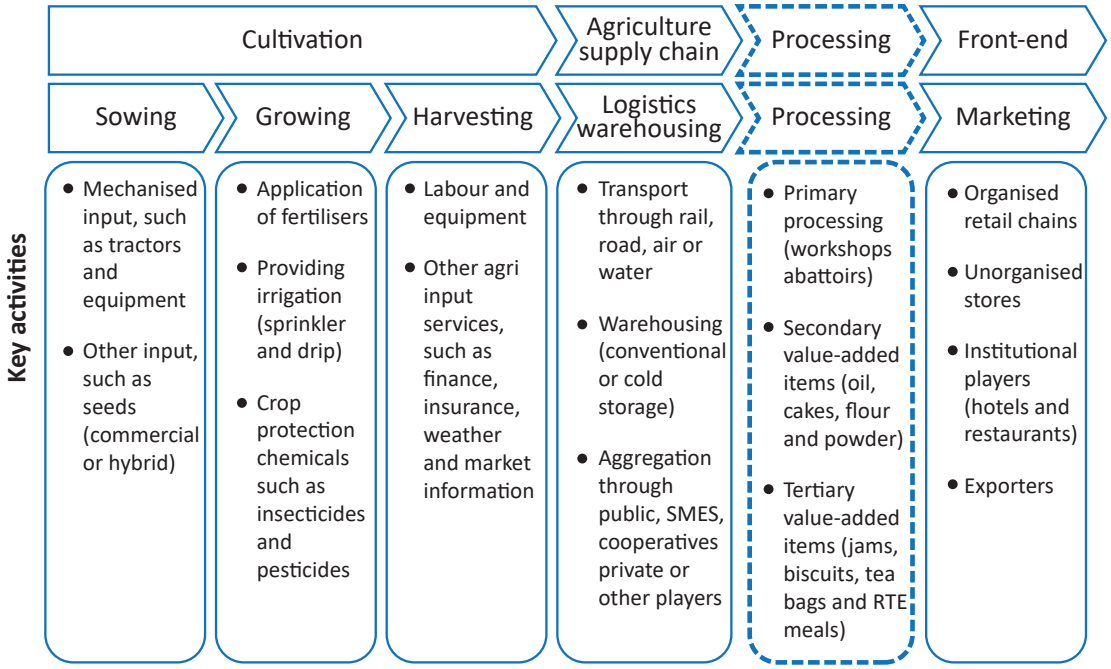


Fig. 1.4.2: Value Chain- Food processing industry (Source: KPMG: India Analysis)

[12] NSDC Skill Gap Report on "Human Resource and Skill Requirements in the Food Processing Sector (2013-2017) (2017-2022)" Vol 10. Report prepared by KPMG advisory services pvt. Ltd. (https://mofpi.nic.in/sites/default/files/SkillDevelopmentStudyonFood-Processing.pdf_0.pdf)

Exercise

1. **What are the roles and responsibilities of a Food Microbiologist?**

2. **Classify major agro and food processing industries.**

3. **What are the current major bottlenecks for the growth and development of food processing business in India?**

Skill India
कौशल भारत-कुशल भारत

सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation
Transforming the skill landscape

FICSI
Food Industry Capacity and Skill Initiative

2. Organizational Standards & Norms

Unit 2.1 - Organizational Policies and Procedures

Unit 2.2 - Workplace Ethics

Unit 2.3 - Personal Hygiene and Sanitation Guidelines of the Organization

Unit 2.4 - Understanding Food Analysis Laboratory

Unit 2.5 - Food Safety Requirements at the Workplace

FIC/N7610

Key Learning Outcomes

At the end of this module, you will be able to:

1. Describe organizational policies and procedures.
2. Explain the key points related to workplace ethics.
3. Describe the communication flow and develop interpersonal skills.
4. Discuss How to Work as a team.
5. Explain personal hygiene and sanitation guidelines.
6. Explain the structure and manpower requirements of food laboratory.

UNIT 2.1: Organizational Policies and Procedures

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the roles of different departments in food industry.
2. Describe organizational policies and procedures.

2.1.1 Knowledge and understanding of the organization

Knowledge and understanding different departments and their role is neccesary to work efficiently in the ecosystem. This will not only enhance coordination among various employees but will aid in increasing prodcutivity of the organizaton on the whole. Thus, different organizations with there roles are depicted below:

Department in the organization	Role
1. Production	The largest department in the organization where actual production happens.
2. Quality	Department that ensures every product made by the production unit met the standards.
3. Sales and Purchasing	It ensures necessary materials needed for production or daily operation of the company are met.
4. Information technology (IT)	It ensures smooth running of computer and different software's
5. Mechanical and Engineering	They are responsible for buying equipment’s needed for production, ensuring its running with company's specifications, and training employees from Production with new machines
6. Accounting section	This department is responsible for counting up money spent anywhere in the company.
7. Environmental Health and Safety (EHS)	They are responsible for development and implementation of all the health and safety programs in the company. They are also responsible for all employees' safety at work and the use of proper safeguards

Table 2.1.1: Roles of Different Organizations in Food Industry

2.1.2 Organizational policies and procedures

A Food Microbiologist shall understand the organizational policies and procedures clearly so as to provide the action plan to subordinates within the frame of business policies. It includes:

- The organizations norms, standards and accreditation mark;
- Different types of products produced by the organization and its flow chart;
- Production planning and raw material utilization;

- Provision of wages and working hours for employees;
- Safety and hygiene standards and impact of the same if not followed;
- Dress codes used for different works;
- Relevant people in the organization and their roles;
- Contact persons for procurement/ inventory and quality related information;
- Make the policies and procedures easily accessible subordinates;
- Knowledge of Human Resource (HR) policies and reporting structure.

A Food Microbiologist shall understand the HR policies regarding own job role and responsibilities and sources for information pertaining to employment terms, entitlements, reporting structure, inter-dependent functions, lines and procedures in the work area.

Standard operating procedure (SOP)

It is a set of instructions compiled by an organization to help employees to carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations. A food microbiologist or any other employee shall understand SOP's pertaining to his work. Understanding regulatory standards applicable to food processing industry can be referred from table 2.1.2.

1. Food Safety and Standards Regulations, 2011	• Food Safety and Standards (Licensing and Registration of Food businesses) Regulation, 2011 • Food Safety and Standards (Packaging and Labeling) Regulation, 2011 • Food Safety and Standards (Food product standards and Food Additives) Regulation, 2011 (part I & part II) • Food Safety and Standards (Prohibition and Restriction on sales) Regulation, 2011 • Food Safety and Standards (contaminants, toxins and residues) Regulation, 2011 • Food Safety and Standards (Laboratory and sampling analysis) Regulation, 2011
2. ISO (International Organization for Standardization)	• ISO 9000 covers quality management. • ISO14000 covers environmental management. • ISO 22000 specifies the requirements for a food safety management system. ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission.
3. Occupational Health Safety (OH & S)	• It ensures an accident-free industrial environment
4. Factories Act – 1948	• No employee is supposed to work for more than 48 hours in a week and 9 hours in a day. Any employee who works for more than this period is eligible for overtime remuneration prescribed as twice the amount of ordinary wages

	• When the minimum wages of an employee are fixed for a particular period of time and the employee works beyond that period, then the employee has to be paid overtime wages for the extra time
5. Employment and labor law 2019	• Covers common issues in employment including terms and conditions of employment, employee representations and industrial relations, discrimination, maternity and family leave rights and business sales
6. The Workmen's Compensation Act	• This is an Act that provides for the payment of compensation for injury by accident by certain classes of employers to their workmen.
7. Food safety and standards (packaging and labeling) regulations, 2011	• Covers general packaging and labeling requirements for various types of foods.

Table 2.1.2: Regulatory standards applicable to food processing industry

UNIT 2.2: Workplace Ethics

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the key points related to workplace ethics.
2. Describe the communication flow in an organization.
3. Explain how to develop interpersonal skills and work as a team.
4. Describe the personnel conduct in food analysis laboratory.

2.2.1 Workplace Ethics

It is described as a set of moral guidelines and obligations that guide a person's actions in his/her respective field of work. These standards can vary from industry to industry, and from position to position within an industry. It outlines the ethical principles that govern decisions and behaviour at a company or organization. They give general outlines of how employees should behave, as well as specific guidance for handling issues like harassment, safety, and conflicts of interest.

Some important points to be remembered are:

- Address seniors, assistants, and workers with respect;
- Follow the processes laid out in the manufacturing unit;
- Follow food safety norms at all times;
- Do not compromise with the quality of the product at any given cost;
- Perform your work with complete honesty;
- Perform your roles and responsibility with integrity;
- Be a team player.

Disciplined behavior and Code of ethics in Food Processing Organization

Disciplined behavior is important to improve workplace performance and to provide a safe and honest working environment. All organisations including yours have the Model Code of Ethics which defines the minimum non-negotiable standards and are governed by integrity, honesty, fair-dealing and full compliance with all applicable national and international laws. This is however not restricted only to our stated code and may not cover all situations; hence we provide a framework of reference. Doing business is based on the four tenets of our Professional Code of Ethics in our organisation:

- **Human Rights –** Organization should follow & practice fair employment practice, diversity and inclusion, free from any discrimination based on origin, nationality, religion, race, gender, age or sex. Freedom of association, defined work time, work days, overtime, wages and benefits, minimum age for employment as required.
- **Safety and Health –** Organization should provide a healthy and safe work place environment; emergency preparedness; housing condition and privacy where provided; product quality and safety; safe andtraceable ingredients; & ensure good manufacturing practices.
- **Environmental Standards –** Organization should follow and recommend following of all basic norms for preserving the environment. We diligently observe all environmental laws; obtain necessary permits and honest reporting on violations due to any reason. Conserving of consumption of resources, pollution prevention and waste control.
- **Business Integrity –** We are committed to anti-bribery, grievance mechanism; records and origin.

2.2.2 Communication

Communication is the process of exchanging information by speaking, writing, or using some other medium. Effective communication is a basic prerequisite for the achievement of organizational goals.

Communication flow in an organization

Within an organization, communication flows in five major directions:

1. **Downward:** Communication from management to subordinates is downward communication
2. **Upward:** Communication that flows to a higher level in an organization
3. **Lateral:** Communication between the same levels of hierarchy in an organization is called lateral communication
4. **Diagonal:** Communication between a supervisor-supervisors or worker - worker of other workgroups is called diagonal communication
5. **External:** Communication between a management and external groups such as - suppliers, vendors, banks, financial institutes etc.

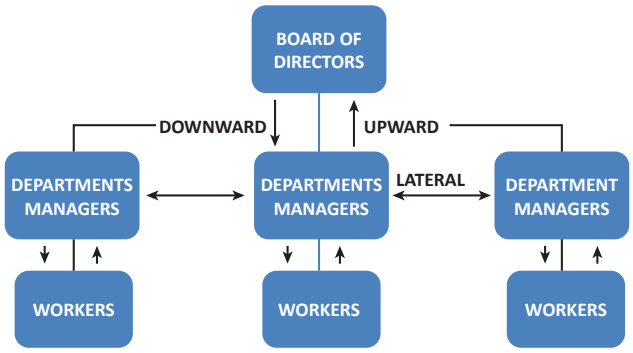


Fig. 2.2.1: Communication Flow in an Organization

The main components of communication process are:

- **Context -** The context may be physical, social, chronological or cultural.
- **Sender/Encoder -** The individual who sends the message.
- **Message -** The main idea that the sender needs to communicate. It is a signal that obtains the response of recipient.
- **Medium -** Medium is a channel used to transfer the message.
- **Recipient/Decoder -** The person for whom the message is intended.
- **Feedback -** Feedback is the major component of communication process and it grants the sender to evaluate the efficacy of the message sent.

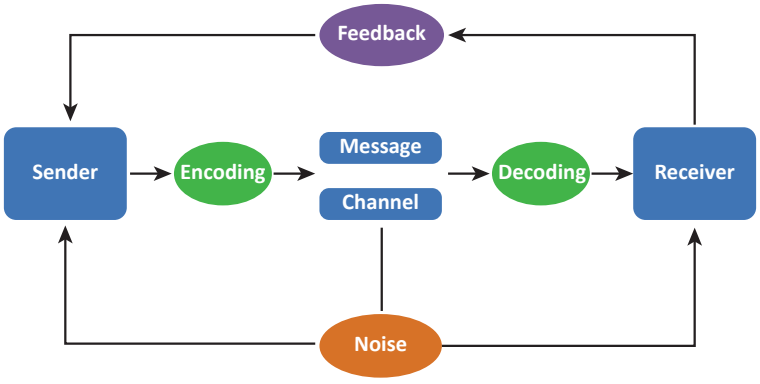


Fig. 2.2.2: Main Components of Communication

Communication in the workplace

- Encourage two-way communications in the workplace. Speak up if you are not clear the information received.
- Provide information to others clearly which help them understand.
- Provide specific and descriptive feedback.
- Be a good listener.

Listening is a skill which allows one to understand what another person is saying. A good listener can;

- Improve relationships in their personal and professional lives
- Avoid conflicts and misunderstandings and gain more clarity through listening well
- Higher confidence level as they have access to information
- A good source of information

2.2.3 Inter personal skills

Interpersonal skills are the ability to develop fruitful relationships with others. Knowing how to develop healthy working relationships with people at the workplace contributes significantly to your success as a superior.

How to Develop Good Interpersonal Skills

Effective communication plays a key role in developing good interpersonal skills.

1. **Nonverbal communication** which results in achieving positive interpersonal skills are:
   - Smile and eye contact
   - Correct postures and gestures
2. **Good listening skills**
   - It conveys that “you care”
   - It enables you to understand other people's viewpoints and empathize with their situation.
3. **Verbal communication** which results in achieving positive interpersonal skills are:
   - Use of voice and intensity.

2.2.4 Work as a Team

Team work promotes strong working relationships which eventually contribute higher productivity. When employees work together and succeed as a team, they are more likely to;

- Communicate well with others
- Support and get motivated
- Work cooperatively for the success of the organization

Fig. 2.2.3: Benefits of team work

2.2.5 Conflict Resolution skills

Interpersonal conflicts: The conflict comprises a series of human affective states including anxiety, hostility, resistance, aggression, and competition. The common reasons for interpersonal conflicts in a workplace are;

- Lack of effective communication
- Individual differences on values and beliefs
- Lack of trust
- Incivility
- Stress

2.2.6 Grievance management in workplace

Grievance is a concern, problem, or complaint that an employee has regarding the work/workplace, or someone they work with which made him/her feel dissatisfied.

Types of grievances in the workplace include;

- Pay and benefits.
- Bullying/ harassment.
- Work place risks and safety concerns.
- Workload.

Grievance procedure

- The organization shall have a written grievance procedure, by which employee can escalate his/her issues.
- Investigating grievance: the organization carryout investigation.
- Grievance meeting: the organization holds a meeting so that the employee gets opportunity to explain the complaint.
- Considering the evidences, the organization decides whether to reject or hold the grievance.
- The employee can go for appeal if he feels unfair to the decisions made by organization.

2.2.7 Personnel Conduct Guidelines

For effective working in the laboratory, correct personnel conduct by food microbiologist will ensure increased work productivity and enhanced time management. The following conduct is recommended for food microbiologist to follow in the laboratory environment.

- To reduce the risk of infection, do not smoke, eat, drink, or bring food or drinks into the laboratory room—even if lab work is not being done at the time.
- Don't apply cosmetics or use contact lenses in the laboratory.
- Wash your hands meticulously with soap and water before working in the lab, after handling living microbes, and before leaving the laboratory at any given time. Remember to wash your hands after removing gloves.
- Do not remove any organisms or chemicals from the laboratory.
- Lab time is precious, so come to lab equipped for that day's work. Figuring out what to do as you go along is likely to produce confusion and accidents.
- Work carefully and systematically. Do not rush through any laboratory procedure.
- The personnel should be technically competent to perform their duties as allotted to them whether operating on specific equipment's/ performing tests /evaluating results/signing the reports.
- Qualification for doing specific tasks shall be judged on the basis of their education, training, specific experience and demonstrated skill.
- Regular and refresher training should be organized to keep the personnel update in their domain of activity.
- Specific job description for each personnel should be defined with their role and responsibility.
- Personnel should wear proper uniform and protective clothing's, etc as required depending upon the test method.
- If disposable gloves are used by microbiologist while handling microorganisms, microbiologist should ensure to remove them before leaving laboratory. The appropriate method for removal is with the thumb under the cuff of the other hand's glove and turning it inside out without breaking it. Gloves should then be disposed of in the container for contaminated things. Then, washing of hands is necessary.
- Microbiologist should wear throwaway gloves while staining microbes and handling blood products—plasma, serum, antiserum, or whole blood. Consult instructor before trying to work with any blood products.

Fig. 2.2.4: Food microbiologist with safety gears

Fig. 2.2.5: Sharp Container

- Needles, glass, and other contaminated items that can penetrate the skin or an autoclave bag should be disposed of in a sharp's container.
- Use an antiseptic (e.g., Betadine) on your skin if it is exposed to a spill encompassing microorganisms.
- Never pipette by mouth. Always use mechanical pipettors.
- Dispose of broken glass or any other item that could puncture an autoclave bag in a proper "sharps" or broken glass container.
- While doing test no phone calls/ cell calls should be attended to avoid any type hazards and carelessness while performing the test.
- Normally blank determination along with the known-standards must be carried out in duplicate/ replicate to check the accuracy of the results obtained and human error etc.
- All the analysis records must be documented either through hardcopy or through soft copy to demonstrate that the tests are really been carried out.
- Random checking of the result should be done inter-laboratory and intra-laboratory to check the proficiency of the personnel.
- In case of hazardous analysis, special precautions as provided in the methods should be taken for self and surroundings.
- While opening and closing the laboratory room, safety precaution should be taken care of depending upon the nature of the laboratory, equipment and test method. Special care should be taken for microbiological lab. Instructions in this regard must be displayed in the lab.

UNIT 2.3: Personal Hygiene and Sanitation Guidelines of the

Unit Objectives

At the end of this unit, you will be able to:

1. Explain personal hygiene and sanitation guidelines.
2. Discuss the general safety policy of food industry.
3. Explain general Hygienic and Sanitary practices to be followed by food business laboratories.

2.3.1 General Personal hygiene and Sanitation Guidelines

Introduction

The most effective way to protect ourselves and others from illness is practicing good Personal Hygiene. It will involve not just washing your hands, especially, but also your body. It means being careful not to cough or sneeze on others, cleaning things that you touch if you are unwell, putting items such as tissues (that may have germs) into a bin, and using protection (like gloves or clothing) to avoid being at risk of catching/passing an infection. It can prevent food poisoning. Bacteria that cause food poisoning can be on everyone – even healthy people who are part of your team or working or dealing with you in the workplace. Avoid spreading bacteria from yourself to the food if you touch your nose, mouth, hair or your clothes, and then on to food. Personal Hygiene symbolises good business sense. Inculcate and encourage employees who are part of the food production process to take hygiene seriously and practise safe food handling procedures. Good Personal Hygiene policies and practices are the foundation for successful food safety and quality assurance in all food manufacturing facilities. Plant personnel are among the most significant reservoirs and vectors of microorganisms, chemical residues and foreign materials in the food facility, and as such, can be a source of unwanted contamination to the food products.

Health Status

No individual suffering from contagious disease shall not be allowed to enter in any food production, handling area. Any person if suffering from some disease shall inform his/her illness to management. The medical examination of such food handler shall be carried out on priority. The medical examination for all personnel working in food handling area shall happen in a year and further records shall be maintained for such examination. All personnel should be inoculated against enteric group of diseases. In case of an epidemic, all personnel shall be vaccinated irrespective of the scheduled vaccination. Medical examination to be concluded:

- General Physical examination
- Eye vision Test
- Examination of skin for any infection.
- Vaccine to be inoculated against enteric group of diseases as per schedule

Any test required to confirm any communicable or infectious disease which the person suspected to be suffering from on clinical examination

Fig. 2.3.1: Personal Protection Equipment

Personal Protective Equipment's		
 Protective Gloves	 Head Cap	 Aprons
 Safety Goggles	 Safety Boots	 Mouth Mask
 Sanitizer		

Table 2.3.1 Different Types of PPE

Personal Cleanliness is the most vital link in preventing food borne diseases. Personnel handling food needs to maintain personal hygiene habits inculcating this into their behavior.

1. Suitable clean protective clothing shall be provided to all personnel handling food which includes: footwear, head covering, face mask and gloves;
2. Soap must be used by all personnel to wash their hands and disinfect it. Which should be followed by hand drying, before entering food handling area;
3. Food handlers shall always wash their hands at the beginning of food handling activities immediately after handling raw food or any contaminated material, tools, equipment or work surface, where this could result in contamination of other food items or after using the toilet;
4. No personnel shall be engaged in smoking, spitting, chewing, sneezing or coughing over any food and eating in food preparation and food service areas;
5. The food handlers must trim their nails and hair periodically;
6. Food Handlers shall avoid certain hand habits such as scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching beard, scratching parts of bodies etc. When unavoidable, hands should be effectively washed before resuming work after such actions;
7. Street shoes should not be worn while handling & preparing food inside the food preparation area;
8. Food handlers must not handle soiled currency notes/cards to avoid cross contamination;

Fig. 2.3.2: Correct Use of gloves in Food Industry

2.3.2 General Health and Safety Policy of Food Industry

General Safety policy of food industry is as follows:

- To provide a safe work environment for all employees working in industry premises;
- To provide the same safe and healthful environment for the company visitors;
- Safety policy shall be a cooperative effort between labor and management in order to prevent hazards, work related causes and minimize losses of property damage;
- The safety policy should have the first of management level. The occupier shall prepare as often as may be appropriate, revise a written statement of his general policy in respect of Health & Safety of workers;
- Policy should also contain:

- Assigning work responsibility related to particular safety hazard to each level in the unit;
- Arrangement for involving the workers at different work of health and safety issues;
- Relevant techniques and method (such as safety audits and risk assessment) for periodical interval at least once in every two years on the status of Dairy employee's health and safety;
- Arrangements for informing, educating and retraining own employees at different levels and the visitor.

2.3.3 Schedule 4 Requirements: General Hygienic and Sanitary practices to be followed by Food Business operators (FBO)

The Food Safety and Standards Authority of India (FSSAI), has made Schedule 4 under Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011. Under these regulations, it is mandatory that every Food Business Operator has to follow hygienic and sanitary practices in the premises where food is being manufactured. Schedule 4 is a set of basic - mandatory requirements to ensure safety of the food made in any premise and Food Business Operator shall continuously try to improve hygienic conditions and sanitary practices at the premises with an aim of attaining India HACCP standards.

The Schedule 4 is divided into five parts, naming Part I to Part V. The title of parts is as follows:

Part I – General hygiene and sanitation practices to be carried out by Petty Food Business Operators who are applying for Registration

Part II – General requirements on various Hygiene and Sanitary Practices to be accomplished by all FBO applying for License

Part III – Specific Hygiene and Sanitary Practices to be carried out by FBO engaged in, processing, manufacture, storing and selling of milk as well as products related to Milk.

Part IV – Specific Hygiene and Sanitary Practices to be carried by FBO engaged in manufacture, processing, storing and selling of Meat and Meat Products.

Part V – Specific Hygiene and Sanitary Practices to be carried out by FBO engaged in catering / food service establishments

The general sanitary and hygienic requirements are part of Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP). For food manufacturer/ processor/handler below indicated generic guidelines are provided which will give fair idea about the practices to be followed. The premises where food is made, or handled shall comply with the below indicated general requirements:

1. The food processing unit should be free from filthy surrounding and shall maintain overall hygienic environment. All units shall be set away from polluted areas;
2. There should be adequate space for the manufacturing of food and its storage in order to maintain overall hygienic conditions;
3. The premises need to be well lighted and ventilated with sufficient free space for movement;
4. The walls, floors and ceilings must be maintained in sound condition. They should be easy to clean and smooth without any flaking plaster or paint;
5. Disinfection should be done for the floors and walls as per condition/requirement and the premises shall be kept free from pest and insects. Net and screen should be fitted in windows, doors and other openings, in order to make the premise insect free. Spraying shall not be done during the

conduct of business, but in place fly flaps/ swats should be used in order to kill flies getting into the food premises. Potable water should be used in the manufacturing process and if necessary microbial and chemical testing should be done at regular intervals at any recognized laboratory;

6. Continuous potable/ fresh water supply shall be ensured in the premises. Sufficient storage arrangement for water should be done in case of irregular supply of water in food or for washing purpose;
7. Machinery and equipment's when used shall be of design which will permit easy cleaning. Arrangements for cleaning of tables, containers and working parts of machines, etc. shall be provided;
8. None of the container or equipment, the use of which may cause contamination due to metal should be employed in the food preparation or packing or its storage;
9. All equipment's shall be washed and kept clean, dried and stacked to ensure freedom from fungal infestation;
10. In order to ascertain correct inspection equipment's shall be placed away from the walls;
11. Efficient drainage system with adequate provisions for disposal of refuse shall be there;
12. The workers shall use clean aprons, head wears and hand gloves while working in the preparation process;
13. Persons suffering from transmissible diseases shall not be allowed to work. Any cuts or wounds shall be covered all time and there should not be any direct contact with food and the person infected;
14. Finger nails should be trimmed, cleaned and washed with soap, or detergent and water by food handlers before beginning the work and every time after the toilet is used. Scratching of body parts and hairs should be strictly avoided;
15. Wearing of false nails or other items like loose jewelry should be avoided by the food handlers as they may fall into food;
16. There should be strict prohibition of eating, smoking, spitting, chewing and nose blowing within the premises while handling food;
17. All articles that are intended for sale shall be fit for utilization and have suitable cover to keep away from contamination;
18. The transportation vehicle used for the article of foods should be kept clean and maintained;
19. Required temperature should be maintained for Foods while in transport in packaged form or in containers;
20. Disinfectants /Insecticides should be kept `away from food manufacturing or handling or storing areas.

UNIT 2.4: Understanding Food Analysis Laboratory

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss the Structure of the lab.
2. State types of analysis in a Laboratory for Food Analysis.
3. Discuss the manpower requirements for a regulatory Food Analysis Laboratory.

2.4.1 Food Testing Laboratories

Introduction

Food safety issues and the enhancement of health security are of growing national and international concern. Key global food safety concerns include spread of microbiological hazards, chemical food contaminants, assessment of rapidly changing technologies in food production, processing and marketing. Increasing scientific understanding of the adverse consequences of unsafe food, amplified by the rapid global transmission of information has heightened consumer awareness about food safety risks to new levels. Microbiological hazards, contaminants in the form of pesticides and heavy metals and economically motivated adulterants (substitution of cheaper raw materials or look alike) are a major food safety concern all over the world.

The Indian food consumption basket has diversified from cereals towards higher value and more perishable products, such as fruits and vegetables, dairy, meat and fish. Higher disposable incomes to spend on non-home cooked foods and increased women in the workforce are the key drivers for the demand of ready to eat, ready to cook and semi-prepared foods, and as a result the growth of the processed food industries. These trends bring increased attention to safety concerns in the handling, processing and packaging of foods. Increasing international trade has expanded food safety into a global business. Such movements will continue to drive the market for high-quality lab testing National standards for both domestic and export trade lay down parameters for pesticide residues, antibiotic and veterinary residues, heavy metals, mycotoxins, pathogens, and other contaminants.

Therefore, a food analytical laboratory is a critical and integral part of the supply of safe and quality food. It is the silent 'expert system' ensuring that the customer gets the safe and quality food he or she is expecting.

Food testing laboratories, deploying a comprehensive range of state-of- the-art analytical techniques are a necessary and vital arm of a responsible, responsive food regulatory system, important for robust implementation and enforcement These laboratories with adequate infrastructure, facilities, equipment, supplies, reference materials, access to calibration and maintenance, and operating under an international quality assurance programme, are benchmarks that support the increasingly stringent quality and safety standards. An adequate number of food analysts with suitable qualifications, training, experience and integrity; management and support staff form the heart of a testing laboratory. Formal accreditation, operation of effective internal quality control procedures together with participation in laboratory proficiency testing (PT) schemes are key elements in ensuring the quality of results generated by analytical laboratories. Food testing laboratories that meet recognized best practices of analytical competency will allow FSSAI the regulatory agency to more expeditiously utilize laboratory data to identify, prevent and remove unsafe food products from the market shelf[13].

[13] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

The types of analyses can be divided or categorized as shown in Figure 2.4.1

General Parameters
Moisture
Total Ash,
Acid Insoluble Ash
Water Soluble /Insoluble Ash Alkalinity of Ash
Acidity,
Total soluble solids,
Total volatile extracts

Nutritional Evaluation
Fat,
Protein,
Crude fibre,
Dietary Fibre
Carbohydrates)
Calories,
Fatty acid (MUFA, PUFA)
Cholesterol
Amino acid composition
Vitamins
Minerals

Food additives & Contaminants
Colors
Antioxidants
Preservatives
Artificial sweeteners
Pesticide residues analysis
Heavy metals
Drug and antibiotic residues Mycotoxin analysis Food adulterant

Microbiology
Total Plate Count,
Coliform count,
Aerobic spore count
Anaerobic spore count
Yeasts and mold count.
E. coli,
Salmonella spp.
Shigella Spp,
Vibrio cholera
Vibrio parahaemolyticus,
S. aureus,
Listeria monocytogenes,
Clostridium botulinum

Fig. 2.4.1: Types of analysis in a Laboratory for Food Analysis

The types of analysis will determine the investment and space needed. Proximate analyses are used for characterization for general nutritional parameters, and the capacity to perform these analyses should be seen as the minimum requirement for every laboratory. Other types of analysis (contaminants, drug residues authenticity etc) are more specialized and need specific high-end equipment and facilities. Consequently, these analyses require highly skilled personnel with deep knowledge and sensitive and expensive equipment, but also demand superior working environment to avoid contamination.

The high-quality demands in reference /state food testing laboratories therefore, require large investment in personnel, equipment and infrastructural facilities and guarantee the independence of the laboratory and avoid conflict with commercial interests.

2.4.2 Analytical process for regulatory compliance

The foundation of a regulatory laboratory is the analytical process which ensures that procedures and protocols are followed to consistently meet the rigor and high standards of regulatory compliance and international Quality Assurance requirements.

The various stages of the analytical process are shown in Figure 2.4.2. This process starts with the receipt of samples with a request for the analysis. On receipt of the samples security and appropriate storage is initiated followed by, sample preparation and analyses. The results of these tests are collated, verified and following approval from an authorized person, a final report, is dispatched to the concerned authority. It is important to ensure that the accountability, security, integrity and chain of custody of the sample is met. The laboratory must ensure the legal defensibility of analytical data produced by the laboratory. Responsibility for all these details should be clearly defined. Sample materials are stored in the laboratory for a fixed time, e.g., one month, from completion of analyses and either discarded or destroyed.

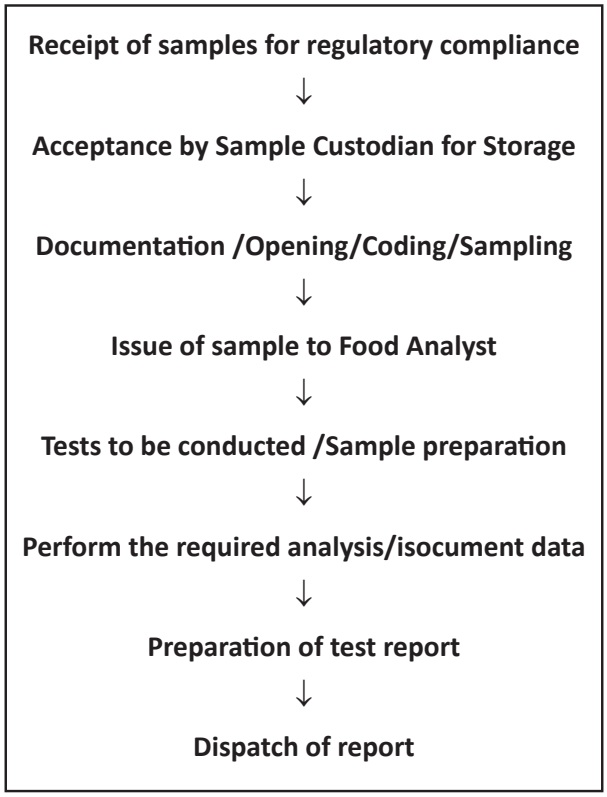


Fig. 2.4.2: The various stages of an analytical process

2.4.3 Manpower requirements for a regulatory Food Analysis Laboratory (indicative list)

The number of personnel and their educational and experience levels depends on the analyses to be offered, the methods chosen and the expected sample throughput. The analysis of enforcement and surveillance food samples can be carried out analytical parameter wise or product wise to meet compliance. In either case microbiological, heavy metals and pesticide/antibiotic residue analysis need specialised independent facilities and personnel with high analytical skills[14]. A detailed typical organisational structure is shown in Figure 2.4.3.

[14] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

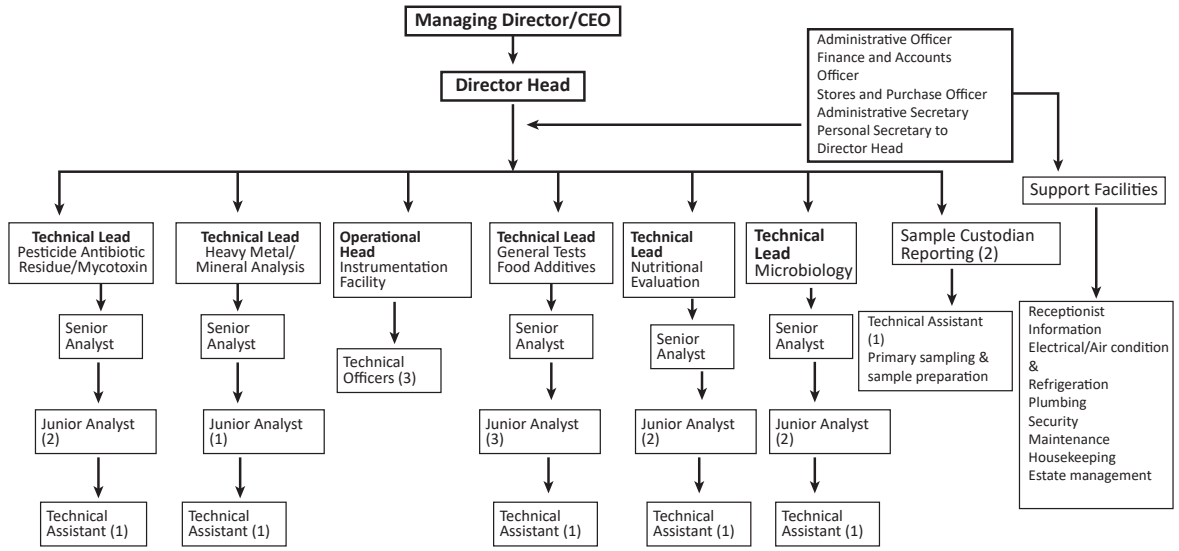


Fig. 2.4.3: A typical organisation chart for a food analysis laboratory.

2.4.4 Quality Control Section

The goal of the food analysis laboratory is to guarantee the generation of accurate and reliable analytical results. Having a quality control section, which is optional minimizes reporting of erroneous results, prevents excessive repetition of analytical runs. These procedures are designed Quality control is designed to detect deficiencies in a laboratory's internal analytical process and to make certain that samples are representative and data are reliable and defensible prior to the release of results. Quality control samples are samples taken at random and the testing process carried by analysts in the QC division using the same method and operating conditions. The purpose of including analysis of samples by the QC division is to evaluate the reliability of lab results. The analysts of the QC division play an important part in assuring the quality of laboratory tests. The manpower required is one senior analyst, two junior analysts and one technical assistant.

UNIT 2.5: Food Safety Requirements at the Workplace

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the environmental conditions, safety and related requirements in the microbiological laboratory.
2. Explain safety measures in the laboratory.

2.5.1 Environment Conditions, Safety and Related Norms

Environmental Control

The following environmental or external control is required in the laboratory[15]:

- Acceptable control of temperature, humidity and dust is important to staff comfort, instrumental performance and safe working (e.g., with flammable solvents). If they are to perform properly optical instruments often require stable temperature conditions.
- Electronic equipment may have prescribed operating ranges for environmental temperature and humidity.
- Computers may need to be protected from strong magnetic fields from other equipment; any staff or visitors with heart pace-makers must avoid such fields.
- Cooling water, either from mains supplies or localized refrigeration may be necessary for the proper functioning of some equipment.
- Test materials, reagents, standards may need to be stored under controlled conditions. Some substances are affected by sunlight or fluorescent lights and must be protected from it.
- Delicate balances and optical instruments may need to be protected from vibration (e.g., from blenders, shakers and centrifuges) or may even need stabilized supports. All these needs have to be identified and documented so that proper procedures for monitoring them and taking necessary action can be included in the quality assurance system.
- Records will be essential to be maintained which show that: samples are received, stored, handled and analyzed under environmental conditions that will not adversely affect analysis; temperature, humidity and light controls are adequate in sensitive areas to protect samples, extracts from them, personnel and equipment; the results of environmental sampling in laboratory areas are recorded; these should include records of air-flow rates across fume cupboard apertures.

Housekeeping Control

As with any other aspect of the laboratory's activities, the responsibility for housekeeping activities must also be clearly defined. Cleaning staff and laboratory staff must each have clear instructions as to their respective duties in relation to:

1. Cleaning of floors, vertical surfaces (e.g., cupboards, walls, windows and doors);
2. Horizontal surfaces (e.g., work surfaces, shelves), equipment, interiors of refrigerators, freezers, fume cupboards, controlled environment stores;

[15] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

3. Control of the contents of refrigerators, freezers, fume cupboards, controlled environment stores;
4. Checking the performance of air-conditioning and dust extraction equipment and fume-cupboards;
5. Pest control
6. The quality assurance Programme will include work schedules, records of observations and of action required/taken covering housekeeping activities of this nature.
7. The Quality Assurance Programme is discussed in detail in module 8.

Safety Features recommended for food analysis laboratory

The building and laboratory design should include a number of safety features including:

1. The fire areas of corridors should be formed of concrete blocks;
2. Services should include a shower sprinkler system near each doorway so that a worker can take an immediate shower, clothes and all, in the case of accidental general contact with corrosive or poisonous liquids or fire;
3. There should be built-in eye wash fountains or at least portable eyewash stations (obtainable from most chemical supply firms);
4. The traffic flow, the door pattern and the proportions of the laboratory are all safety considerations. It must always be possible to leave the laboratory safely irrespective of the initial site of a fire. Serious thought must be given to the number and location of fire extinguishers and stand pipe systems, and to the availability of sprinkler systems;
5. Laboratories should be well-lit so that the operator does not have to peer too closely over potentially hazardous material in order to see what he is doing. There should be ample working space and bench tops and other surfaces should be kept clear of all material except that in current use;
6. Benches are best without shelves, only services, these being operated from the front so that the operator does not have to stretch across the bench. It is still common to see reagents on shelving at the back of benches (or above the center of double-width benches) but it is probably safer if such reagents can be kept on side - shelve or in trays which are brought to the bench as required;
7. Flooring needs to be of a non – slip material, resistant to acids and solvents, but not so hard as to be tiring to stand on for a few hours at a time. No material is entirely satisfactory. Well-laid linoleum and a filled epoxy resin on top of concrete are among the best available. It is advisable not to polish laboratory floors;
8. Pollutants generated within the laboratory must be removed safely, quickly and efficiently. In particular, toxic or noxious gases must be removed expeditiously through a duct system that does not exhaust near the building air conditioning intake;
9. The building must be planned for security. Restriction of access is of considerable importance because of the extremely valuable and sensitive equipment used in the laboratory work as well as to protect the integrity of official samples;

Designing a laboratory to afford protection against every kind of hazard should be aimed at, but, the level of safety for the most general applications and to provide supplementary systems in areas of higher hazard has to be achieved;

A safe solvent storage area is ideally separate from the laboratory building in a standalone structure. It can be a small building of one room and some possible design features are:

1. Construction of cement blocks or bricks (Only non-flammable materials surround the solvents);
2. For a stand-alone building, double walls with insulation between. The exterior wall can be material other than block or brick. (Provides insulation from the sun and makes air conditioning more effective);

3. An epoxy film to cover the entire floor plus 10 cm up the base of the walls. (Any solvent spillage will pool and evaporate, rather than soak through the floors or walls);
4. A copper pipe (about 25 mm) inside the room, which goes through the floor and is embedded about 2 m in earth. (A ground pipe to bleed off any static electricity charges - which often build up when solvents are poured). All metal objects in the room are to be attached to the pipe using heavy gauge single strand copper wire. Also, attach a short wire with an alligator clip. (These grounds all metal. The clip is used to ground any metal cans used for solvent transfer.)
5. Storage shelves of metal and connected by wire to each other and the grounding pipe;
6. Air conditioning is external, with the entrance duct at the top of one corner of the room and the exit duct at the base of the opposite corner. (The room must be cooled as many solvents will boil at hot outside temperatures. The air entrance on top and exit on the bottom diagonally across the room, will cool the room and will also serve to sweep and remove any solvent fumes on the floor - solvent fumes are generally heavier than air and will pool on the floor.);
7. The door is of metal and fire-rated for at least one hour, with a positive closure. It must seal well when closed. The door sill is at least 10 cm high. (Fire doors are metal sheathed around cement. The closure, the sea land the high sill all act to prevent escape of solvent, either floor spillage or fumes.);
8. Air conditioner exits duct with a fire baffle (to prevent flashback) and ducted to exit in the outside air at building roof height. (Fumes have a better chance of being carried away by breezes and someone smoking nearby will not present a fire risk.);
9. An extinguisher system, which should be carbon dioxide or Freon type and not water sprinklers.

Fig. 2.5.1: Biological Safety Cabinet in a BSL-2 Laboratory

2.5.2 Laboratory and Personnel Safety

Use of Safety Equipment

The availability and use of a number of types of safety equipment is essential and must be present in well-marked, highly visible, and easily accessible locations in or near all laboratories in the facility and must be maintained in working conditions. All laboratories should be provided with the following Safety and Emergency Equipment's.

- Fume hoods (60–100 ft/minute capture velocity, vented outside) and Safety shields with heavy base;
- Hand wash facility;
- Hand-free eye-wash stations (not eye-wash bottles) that conform to American National Standards Institute (ANSI) Z358.1– 2004;
- Safety showers that conform to ANSI Z358.1–2004;
- Fire extinguishers (dry chemical and carbon dioxide extinguishers) and Sand bucket
- Fire blankets;

- Fire detection or alarm system with pull stations;
- Chemical storage cabinets (preferably with an explosion proof ventilation system);
- Emergency lights;
- Emergency signs and placards;
- First-aid kits;
- Spill control kit (absorbent and neutralizing agents);
- Large plastic buckets for carrying chemical bottles;
- Ground-fault interrupter electrical outlets;
- Separate Containers for broken glass and sharps;
- Material Safety Data Sheets (MSDSs) of all hazardous chemicals;
- Emergency Action Plan for the laboratory.

Safety design in labs

- In most cases, labs should be organized with the highest hazards (e.g., fume hoods) farthest from the entry door and the least hazardous elements (e.g., write-up stations) closest to the door;
- Write-up desks and benches should be accessible without having to cross in front of fume hoods;
- All safety equipment such as emergency showers, eyewashes, first-aid kits and spill kits should be readily accessible;
- An emergency Centre in a central location on each floor, provides easy access for everyone. This center should have reagent neutralizers, spill kits, first aid etc.;
- There should be at least one fire extinguisher either inside the lab, or in close proximity;
- Extinguishers should not be blocked access or covered up;
- In each lab, there should be an eyewash unit;
- Provided at least 10 seconds away from any analyst;
- It should supply a multi-stream cross flow of water at 20-25 °C (65°- 75°F);
- Contaminated eyes should be flushed for 15 minutes;
- Water flow at a rate of 10-20 L (3 to 7 gallons) of water per minute;
- Safety showers should never be more than 100 ft. away from the analyst, along a clear and unobstructed path;
- Safety showers have historically been placed in the corridor, highly visible from the lab exits. a door is now considered an obstruction therefore preferable inside the lab. All safety showers should include an eyewash;
- Putting a floor drain under the shower is not recommended. To prevent contamination, it is preferable to allow the chemicals at the shower to be mopped up;
- Electrical apparatus, telephones, thermostats, electrical control panels, or power sockets should not be located within 0.5 m of the emergency shower or eyewash or within any area that may be considered as a splash or flood zone;
- Safety showers should provide low-velocity water at 25-30 °C (70° to 90° F);
- Manual close valves are recommended for all safety showers. A safety shower should be designed with an automatic cutoff.

Electrical Services and Safety

In the laboratory, a wide variety of electrically-powered equipment including stirrers, shakers, pumps, hot plates, heaters, power supplies, ovens, and others are used. The following are some basic guidelines for electrical services in the laboratories:

- Electrical outlets should have a grounding connection and accept three-prong plugs. Multiple plug outlet adapters should not be used.
- General power outlets should be above the bench height. Ceiling-mounted, or floor- mounted receptacles should be provided as needed for laboratories where equipment will be located away from walls to avoid trailing cables on the floors.
- Electrical socket outlets, outlets for telecommunication appliances and outlets for computer networks should positioned away from sinks/showers etc.
- Electrical outlets should also be positioned as far as possible from valves for flammable gas and flammable solvent storage
- Location of electrical panels and shut-off switches must be easily identifiable to quickly disconnect power in the event of an emergency.
- Leave at least a 3-foot clearance around electrical panels, circuit boxes, for easy and ready access. Maintain an unobstructed access to all electrical panels.
- Uninterrupted power supply required for equipment must be considered while designing the laboratory power supply system.
- Emergency lighting and illuminated exit signs are mandatory to facilitate emergency evacuation in the event of power failure.
- All the circuit breakers and the fuses should be labelled to indicate whether they are in the "on" or "off" position
- Fuses must be properly rated.
- Avoid using extension cords
- Electric cables should not be routed over metal objects such as emergency showers, overhead pipes or frames, metal racks, etc.
- Avoid multi-outlet plugs unless they have a built-in circuit breaker.

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3. Introduction to Food Microbiology

Unit 3.1 - Types of Microbes

Unit 3.2 - Best Practices to Avoid Food Spoilage

Key Learning Outcomes

At the end of this module, you will be able to:

1. List the types of food microbes.
2. Explain the process and causes of food spoilage.
3. Illustrate the criteria to check food spoilage.

UNIT 3.1: Types of Microbes

Unit Objectives

At the end of this unit, you will be able to:

1. List the types of food microbes.
2. Describe scope of the microorganisms.
3. Summarize importance of microorganisms in foods.

3.1.1 Food microbiology – It's origin and scope

Food microbiology is an important branch of microbiological science which deals with microorganisms associated with food; playing beneficial roles (food producers), harmful roles (causing spoilage of food and food borne-diseases) or microbes involved in preserving food.

The association between foods and microorganisms was not established up to 1800's although processes of food spoilage, and procedures of food preservation and food fermentation have been recognized since ancient times.

Fig. 3.1.1: Schwann and Pasteur laid the foundation for the development of Food Microbiology

In 1837 Schwann proposed the association of yeast with alcoholic fermentation, and between 1857 and 1876 Pasteur showed that microorganisms were responsible for the chemical changes that take place in foods and beverages. Their observations put the foundation for the progress of Food Microbiology as we know it today. Soon after these early discoveries were made, knowledge about the part that microorganisms play in food fermentation, food preservation, food spoilage and food poisoning fast-tracked until food microbiology increasingly emerged as a discipline in its own right. Food microbiology is now a highly advanced area of knowledge.

Not all groups of micro-organisms are of equal curiosity to the food microbiologist. Bacteria are the most important followed by molds and yeasts and viruses. The associations that these organisms have with the manufacture and consumption of foods are summarized below.

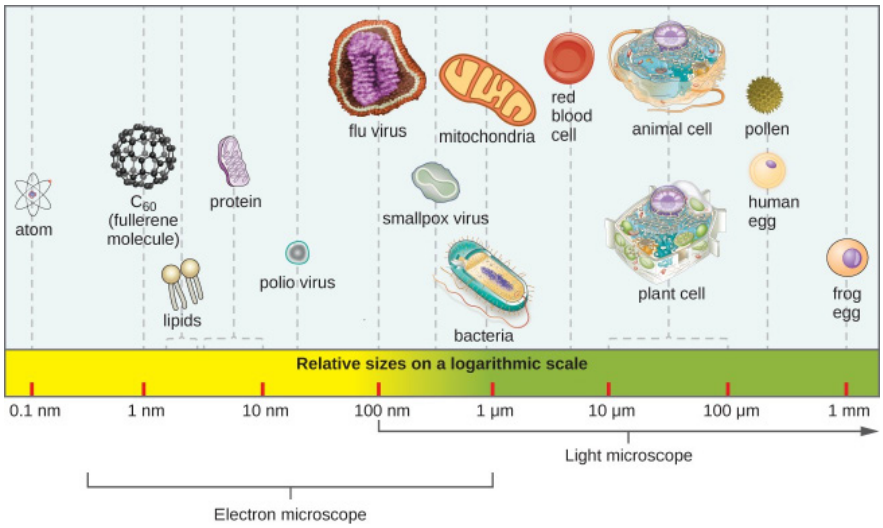


Fig. 3.1.2: Micro-organisms as we know them

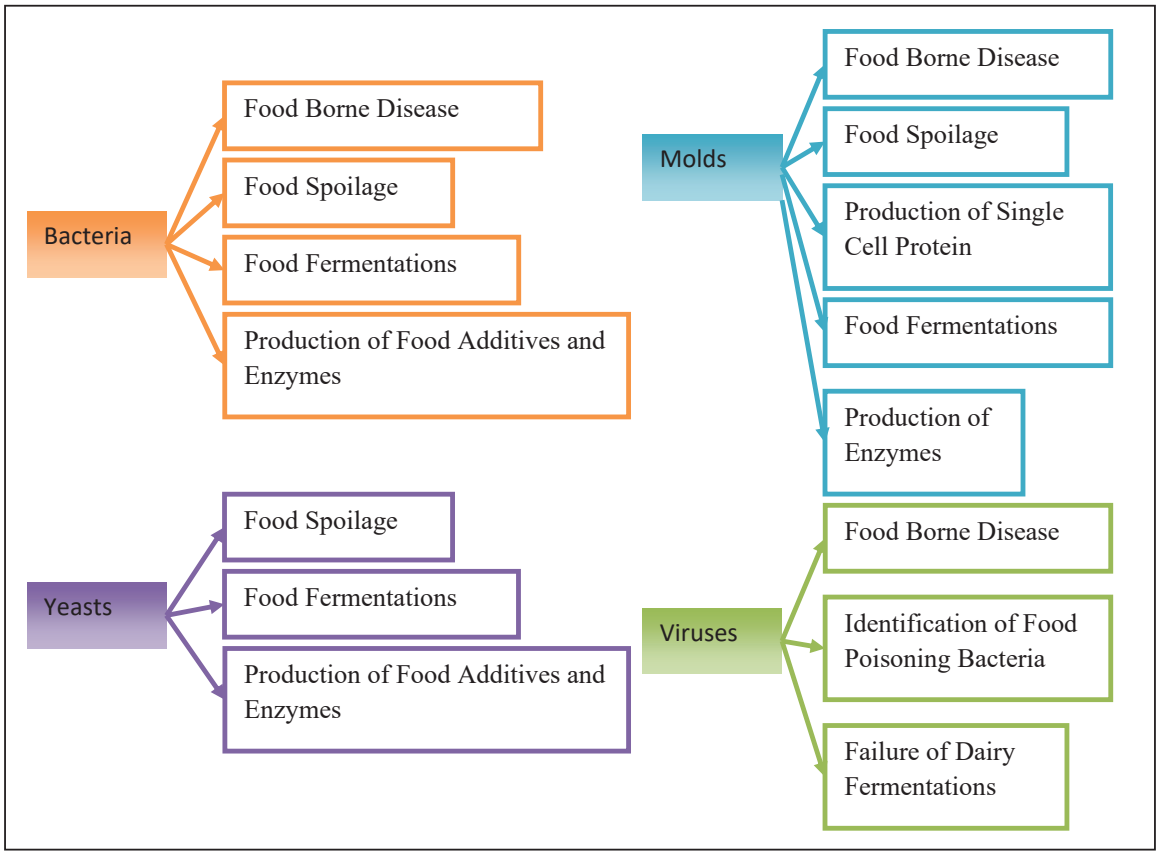


Fig. 3.1.3: Various groups of microorganisms and their associations with food

Protozoa and algae have least direct effect on the production, processing and consumption of food. Food-borne disease can be triggered by some protozoa and others fitting to this group are vital in the treatment of wastes. Algae are used to harvest alginates; some have the potential for use in the production of single-cell protein and some marine species yield toxins that might come in our food along with sea foods.

Importance of Microorganisms in Foods

Since 1900 A.D. our understanding of the importance of micro-organisms in food has improved greatly. Their role in food can be either necessary (food bioprocessing) or unwanted (food borne diseases and food spoilage).

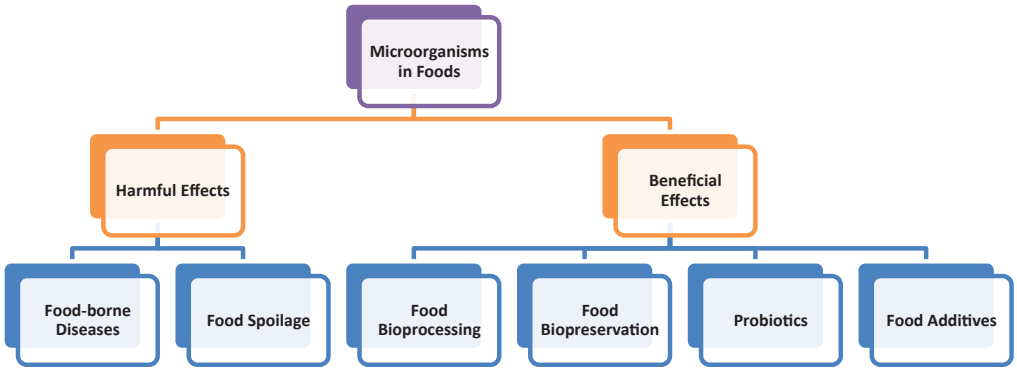


Fig. 3.1.4: Beneficial and Harmful uses of Microbes in Food

3.1.2 Harmful Effects of Microbes on Food

Food-borne Diseases

Numerous pathogenic small-scale life forms (microscopic organisms, molds and infections), if present in food can cause food borne diseases. A foodborne illness is one that originated from food. We also refer to it as a foodborne disease or as food poisoning. Any disease or illness that caused from contaminated food is a foodborne illness. Bacteria, viruses, parasites, fungi, and other poisons, for example, may have contaminated the food that caused an illness.

Mass manufacture of food, introduction of new technologies in the processing and food storage, changes in food consumption patterns, and increased import of food from other countries have enhanced the chances food borne diseases. There are also chances of introduction of new pathogens. But development of new technologies and execution of sanitation and safety standards helps to ensure the safety of consumers against food borne diseases. New methods are also being established to efficiently and swiftly identify the pathogens in contaminated foods.

Food Spoilage

All foods will have presence of some micro-organisms, except sterile foods. Food spoilage stems from the development of these micro-organisms in food or is due to the action of microbial enzymes. New marketing inclinations, consumers' desire for foods that are not excessively processed and preserved, stretched shelf life, and chances of temperature misuse between production and consumption of foods have significantly increased the chances of food spoilage and, in some instances, with new types of micro-organisms. The major apprehensions are the economic loss and wastage of food. New concepts are being considered to decrease contamination as well as control the growing of spoilage microbes in foods.

Food decay results from the development of food of these micro-organisms or is caused by the action of microbial enzymes. Chances of increase spoilage of food are due to:

- New marketing patterns
- consumer's demand for food that its highly refined and stored,
- storage temperature abuse during food processing and consumption

Food Bioprocessing

Many food grade micro-organisms are used to produce various types of fermented foods using raw materials from animal and plant sources. Consumption of these foods has increased significantly over the last 15 to 20 years and is likely to increase further in the future. There have been great variations in the production and availability of these micro-organisms (starter cultures) to meet the huge demand. In addition, novel and better strains are being established by using genetic engineering techniques.

Food Additives

Microbial enzymes are also found in food and dietary additives. Enzymes of higher purity & activity are obtained by using genetic recombination techniques and using different microbial sources. Many forms of additives are being produced from microbial sources and used in food. Many of them include single-cell proteins, essential amino acids, compounds of color, compounds of taste, stabilizers and organic acids.

Food Bio preservation

Antimicrobial metabolites such as bacteriocins and organic acids like acetic, propionic and lactic acids of desirable micro-organisms are being utilized in foods in place of preservatives of non-food (chemical) origin to governor pathogenic and spoilage micro-organisms in food. Economic manufacture of these antimicrobial compounds and their effectiveness in food systems have generated wide interest.

Probiotics

Probiotics are living bacteria and yeasts that are good for individual's digestive system. One usually thinks of these microbes as source of diseases, but your body is full of bacteria, both good and bad. Probiotics are often called "good" or "helpful" bacteria because they help keep your gut fit.

3.1.3 Classification and Nomenclature of Microorganisms

Living cellular organisms, on the basis of phylogenetic and evolutionary relationships, are gathered into five domains in which bacteria belong to prokaryote (before nucleus), while the eukaryotic (with nucleus) molds and yeasts are grouped under fungi. Viruses are not considered as living cells and are not encompassed in this classification system.

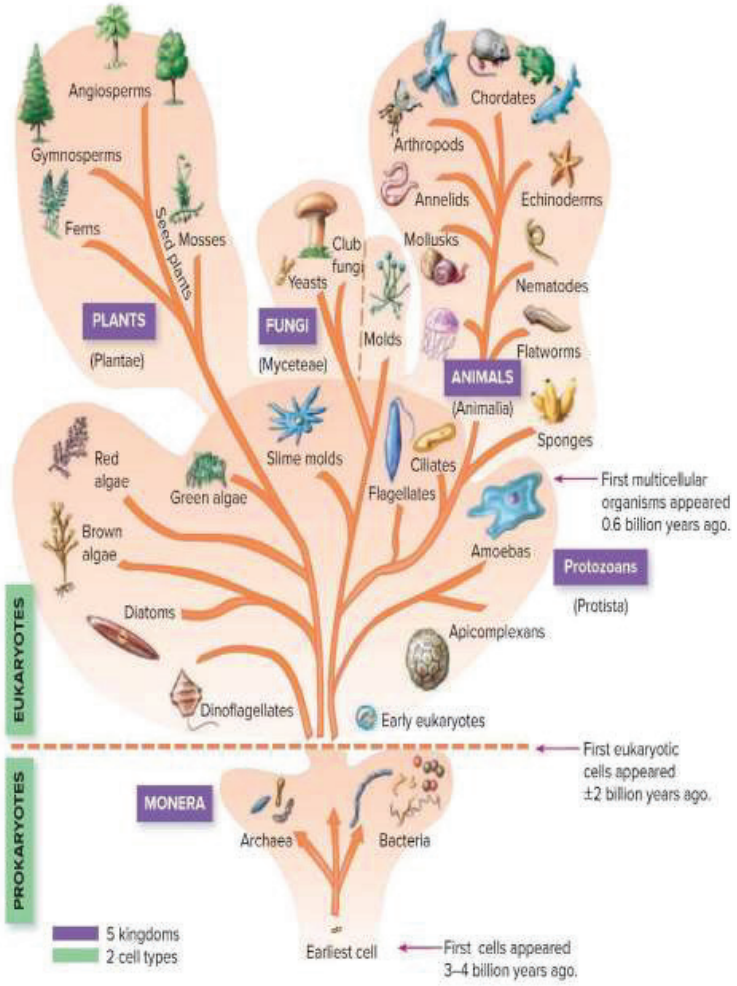


Fig. 3.1.4: Classification and Nomenclature of Microorganisms

For the type of yeasts, molds, and bacteria, several ranks are used after the kingdom. These are divisions, classes, orders, families, genera (singular, genus), and species. The fundamental taxonomic institution is the species. Several species with similar traits form a genus.

Fig. 3.1.5: A Student Microscope

3.1.4 Taxonomic Rank

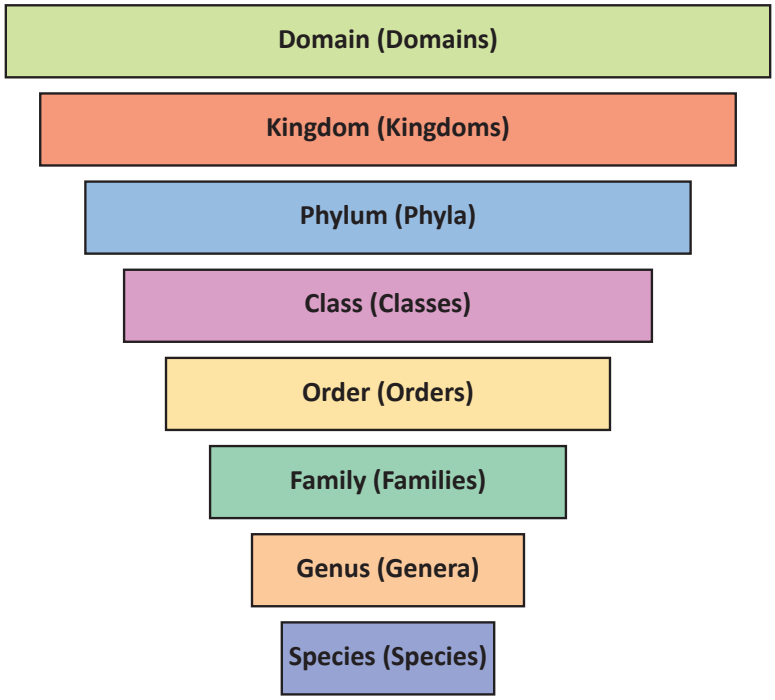


Fig. 3.1.6: Taxonomic Rank

The primary taxonomic group in bacteria, yeasts, and molds is the species, and every species is given a name. The name has two parts (binomial call); the first component is the type name and the second one part are the unique epithet (adjective). Both parts are Latinized; when written, they are italicized (or underlined) with the first letter of the type written in a capital letter and species call in small letters. For e.g., Bacillus subtilis (genus is Bacillus and species is subtilis). A family is made up of several genera, and the same technique is followed in the hierarchy. Ranks above species, genus, and circle of relatives are seldom used in food microbiology. Among microorganism, a species is regarded as a collection of traces having many not unusual features. A pressure is the descendent of a single colony (single mobile). Among the traces in a species, one is assigned as the type stress; it's far used as a reference stress even as comparing the characteristics of an unknown isolate. Let’s now examine certain businesses which are crucial biologically:

1. The Microorganisms most not unusual to food are microorganism and fungi. The fungi consist of two major styles of Micro- organisms, viz. Molds and yeasts. Apart from these, food may include of viruses and other parasites inclusive of protozoans, worms etc.
2. Bacteria are unicellular Micro-organisms which can be about one micro meter (10-3 micrometers) in diameter with variations in morphology from quick and elongated rods (bacilli), spherical or ovoid forms(cocci), vibrio (comma shaped) and even spiral in shape (Refer Figure 3.1.7). Cocci (meaning “berry”) are sphere shaped bacteria. Individual microorganism very well integrates in diverse forms in step with genera. Some sphere-shaped bacteria occur in clusters similar to a bunch of grapes (i.e., Staphylococci). Other bacteria (rod formed or sphere formed) are linked collectively to form chains (i.e., Streptococci in case of cocci chain).

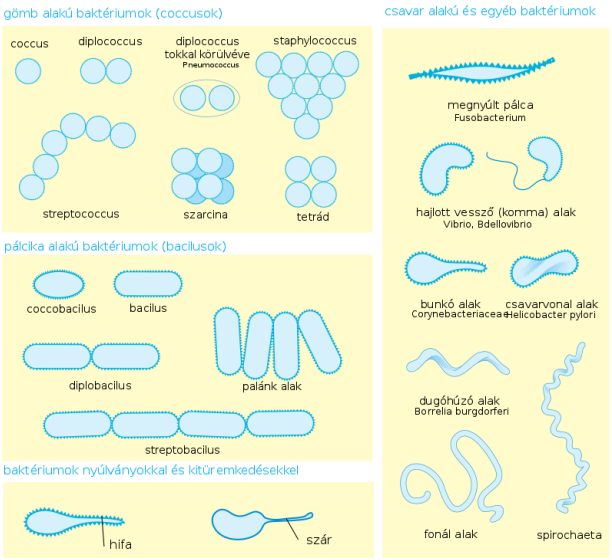


Fig. 3.1.7: Types of Bacteria

3. Certain genera of sphere-shaped microorganism are determined collectively in pairs (diplococci i.e., Pneumococci) or as a collection of four (Square or cubical packets formation; i.e., Sarcinia), at the same time as different genera seem as male or female bacterium. Other microorganism (in majority) is rod fashioned and own flagella and are motile. Bacteria produce diverse pigments which variety from sun shades of yellow to darkish pigments which includes brown or black. Certain microorganism has pigmentation of intermediate colorations which includes red, pink, orange, blue, green, or purple. These microorganism cause food discolorations, especially, among foods with unstable shade pigments which includes meat. Some bacteria also reason discoloration by means of slime formation.
4. Fungi or Molds are multicellular micro-organisms with mycelial (filamentous) morphology. These microbes are also characterized through their display of a number of colorings and are generally diagnosed by using their mildew or fuzzy, cotton like look. Molds can develop several tiny spores which can be located inside the air and may be spread through air currents. These spores can produce new mold increase if they may be transferred to a region that has conditions conducive to germination. Molds normally withstand more fluctuation in pH than bacteria and yeasts and can frequently tolerate extra temperature fluctuation. Although molds thrive first-class at or near a pH of 7.0, a pH range of 2.0 to 8.0 can be tolerated, even though an acid to impartial pH is preferred. Molds thrive higher at ambient temperature than in a chillier environment, even though increase can occur below 0°C and want a good quantity of moisture to grow. That is why foodstuffs, which include pastries, cheeses, and nuts, which are low in moisture content are much more likely to spoil from mold increase.

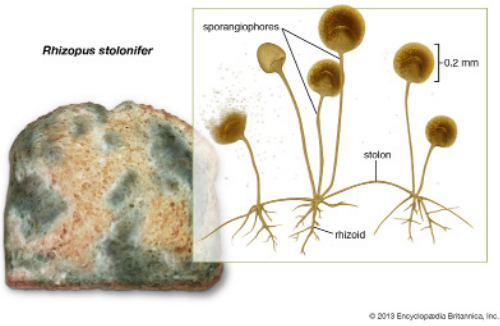


Fig. 3.1.8: Functional types of hyphae using the mold Rhizopus

These fungi have two types of branches or hyphae:

5. Vegetative hyphae are those surface and submerged filaments that digest, absorb, and distribute nutrients from the substrate. This species also has special anchoring structures referred to as rhizoids. During the asexual life cycle, the loose mold spores decide a substrate and ship out germ tubes that elongate into hyphae. Through continued growth and branching, an in-depth mycelium is produced.
6. Later, as the fungus frame matures, it sprouts reproductive hyphae that produce asexual spores. So prolific are the fungi that a single colony of mold can easily comprise 5,000 spore-bearing structures. Yeasts are commonly unicellular and fluctuate from microorganism in their big mobile size and morphology, and due to the fact, they produce buds for the duration of the manner of reproduction with the aid of division. Like molds, yeasts may be spread through the air, or different means, and alight on the floor of foodstuffs. Yeast colonies are normally moist or slimy in look and creamy white colored. These micro-organisms develop exceptional in the intermediate acid range, pH from 4.0 to 4.5. Food this is notably infected with yeasts will frequently have a fruity odor.

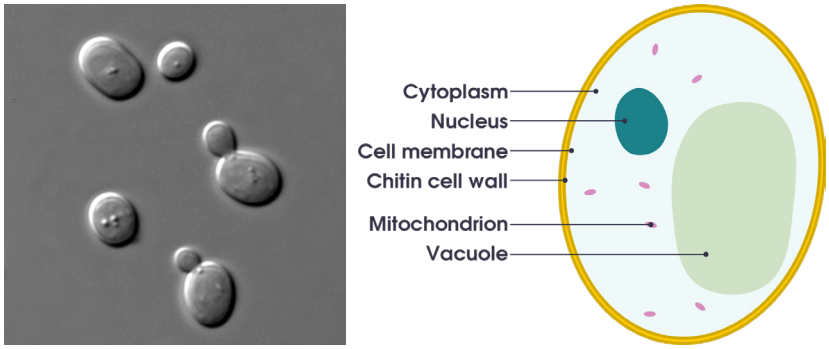


Fig. 3.1.9: Yeast cell

7. Viruses are 10- 450 nm in length; cannot reproduce without a living host; attack simplest prone host cellular lines; infect plants, animals, and microorganism; and have the capability to produce unique illnesses in specific hosts. Transmission happens in foods, water and air. Viruses that infect microorganism are called bacteriophages. Viruses are too small to be seen with a compound microscope. Only after the electron microscope changed into developed, the direct statement of viruses was possible. Viruses include a DNA or RNA middle surrounded by means of a protein coat. Because they lack all the equipment for ordinary mobile metabolism, they need to make use of the cellular equipment of the host cellular as a way to grow and divide. Once they invade a host mobile, however, viruses can multiply very rapidly.

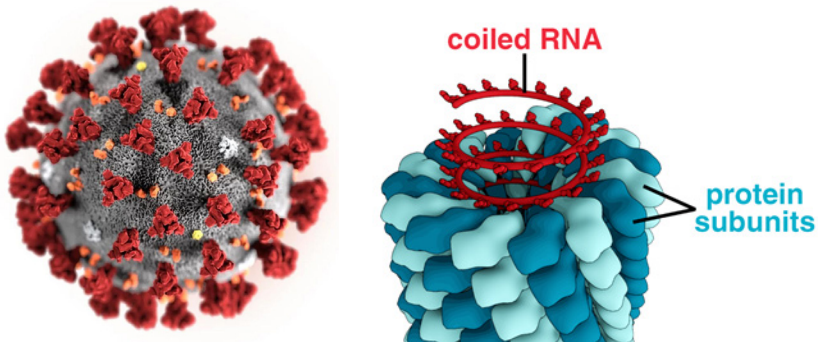


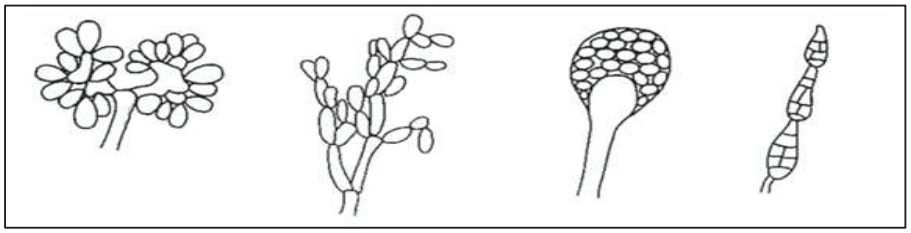
Fig. 3.1.10: Generalized structure of viruses

3.1.5 Important microorganisms in food

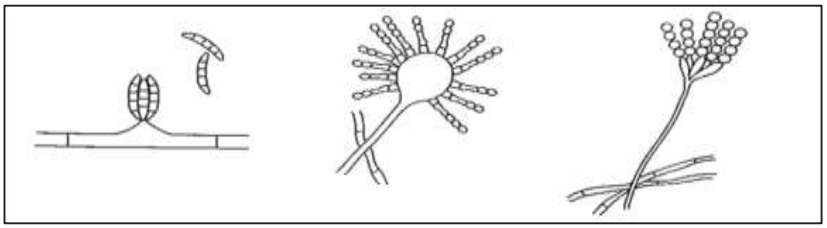
Common Molds Found in Food

Molds are important in food because they may grow in conditions where other bacteria are unable to do so, such as low pH, low water activity (a_w), and high osmotic pressure. These are essential micro-organisms in spoilage. Many strains also contain mycotoxins and had been involved in intoxication-borne food. Many are used in the bioprocessing of food. Finally, others are used to produce food additives and enzymes. Below are listed some of the most common genera of molds seen in the food.

- **Aspergillus:** These are commonly dispensed, and include many food-critical organisms. They have septate hyphae, and contain asexual (black) or conidia spores. Most are xerophilic (capable of growing at low a_w) and can grow in cereals, causing spoilage. They are also concerned with food spoilage along with jams, cured ham, nuts, and end result and vegetables (red). Some species / strains produce mycotoxin (for example, Aflatoxin is released by Aspergillus flavus). Many species / strains are also used in food and in processing food additives. Aspergillus oryzae is used in sake making to hydrolyze starch through alpha-amylase. Aspergillus Niger is used for the extraction and production of citric acid from sucrose.
- **Alternaria:** These are also septate, and several lad conidia on the conidiophore type dark-brown colored. They provide a cause of tomato rot and rancid taste in dairy products. Species: Alternaria tenuis.
- **Geotrichum:** The hyphae are septate and form asexual rectangular arthrospores (oidia). They grow yeast-like shaped, cotton-like, creamy colony. They are easily found in machinery and sometimes grow on dairy products (also known as milk mold). Species: Geotrichum candidum.
- **Mucor:** They are common. They contain non-septate hyphae and sporangiophores. They harvest colonial cotton. Many organisms are used to ferment foods and to produce enzymes. They cause vegetable spoilage. Species: Mucor rouxii.
- **Penicillium:** They are widely distributed, and they include several species. These have septate hyphae on a blue-green, brush-like head of conidia, which form conidiophores. Some species are used in food production, such as Penicillium roquefortii and Penicillium camembertii in cheese. Many species are a reason of fungal rot in fruits and vegetables.
- **Rhizopus:** The hyphae in sporangium are aseptate, and form sporangiophores. They cause many fruits and vegetables to spoil. Rhizopus stolonifer is the common black bread mold.



Botrytis **Cladosporium** **Rhizopus** **Alternaria and for enzyme production.**



Fusarium **Aspergillus** **Penicillium**

Fig. 3.1.11: Most common genera of molds found in food

Common Yeasts Found in Food

Yeasts are important in food due to their ability to cause spoilage. Many are also used in food bioprocessing. Some are used to produce food additives. Several important genera are briefly described below.

- **Saccharomyces:** This is the most important genus which contains heterogeneous species. Cells are round, rectangular, or elongated. *Saccharomyces cerevisiae* variants are used in baking for leavening of bread and in alcoholic fermentation. They are also involved in spoilage of food with the production of alcohol and CO_2.
- **Pichia:** They are oval to cylindrical cells and form pellicle in beer, wine, and brine to cause spoilage. Some are also used in oriental food fermentation. Species: Pichia membranaefaciens.
- **Rhodotorula:** They are pigment (red, pink or yellow) forming yeasts and can cause discoloration of foods, such as in meat, fish, and sauerkraut. Species Rhodotorula glutinis.
- **Torulopsis:** They have spherical to oval structure. They cause spoilage of milk due to the ability to ferment lactose (Torulopsis sphaerica). They also spoil fruit juice concentrates and acid foods.
- **Candida:** Many spoil foods with high acid, salt, and sugar and form pellicle on the surface of liquids. Some can cause rancidity in butter and dairy products (Candida lipolytica).
- **Zygosaccharomyces:** Involved in spoilage of foods, containing high sugar/ salt levels ex. honey, syrups, molasses, soy sauce. (Zygosaccharomyces nussbaumeri). Such yeasts are called osmophilic, because they can grow at high solute concentrations.

Common Viruses Found in Food

Viruses are vital in food for three reasons. Some are able to cause enteric disease and thus, if found in a meal, can lead to meal borne diseases. Hepatitis A and Norwalk viruses had been implicated in food borne outbreaks. Several other enteric viruses, inclusive of Poliovirus, Echovirus, and Coxsackievirus, have the ability of inflicting food borne diseases. In some countries where the extent of sanitation isn't always very excessive, they could contaminate ingredients and motive disorder.

Common Bacterial Groups in Foods

Among the micro-organisms determined in foods, bacteria constitute a major important group. This is not only due to the fact many distinctive species can be present in foods, but is also due to their rapid boom rate, capacity to make use of food nutrients, and their potential to grow beneath a wide range of temperatures, aerobiosis, pH, and water activity, as well as to survive under unfavorable situations, which include survival of spores at high temperature. For convenience, bacteria critical in ingredients were randomly divided into several groups on the basis of similarities in positive characteristics. This grouping does not have any taxonomic significance. Some of these corporations and their importance in ingredients are indexed below in table 3.1.1.

Type of Bacteria	Characteristics	Species
Lactic Acid Bacteria	Produce relatively large quantities of lactic acid from carbohydrates	Lactococcus, Leuconostoc, Pediococcus Lactobacillus and Streptococcus thermophilus
Acetic Acid Bacteria	Produce acetic acid	Acetobacter aceti
Propionic Acid Bacteria	Produce propionic acid and are used in dairy fermentation	Propionibacterium freudenreichii
Butyric Acid Bacteria	Produce butyric acid in relatively large amounts	Clostridium butyricum

Type of Bacteria	Characteristics	Species
Proteolytic Bacteria	Capable of hydrolyzing proteins due to production of extracellular proteinases	Micrococcus, Staphylococcus, Bacillus, Clostridium, Pseudomonas
Saccharolytic Bacteria	Hydrolyze complex carbohydrates	Bacillus, Clostridium, Aeromonas, Pseudomonas, and Enterobacter
Thermophilic Bacteria	Able to grow at 50^{O}C and above	Bacillus, Clostridium, Pediococcus Streptococcus, and Lactobacillus
Psychotropic Bacteria	Able to grow at refrigerated temperature (<20^{O}C).	Pseudomonas, Alteromonas, Alcaligenes, Flavobacterium, Serratia, Bacillus, Clostridium, Lactobacillus, Leuconostoc, Listeria, Yersinia and Aeromonas
Thermoduric Bacteria	Able to survive pasteurization temperature	Micrococcus, Enterococcus, Lactobacillus, Pediococcus, Bacillus (spores) and Clostridium (spores).
Halotolerant Bacteria	Able to survive high salt concentrations (>10%)	Bacillus, Micrococcus, Staphylococcus, Pediococcus Vibrio Streptococcus, Clostridium and Corynebacterium
Aciduric Bacteria	Able to survive at low pH (below 4.0)	Lactobacillus, Pediococcus Lactococcus, Enterococcus and Streptococcus
Aerobes	Require oxygen for growth and multiplication	Pseudomonas, Bacillus, and Flavobacterium
Anaerobes	Cannot grow in the presence of oxygen	Clostridium
Fecal Coliforms	Used as index of sanitation	Include mainly Escherichia coli

Table 3.1.1: Bacterial Association with foods

UNIT 3.2: Best Practices to Avoid Food Spoilage

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the process and causes of food spoilage.
2. Illustrate the criteria to check food spoilage.

3.2.1 Growth of Micro-organisms

Spoilage is decomposition. It results due to certain kinds of bacteria, or their toxins, in wide variety or quantities which make the food poisonous and thus undeserving for human consumption.

The criteria for quality assurance of foods fit for human consumption are:

- The maturity of food object in question;
- Contamination of the food at any degree inside the manufacturing;
- Contamination of the food at any degree of dealing with of the food;
- Absence of any form of chemical and physical adjustments resulting from action of food enzymes; interest of microbes;
- Absence of harm from pressure, freezing, heating, drying etc.;
- Independence from micro-organisms and parasites causing food borne illnesses.

Enzymatic and microbial activities are unwanted when they're undesirable or uncontrolled. An example is the souring of milk; if unwanted, it is spoilage, yet the same procedure is purposely used in the production of positive cheeses and different fermented products crafted from milk.

Types of Spoilage

The food may become unacceptable due to the following factors:

- Uncontrolled growth of micro-organisms which include bacteria, yeasts and moulds;
- Undesired sports of food enzymes;
- Action of insects, parasites and rodents;
- Chemical changes in a food that is not catalysed by way of enzymes of the tissues or of micro-organism. For example, the chemical oxidation of fat generating rancidity;
- Physical modifications or damages which includes those as a result of freezing (freezer burn), by using drying (caking) etc.

Classification of Foods on the Basis of Stability Foods are often classified on the basis of their constancy as nonperishable, semi perishable, and perishable.

Fig. 3.2.1: Classification of Foods on the Basis of Stability (Source: FSSAI)

The multiplication of spoilage organisms on or in the food materials depends on many factors:

Fig. 3.2.2: Factors Affecting Growth of Organisms

Phases of Growth of Microorganisms

A typical boom curve has four regions. A preliminary duration of no increase known as lag phase, followed with the aid of rapid boom known as logarithmic phase. No increase is discovered in stationary section and death phase. The time a bacterium takes to multiply (double its number) is referred to as its technology time.

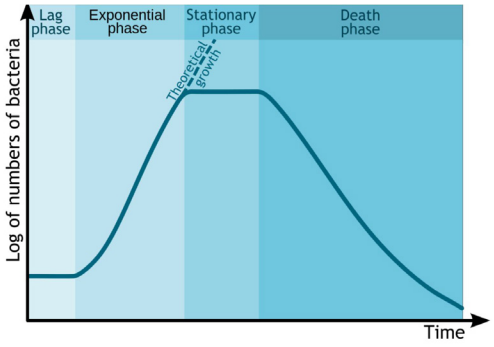


Fig. 3.2.3: Phases of Growth of Microorganisms

As micro-organisms grow, they form colonies. Each colony is made up of tens of millions of cells. After a colony matures the substrate available to each cell is restrained this happens in the stationary phase. If we can control bacterial boom, in its early stages we are able to manipulate the major purpose of food spoilage.

Factors affecting Spoilage

Food is a chemically complex, and predicting whether, or how fast, micro-organisms will develop in any given food is difficult. Because the ingredients contain sufficient nutrients and can easily assist microbial increase. Several elements encourage, prevent or limit the boom of micro-organisms in foods; the most essential are moisture content, pH and temperature.

Factors affecting microbial boom are divided into groups -intrinsic and extrinsic parameters. These factors have an effect on the boom of microorganisms on food. When spoilage of a food occurs under a given set of circumstances, not all the organisms contaminating a food are associated with the spoilage system. Infact, the spoilage is usually dominated by means of only a few and sometimes most effective single organism. Components of the micro flora compete with each other for the vitamins and the organism(s) with fastest boom beneath a selected set of circumstances turns into dominant and give upward push to the spoilage symptoms.

Intrinsic parameters	Extrinsic parameters
Moisture content	Temperature
Oxygen availability	Relative humidity
pH, acidity, acidulant identity	Atmospheric composition
Buffering capacity	Packaging
Available nutrients	
Natural antimicrobial substances	
Presence and identity of natural microbial flora	

Table 3.2.1: Intrinsic and Extrinsic Parameters Affecting Microbial Growth

Knowledge of the intrinsic and extrinsic parameter determines which group of microorganisms is likely to spoil a particular type of food, for example, foods that have a high-water content and a pH above 5.0 are likely to be damaged by bacteria simply because under these conditions' bacteria grow the fastest. Foods with pH below 4.2 are likely to be spoiled by yeasts and molds.

1. **Extrinsic Factors**

   Extrinsic factors relate to the environmental factors that affect the growth rate of micro-organisms. They are as follows:

   - **Temperature**

     Microbes have an optimal temperature as well as minimum and maximum temperatures for growth. Therefore, the environmental temperature determines not only the growth rate but also the type of microbe that will grow at the temperatures. A difference of only a few degrees in temperature may favor the growth of entirely different organisms and result in a different type of food spoilage.

     The optimum temperature for the proliferation of most micro-organisms is from 15° to 40° C. However, many genera of microbes are capable of growth from 0° to 15° C and other even

micro-organisms will grow at subzero temperatures. Still other genera will grow at temperatures up to and exceeding 100° C.

Microbes classified according to temperature of optimum progress include:

- Thermophiles (high-temperature-loving micro-organisms), with growth optima at temperatures above 45°C (e.g., Bacillus stearothermophilus, Bacillus coagulans, and Lactobacillus thermophilus).
- Mesophiles (medium-temperature-loving micro-organisms), with growth optima between 20° and 45° C (e.g., most Lactobacilli and Staphylococci).
- Psychrotrophs or psychrophiles (cold-temperature-tolerant micro-organisms), which tolerate and thrive at temperatures below 20° C (e.g., Pseudomonas and Acinetobacter).

As temperature approaches 0° C, fewer micro-organisms can thrive and their growth is slower.

- **Oxygen Availability**

  As with temperature, the availability of oxygen determines which microorganisms would be active. Some micro-organisms have a total requirement for oxygen, whereas others grow in total absence of oxygen. So microbial spoilage can occur even in sealed cans. Yet other class of microorganisms can grow either with or without available oxygen.

  - Micro-organisms that need oxygen are called aerobic micro-organisms (e.g., Pseudomonas spp.)
  - Micro-organisms that can grow with or without the existence of free oxygen are called facultative micro-organisms (e.g., Lactobacillus spp.).

- **Humidity**

  This extrinsic factor affects microbial growth and can be affected by temperature. All micro-organisms have high necessities for water to support their growth and activity. High humidity can cause moisture condensation on food, which are provides optimal conditions for microbial growth and spoilage. But microbial growth is inhibited at low humidity. The optimal relative humidity for bacteria is 92% or higher, whereas yeasts need 90% or higher and for molds, the value of relative humidity is 85-90%.

2. Intrinsic Factors

Intrinsic factors that influence the rate of propagation relate more to the characteristics of the substrates (foodstuff or debris) that support or affect growth of micro-organisms. These major intrinsic factors are:

- **Water Activity (a_w)**

  Water is required by micro-organisms, and a reduction of water availability is a method of food preservation. But it is not the total amount of moisture present that determines microbial growth, but the amount of moisture which is readily available for metabolic activity of microbes. The unit of measurement for water requirement of micro-organism is usually expressed as water activity (a_w). Bacteria have the highest water activity requirements of the microorganisms. Molds usually have the lowest (a_w) requirements, with yeasts being intermediate. The relationship between microbes and their water activity is depicted in table no. 3.2.2.

Organisms Groups	Water Activity
Most spoilage bacteria	0.90
Most spoilage yeasts	0.88
Most spoilage molds	0.80

Table 3.2.2: Organisms group and water activity (a_w)

- **pH**

  The pH for optimum growth of most micro-organisms is close to neutrality (7.0). Yeasts can grow in an acid environment, but grow best in an intermediate pH (4.0-4.5) range. Molds stand a wider range of pH (2.0-8.0), although their growth is usually more with an acid pH. Molds can thrive in a medium that is too acid for either bacteria or yeasts. Bacterial growth is usually preferred by near-neutral pH values.

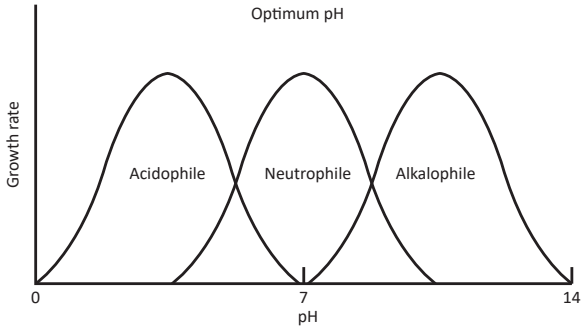


Fig. 3.2.4: The pH and microbial survival

- **Oxidation – Reduction Potential**

  The oxidation – reduction (redox) potential is an indication of the oxidizing and reducing power of the substrate. To attain optimal growth, some microorganisms require reduced conditions while others need oxidized conditions. Aerobic micro-organisms grow more readily under a high oxidation – reduction potential (oxidizing reactivity). A low potential is more optimal for growth of anaerobes. Facultative micro-organisms are capable of development under either condition.

- **Nutrient Requirements**

  In addition to water and oxygen micro-organisms have other nutrient requirements. Most microbes need nitrogen, energy (i.e., carbohydrates, proteins, or lipids), minerals, and vitamins to support their growth. Nitrogen is normally obtained from amino acids and other non-protein nitrogen sources; however, some micro-organisms utilize peptides and proteins. Molds are the utmost effective in the utilization of proteins, complex carbohydrates, and lipids because they comprise of enzymes capable of hydrolyzing these molecules into less compound components. Minerals (micronutrients) are needed by all micro-organisms, but requirements for their vitamins vary.

- **Inhibitory Substances**

  Microbial proliferation can be affected by the presence or absence of inhibitory substances. Substances or agents that inhibit microbial activity are called bacteriostats, and those which destroy micro-organisms are called bactericides. Some bacteriostatic materials are added during food processing (i.e., nitrites). Most bactericides are utilized as a method of decontaminating food or as a sanitizer.

3.2.2 Deteriorative effects of Micro-organisms

Food is considered spoiled when it turns unfit for human consumption. Spoilage is generally equated with the decomposition and putrefaction that result from activity of micro-organisms. Some of the physical and chemical changes due to the micro-organisms have been defined under:

- **Physical Changes**

  Physical changes caused by micro-organisms are more noticeable than the chemical modifications.

Fig. 3.2.5: Aerobic spoilage by bacteria and yeasts results in slime formation

Aerobic spoilage caused by microorganism specially yeasts generally effects by the formation of slime formation; undesirable odors and flavors (taints); color adjustments; and rancid, tallowy, or chalky flavors from the breakdown of lipids. Color changes caused by pigment oxidation results in a gray, brown, or green color.

Fig. 3.2.6: Physical deterioration through aerobic spoilage by molds with whiskers

Physical deterioration through aerobic spoilage by means of molds can supply a filament like appearance frequently mentioned as “whiskers”. Discoloration from molds can supply surface colorations, including creamy, black, or green. Molded surfaces of foods such as meats and cheeses can be trimmed off and the rest is generally suitable for consumption.

Anaerobic spoilage occurs in the interior of food products or in sealed containers, where oxygen is either absent or present in restricted quantities. Spoilage is as a result of facultative and anaerobic bacteria and is expressed via souring or putrefaction. Souring occurs because of the production of organic acids at some stage in the bacterial enzymatic degradation of complex vitamins along with starch and proteins. Souring is usually followed by formation of gases.

- **Chemical Changes**

  Hydrolytic enzymes that are present in foodstuffs results into degradation of proteins, lipids, carbohydrates, and other complex molecules to smaller compounds. Initially, the microbial endogenous enzymes degrade complex molecules of food system in presence of oxygen. Major chemical change occur is the hydrolysis of proteins into peptides and amino acids. Under anaerobic conditions, proteins can be degraded to a sulfur-containing compounds having pungent smelling.

Other chemical modifications include action of lipases secreted via micro-organisms which reak down fats into lipids. Most micro-organisms use carbohydrates as a source of energy. Utilization of carbohydrates through micro-organisms results in the production of number of compounds such as alcohols and organic acids.

3.2.3 Different Examples of Microbial Food Spoilage

Food Spoilage can occur into wide ranges of food products caused by either physical, chemical or microbial changes. The below table 3.2.3 depicts the types of spoilage in various food products such as bread, maple syrup, fresh fruits and vegetables, meat, fish etc. caused by different microbial species.

Food	Type of spoilage	Micro-organisms involved
Bread	Moldy Ropy	*Rhizopus nigricans* *Penicillium sp.* *Aspergillus niger* *Bacillus subtilis*
Maple sap and Syrups	Ropy Yeasty Pink Moldy	*Enterobacter aerogenes'* *Saccharomyces sp.* *Zygosaccharomyces sp.* *Micrococcus roseus* *Aspergillus sp.*
Fresh fruits and vegetables	Soft rot Grey mold rot Black mold rot	*Rhizopus, Erwinia* *Botrytis* *Aspergillus niger*
Pickles, sauerkraut	Film yeasts, Pink yeasts	*Rhodotorula*
Fresh meat	Putrefaction	*Alcaligenes* *Clostridium* *Proteus vulgaris* *Pseudomonas fluorescens*
Cured meat	Moldy Souring Greening, slime	*Aspergillus* *Rhizopus* *Penicillium* *Pseudomonas* *Micrococcus* *Lactobacillus* *Leuconostoc*
Fish	Discoloration Colorless rot	*Pseudomonas* *Alcaligenes* *Flavobacterium*

Food	Type of spoilage	Micro-organisms involved
Eggs	Green rot Colorless rot Black rot	*Pseudomonas fluorescens* *Pseudomonas alcaligenes* *Roteus*
Concentrated orange juice	Off flavor	*Lactobacillus* *Leuconostoc* *Acetobacter*
Poultry	Slime, odor	*Pseudomonas* *Alcaligenes*

Table 3.2.3 The Food, Type of Spoilage and the Micro-organisms Involved

Exercise

1. **What is food spoilage?**

_____

_____

_____

_____

_____

_____

2. **What are the two most common Micro-organisms found in food?**

_____

_____

_____

_____

_____

_____

3. **Give the scientific names of the following:**
   a. Baker's Yeast _____
   b. Bread Mold _____
   c. Cocci in bunches _____
   d. Aerobic spore former _____
   e. Anaerobic spore former _____

4. **Classify bacteria on the basis of their morphology.**

5. **What is a bacteriophage?**

6. **How do bacteria spoil food?**

7. **Define water activity.**

8. **What is a growth curve?**

9. What is temperature danger zone?

_____

_____

_____

_____

_____

_____

Fill in the blanks:

1. The microbial deterioration of a food is usually manifested as a change in ..... : ..... ;,..... and .....
2. Bacteria breakdown complex carbohydrates to ..... which results in. .... of food.
3. Microorganisms require ..... phase to grow in fatty foods.
4. Fats are degraded into .... and ..... by microorganism.
5. Foods that spoil easily are called .... foods.

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4. Prepare and Maintain Work Area and Lab Equipment

Unit 4.1 - Setting up Microbiological Laboratory

Unit 4.2 - Working Principle, Operations and Maintainence of Tools, Equipment and Glassware

Unit 4.3 - Maintaining Hygiene and Sanitation at Work Area

FIC/N7609

Key Learning Outcomes

At the end of this module, you will be able to:

1. Set up a microbiological laboratory following guidelines.
2. Discuss the cleanliness of work area to carry out microbiological analysis.
3. Demonstrate cleaning of equipment and glassware used with recommended sanitizers following specifications and organization standards.
4. Explain Maintenance and repair of lab equipments and glassware.

UNIT 4.1: Setting up Microbiological Laboratory

Unit Objectives

At the end of this unit, you will be able to:

1. Setup a Microbiological Analysis lab.
2. State safety, environmental, and other requirements in accordance with Current Good Manufacturing Practice (cGMP) and FSSAI regulations.

4.1.1 Introduction

Before elucidating the workspace preparation and hygiene requirements of the laboratory, it's must to understand the microbiology laboratory setup.

The setting up of a new laboratory involves[16]:

- Selection, identifying building facilities and construction if required for various analyses;
- Developing an organizational structure and assigning responsibilities;
- Selection of analyses to be performed;
- Selection and purchase of equipment/chemicals;
- Appointment and maintaining qualified analysts/technicians/skilled and unskilled staff;
- Establishing standard operational and working procedures;
- Establishing a Quality Assurance Programme such as Indian Standard Organization (ISO)17025:2005.

Laboratory Facilities must allow the laboratory's work to proceed both effectively and safely. Laboratory design should reflect the general features of the work programme anticipated in the long-term (10-20 years) rather than the specific pattern of current work. Even though the final design of the laboratory is made by architects and engineers, the analytical staff should be involved in some of the decisions that will ultimately affect their working environment and conditions.

The basic objectives of a microbiological research laboratory can be well-defined as follows:

- Safety of the experimenter and staff
- Safety of the surrounding community
- Conservation of experimental validity

The initial step should be taken keeping these three objectives in mind. Designing a microbiological research laboratory is an analysis of the research events that will be done, the hazards associated with each operation, and an assessment of the associations that exist between each activity. This analysis will enable the laboratory design manager to make substantial economic savings as he/she will be able to measure the extent of the hazardous operations and concentrate and minimize the amount of containment equipment required.

[16] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

In addition to looking at the mark of the equipment set up it is also important to consider the number of staff engaged in testing, the services (electricity, water, and gas) required and mechanisms to control the unintended release of microorganisms to the environment as well as cross-contamination. Furthermore, it is judicious to leave room for future development.

4.1.2 General Considerations for setting up of a laboratory

Laboratory layout should be devised with efficiency in mind. There is an argument for designing a laboratory in terms of "generic" activities and "specialised" activities.

- Generic activities can be categorized as "wet chemistry" which will require extensive provision of fixed benches with water, power, sinks, fume cupboards, reagent shelves, glassware cleaning and storage, as compared to "instrument rooms" where less extensive servicing (though with additional piped gas supplies and perhaps stabilised power supplies) and flexible arrangements of movable tables/benches may be adequate.
- Specialised rooms may be required for "clean air" work (e.g., on some environmental contaminants) or for work with substances which need to be handled with special care either for safety or for cross-contamination reasons, e.g., radioactive materials and some particularly toxic substances or for storage and dispensing of standards of pure compounds which are being analysed at trace levels elsewhere in the laboratory. A specialised room for large-scale and/or dusty sample preparation activities, e.g., grinding, blending, mixing, stirring will be invaluable, particularly if work is envisaged on heterogeneous analytes (e.g., aflatoxins in nuts or figs where primary samples of 30 kg are sometimes needed). With this approach the important design parameters are those concerned with correctly identifying the needs for specialised activities and with estimating the relative needs for the generic activities of "wet chemistry", "instrument room" and - for that matter - "food microbiology" if, as is often the case, that is to be carried out in the same premises.
- Offices are needed for management and for clerical staff. There must be toilet and washing facilities for all staff. Eating, drinking, and smoking are always discouraged, and should be prohibited, in the laboratory proper. It is the responsibility of management to provide an appropriate alternative area for these activities. A separate staff room, however small, deserves consideration since it not only provides a greater degree of safety to laboratory personnel but also helps to ensure sample integrity. To provide for a prompt exit in the event of fire or other emergency, at least two entrances/exits must be provided for each laboratory whenever possible. Step-wise key points are elaborated below for setting up of microbial laboratory.

4.1.3 Food Analysis Lab Layout

The food analysis laboratory is generally designed on the basis of the analysis to be carried out and the methods to be used, keeping in mind future analytical requirements and expansions. Laboratories must have separate zones/rooms, depending on types of analysis and functionality. The separation of laboratory space to perform the various activities is primarily required to avoid cross contamination with undesirable substances and to maximize the use of space. Such demarcation would include but not limited to: sample receipt and storage are conducted in designated areas, wet chemistry laboratories are separated from microbiology laboratories, separate storage for standards and reference materials and cultures, and media preparation and sterilization in microbiology labs are separated from work areas.

The typical layout of food analysis laboratory is depicted in figure no. 4.1.1

The layout of a microbiology laboratory installation wishes to deal with physical parting of spaces to hold out features and meet safety, environmental, and other necessities in concord with cGMP regulations.

In 'Laboratory Design for Microbiological Safety' a journal published in Applied Microbiology, Authors G. Briggs Phillips and Robert S. Runkle set out 5 practical zones that a micro-biological lab could be segregated into:

- Clean and transition
- Research region
- Animal keeping and research location
- Laboratory support
- Engineering support

It is projected to establish the primary-secondary barrier concept to prevent cross-contamination and management of microorganism's release.

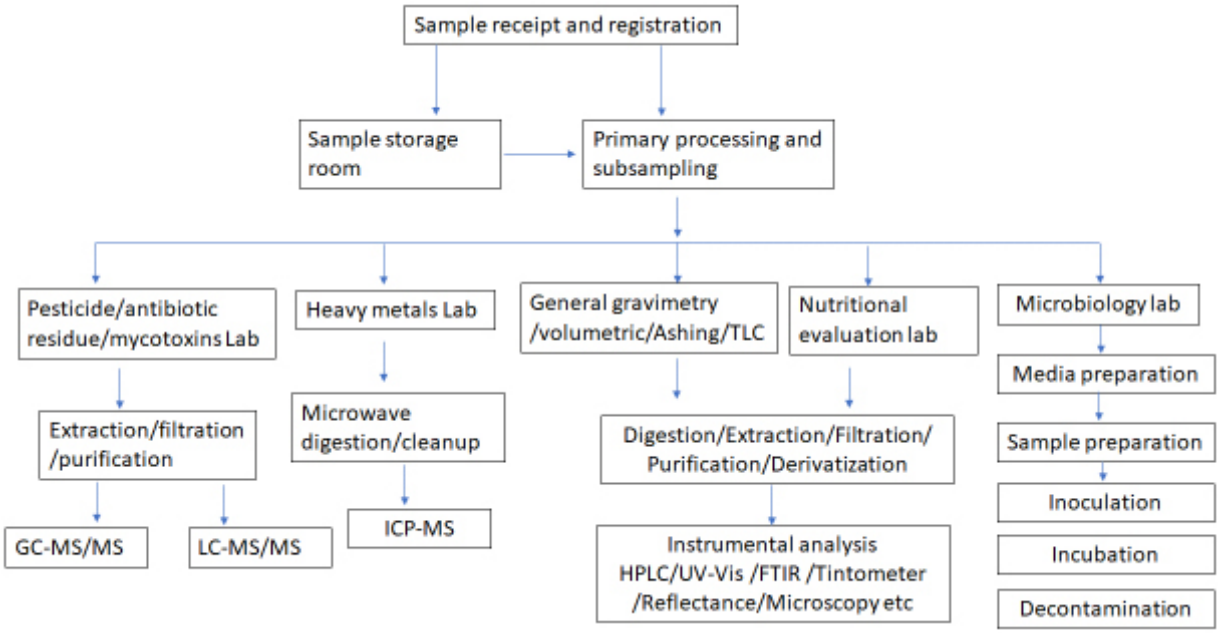

Fig. 4.1.1: Schematic of laboratory sections of a food analysis laboratory

4.1.4 Microbiology Lab Layout

The Microbiology laboratory and support equipment (e.g., autoclaves, Laminar floor, Biosafety cabinet, glassware etc.,) should be dedicated and physically separated from other areas. There should be adequate suitable space with separate storage locations for e.g., biological indicators, reference organisms and media etc. The Lab should be away from restrooms etc. to prevent cross contamination. The air supply to the microbiology laboratory should be through separate air-handling units and other provisions. Temperature and humidity must be maintained. The quality of the air supplied to the laboratory should be appropriate and not be a source of contamination. Laboratory equipment used in the microbiology laboratory should not be used outside the microbiology area. Access to the microbiological laboratory should be restricted to authorized personnel (Biometric or use of card reader. Personnel should follow

- the appropriate entry and exit procedures including gowning;
- the intended use of a clean rooms and corridors;
- the restrictions imposed when working in such areas;
- use the appropriate containment level biosafety (e.g., BSL-2 for Clostridium botulinum);
- use back-fastening laboratory gowns or coats should be worn.

The schematic diagram of microbiological laboratory is depicted in figure 4.1.2

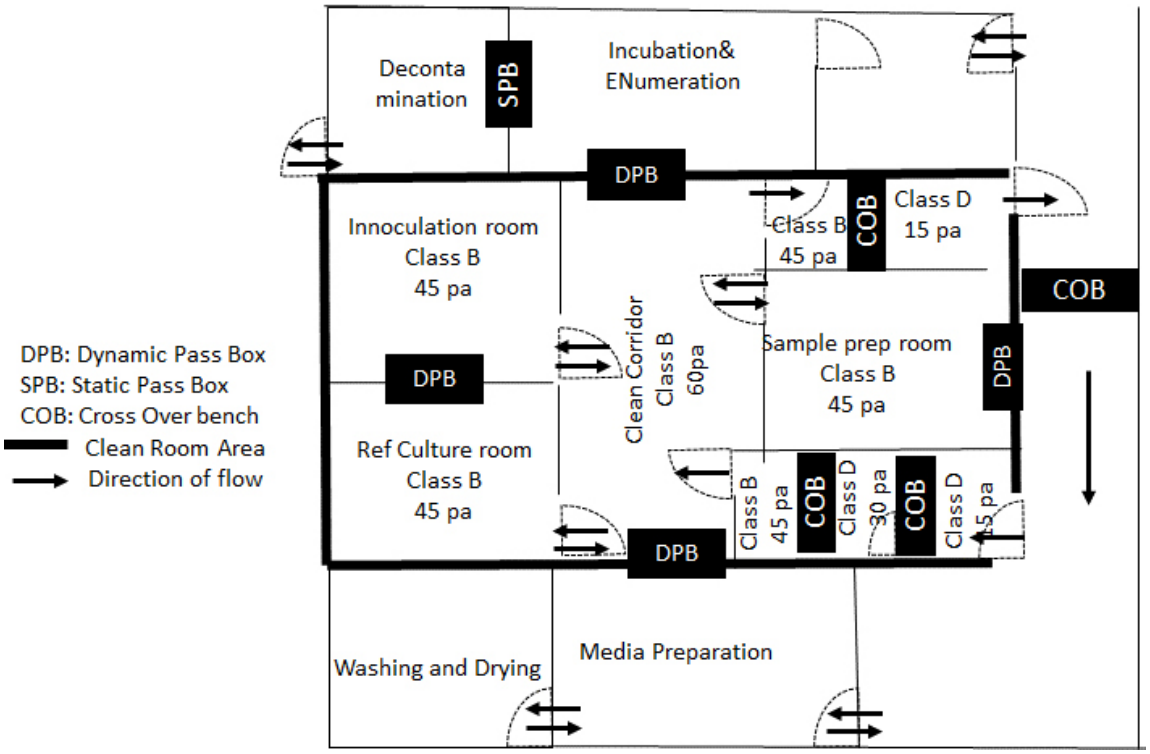

Fig. 4.1.2: A schematic layout for the microbiology section of a food laboratory

General Requirements to be followed in the microbiology lab is listed below:

- If entry to the laboratory is through a lobby, there should be some means of safeguarding the pressure differential between the laboratory and the lobby;
- Operations should be carried out preferably in the following zones;

Working zone	Installation grade	Maximum number of cfu in the
Sample Receipt	Unclassified	Not Applicable
Media Preparation room	Grade D	<200 cfu/m^2
Sample preparation room	Grade B	<50 cfu/m^2
Inoculation room	Grade B	<50 cfu/m^2
Reference culture room	Grade B	<50 cfu/m^2

- A change room should provide lockers to store street clothing, storage shelves for laboratory clothing;
- Floors should be smooth, slip resistant and seamless;
- Coving on the interface between the walls and the floor;
- There should be a documented cleaning and disinfection Programme;
- There should be a procedure for dealing with spillages;
- Entry to the clean room should be through a system of airlocks and change room where operators are required to don suitable clean-room garments;
- The final change room should be the same grade as the room it serves;

- Change rooms should be of adequate size for ease of changing;
- There should be clear demarcation of the different zones;
- Adequate hand-washing and hand sanitization facilities should be available;
- A wash-hand basin(s) should be located near to the exit of the laboratory;
- Appropriate waste disposal containers in each section.

Equipment required for Microbiology Laboratory

Dedicated equipment should be available in each of the clean areas. They should not be moved around. Pass boxes must be used to move the sample from one clean area to another. The microbiology lab ought to have sufficient area for the equipment necessary to carry out all activities. Mix-ups must be avoided at all charges to prevent any threat of cross-contamination. Petri dishes used for counting colonies ought to be stored in dedicated locations and separated from different areas, mainly from manufacturing areas. It is crucial to test that garage is of enough length for glassware, portable instrumentation, microbiological media, supplies, reagents, solvents, chemical compounds, and materials.

Heat generated from equipment needs to also be taken into consideration. Autoclaves, incubators, fridges, and freezers all output large quantities of heat main to a dramatic increase in room temperatures, mainly in smaller microbiology labs. When specifying the air condition cautious consideration must accept the heat generated by using home equipment so that this could be taken account of and the temperature balanced accordingly. Some general and most utilized equipment are listed below:

Sr. No.	Equipment for Microbiology Lab
1.	Anaerobic Jar
2.	Analytical Balance
3.	Autoclave Vertical
4.	Automated Culture Media Preparator with pourer Stacker
5.	Automated glassware washer
6.	Binocular Microscope
7.	Bio Safety Cabinet Class II Type B_2 (Total Exhaust)
8.	BOD Incubator
9.	Carbon dioxide incubator
10.	Circulating water bath
11.	Digital Colony Counter
12.	Digital pH Meter
13.	Frost Free Double door (side by side) Refrigerator
14.	Fumigator
15.	Hot Air Oven
16.	Howard Mold Counter
17.	Incubators: 1) Ambient to 70°C and 2) 5°C to 50°C
18.	Lab Blender (Paddle type)

Sr. No.	Equipment for Microbiology Lab
19.	Laminar Air Flow
20.	Micro Filtration Assembly
21.	Micropipette (6 No)
22.	Orbital shaker/water bath
23.	Sonic water bath
24.	Refrigerated Centrifuge
25.	Trinocular microscope
26.	Upright Frost Free Vertical Deep Freezer (-25°C)
27.	Ultra Violet (UV) Viewing Chamber
28.	UV-Vis Spectrophotometer
29.	Water Bath – Serological

Secondary equipment's of importance in the microbial lab are Test tubes, Petri Dishes, Durham's tubes, Dilution and media storage bottle, Spreaders, Slides and cover slips, Disinfectant jars, Inoculation loops, Non – adsorbent cotton wool etc.

Ventilation Requirements

Managing the odours can be a challenge in microbiology labs, however, there are several ways this can be battled. It is good practice to have separate air supply to laboratories and production areas. It is also important to ensure the air supplied to the laboratory is of suitable quality and not a source of pollution. As mentioned earlier, pressure differentials can help separate cleanroom areas.

Work areas for opening test sample containers should be either a High-Efficiency Particulate Air (HEPA) filtered laminar flow hood or an alternative controlled environment to safeguard the contact of open media and product to contamination.

Hygiene Requirements

The most significant factor when working in any laboratory is cleanliness and sanitation. This applies across all industries but is vital in microbiology labs; there is almost no other field where the impact of contamination can impact the outcome of its work so radically. Microorganisms are invisible, ubiquitous in nature, carried by humans, and could breed into large populations in a short space of time. During testing of microorganisms, laboratories provide a highly conducive atmosphere for microbial growth. Laboratories need to develop systems to manage areas of high microbial populations. Below are some points to consider concerning maintaining a hygienic environment.

- **Chairs –** ensure the exteriors are washable, while at the same time resistant to all common chemicals, as well as disinfectants and cleaning agents. Electrostatic discharge (ESD) is often an underestimated factor in the area of laboratory hygiene and can mean that the tiniest impurities settle on charged surfaces.
- **Sinks –** The under-slung sinks are easy to wipe wastage into, eliminating the problem of contamination in joints and edging surrounding surface mounted sinks and drainers.
- **Entry points –** Entry to sterility test cleanroom should be via an airlock in which operators are required to change into cleanroom garments.

4.1.5 Laboratory Design Requirements

Setting up of microbiology lab requires knowledge on design requirements as per regulatory guidelines. The design of a laboratory should conform to the following principles in accordance to FSSAI guidelines[17]:

1. **Security**
   - The building must be planned for security. Restriction of access is of considerable importance to protect the integrity of the official regulatory samples, prevent unauthorized personnel from gaining access and because of the extremely valuable and sensitive equipment used in the laboratory
   - Fire proof construction for the building, completely separated from outside areas.
   - Adequate office space, isolated from the laboratory, but still nearby. It is prohibited to store and consume food, apply make-up or chew gum in areas where hazardous materials are used/ stored.
   - The laboratory shall have means of securing specifically regulated materials such as legal samples, received controlled substances (cyanide, alcohol, radioactive materials etc.)
   - A security system for a typical lab should include some means of access control, often arranged in layers within a building
     - A computerized security management system (SMS) like
     - Keypad access control systems
     - Biometric
     - Card reader
     - Special door hardware locksets
   - A means of visually monitoring sensitive or secure areas
     - Security Guards
     - Visitor control
     - Video surveillance/Security camera
2. **Laboratory Signages**

   All labs must be provided with the following globally harmonized signs:
   - A Laboratory Information Card at the entrance door of each laboratory shall be identified Emergency exits shall be marked accordingly.
   - A Health and Safety information should be posted on the door of each laboratory indicating accurately the hazards that are present in the laboratory, personal protection required and the emergency contacts.
   - Identifier signs for all safety emergency equipment/devices
   - “Danger” identifier for toxic chemicals
   - “Flammable liquid” identifiers on all cabinets intended for flammable liquids.
   - “Acids” identifier on all cabinets intended for acids.
   - “Bases” or “alkalis” identifiers on all cabinets intended for alkaline liquids.
   - “Oxidizers” identifiers on all cabinets intended for strong oxidizers.

[17] FSSAI Guidelines. “Guidance document for Setting up of a regulatory food analysis laboratory”. (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

3. **Corridors and aisles**
   - Corridor widths and escape routes must be in accordance with the Building Codes of India.
   - Corridors and passages to the exits should be clear of all obstructions, no furniture, instruments etc.
   - The minimum separation between a working bench and floor-positioned equipment (e.g., autoclave, refrigerator, centrifuge) should be according to the following:
     - No worker on either side 90 cm.
     - Workers on one side of the aisle, no through traffic 100 cm.
     - Workers on both sides of the aisle, no through traffic 140 cm.
     - Workers on both sides of the aisle, plus through traffic 145 cm.
   - Heat generating equipment, such as ovens and incubators, should be located away from corridors, aisles, passage ways and frequently occupied spaces.
4. **Exits/Doors and Windows**
   - The number of emergency exits must be in accordance to the building laws and codes.
   - The laboratory should have an Emergency Evacuation Plan and route for all buildings floors and areas and posted in every laboratory section and corridor
   - Two or more well- marked & unobstructed evacuation exits are recommended in a lab
   - Laboratories shall have access doors which swing in the direction of egress (exit travel). Automatic self-closing doors are advisable and should open with minimum effort without the use of a key from inside at all times
   - Exit paths shall not be obstructed by lab furniture or equipment. To prevent blocking egress lab benches, and other furniture should be placed at least 5 feet (1.5m) from the exit door.
   - The main emergency egress from the laboratory shall have a minimum clearance 3 ft (0.90 m).
   - All exit and emergency doors serving hazardous occupancies shall swing in the direction of egress (exit travel).
   - Each door into a laboratory room must have a view panel or alternative means of viewing the laboratory activities from outside. Panels should be made of tempered/toughened glass.
   - On the wall/panel next to each door entry into a laboratory must have a standardized clear frame (Board) with the room number/lab name and any hazard warning signage insert.
   - Inside the laboratory, adjacent to the door latch, provision for light switches, telephone, thermostat/Relative humidity meter and fire extinguisher.
   - Laboratory doors which open to egress/access corridors must not be vented
   - If the laboratory has windows that open, they must be fitted with insect screens
   - Special facilities should be provided for the safe access and egress of disabled persons where applicable.
5. **Flooring**
   - The floor must be a one piece (seamless construction) impervious to water, resistant to acids, alkalis, solvents and disinfectants, easy to clean, slip- and wear-resistant and be chemical resistant and shall have covings to the wall.
   - Tiles and wooden planks are not appropriate because liquids can seep through the small gaps between them.
   - The floor surface shall be coved where it meets the walls and fixed benches/cabinets to ensure spills cannot penetrate underneath floors/cabinets.
   - Floors in storage areas for corrosive liquids shall be of liquid tight construction.
   - All edges at the walls should be sealed or welded to prevent seepage of spilled materials.

- Supported coving should be used to facilitate easier cleaning and prevent contaminants from seeping into floor level service voids behind false walls.

6. Walls and ceiling

- Wall surfaces should be free from cracks and unsealed penetration.
- Walls should be non-porous and painted with a durable, impervious finish to facilitate decontamination and cleaning.
- Ceiling heights should be sufficient to accommodate the safe installation of fume cupboards and Biological Safety Cabinets where applicable.
- Gypsum board ceilings should be finished with durable and impervious paint.
- Ceiling-mounted lighting in laboratories where potentially infectious materials are handled should be recessed with a cover/diffuser flush at the ceiling level.

7. Sinks

- Each laboratory must contain a sink with proper plumbing for hand washing alone. Hand free operation faucet controls (e.g., elbow-, foot-or sensor-operated) to prevent direct hand contact are recommended especially in Biosafety level 2, and other microbiology laboratories
- Hand wash facilities should be provided close to the exit of the laboratory for hand washing immediately before leaving the laboratory.
- Each laboratory where hazardous materials are used should have a sink for hand washing.
- A separate hand-washing sinks should be provided for a Biosafety level 2 and microbiology laboratories.
- Sink faucets and hose bibs that are intended for use with attached hoses must be equipped with back siphon prevention devices.
- Laboratory sinks shall have lips that protect sink drains from spills.
- Stainless steel sinks are preferred.
- In the glassware washing room a sink with a draining board will be more useful. It is preferable to fix two-way or three-way laboratory type taps for the sinks.

8. Lab Furniture

Work Tables

- The working surfaces should be hard and non-adsorbent
- The surfaces must be compatible with any chemicals likely to be used in the laboratory and must be impervious to water, resistant to acids, alkalis, solvents and disinfectants and easy to clean and a drip strip must be cut on the undersurface
- Materials used should be of low emission of formaldehyde.
- Bench tops should be of seamless design. If the bench top is against a wall, it shall be coved or have a backsplash against the wall.
- Work surface front corners may be rounded for ergonomic reasons but rounded work bench front edges should be avoided to prevent spills following the contours onto the under surfaces.
- Bench height should depend on the working position of the laboratory users. Typical bench is about 90 cm high for standing work.
- Typical bench depth is in the range of 60-90 cm (optimum 75 cm) for ease of access to the rear of the bench.
- Work surface area for each worker must be more than 1.2 m across (recommended to be at least 1.5 m) and 0.6 m deep, excluding bench space for laboratory equipment
- Deeper worktop may be required for specific and large equipment where access to back of the worktop from the front is not normally required.

- Sufficient leg/knee clearance should be left under the bench top for persons who use the bench top as a working/write-up area.
- Personnel working within laboratory areas must be able to work and move unimpeded by each other and by fixed equipment.
- As a minimum there must be a 1.5 m passageway between benches, or 1.7 m passageway between back-to-back working benches.

4.1.6 Overall Space Utilization Guidelines for Food Analysis Laboratory

The food analysis laboratory could be managed in space with the support of below mentioned guidelines[18]:

- The laboratory area should include, or have access to, all support spaces required, such as; instrument and preparation labs, laboratory stores, sample stores, chemical stores, wash up, media prep rooms, sterilization facilities, waste storage and waste treatment facilities;
- Administration and office accommodation should not be within the laboratory working area but should ideally be in close physically proximity to the laboratories they serve;
- Access to offices or other non-laboratory areas (lounge seminar hall, restrooms) should not require going through laboratory spaces;
- Write-up areas should not be located right opposite a fume cupboard or biological safety cabinet, but should be located near the exit;
- A laboratory area should contain the microbiological, chemical, radiological or physical hazards as far as possible;
- Sufficient floor space should be provided for refrigerators, freezers, incubators autoclaves and large centrifuges;
- Furniture or equipment should not protrude into passage ways and exit routes of a laboratory.

[18] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

UNIT 4.2: Working Principle, Operations and Maintenance of Tools, Equipment and Glassware

Unit Objectives

At the end of this unit, you will be able to:

1. Demonstrate use of major equipments with explanation of their working principle and operation.
2. Explain maintainance and repair of microbiological equipments with recommended sanitizers following specifications and organisation standards.
3. Discuss maintainence of glasswares.

4.2.1 Working and Operations of the Major Equipment used in Microbiology Laboratory

A modern microbiology laboratory should be equipped with the following equipment. The working principle and operation of major equipment's are described below.

Hot Air Oven

Hot Air Oven is used for dry sterilization of glass wares, tubes, pipettes, and Petri dishes. Dry sterilization is done best for glassware. Liquid substances, such as organized media and saline solutions can't be sterilized in the oven, as they lose water because of evaporation. The glassware's are sterilized at 180°C for 3 hours. An oven has a thermostat-control, the usage of which the required steady temperature may be received through trial and error. The thermostat dial analysis is approximate and the precise temperature is examined with the aid of introducing a thermometer into the oven or on a built-in L-shaped thermometer.

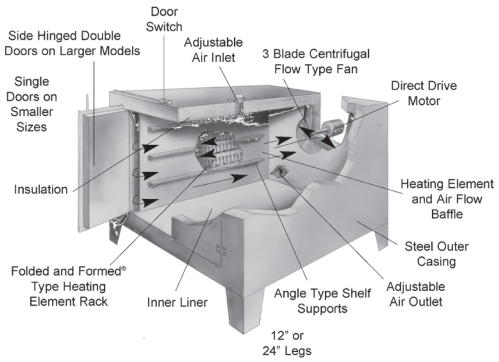

Fig. 4.2.1: A Conventional Hot Air Oven

In a modern oven, there is a digital temperature display and automatic temperature controller to set the estimated temperature without difficulty. Time is set by a digital timer and after loading the glassware's, the door is closed and the oven switched on.

Fig. 4.2.2: A Modern Industrial Hot Air Oven

The required temperature has to be set during operation. After the oven reaches the set temperature, the compulsory time of sterilization is set by the user. Automatically, the oven switches off after the set time and the opens the oven but after the temperature comes down close to room temperature. Precautions to be taken to not open the inside of the oven when it is still very hot because this can cause rushing of cold air may rush in and results into snapping of the glassware's.

The glassware after use should be properly cleaned and washed with distilled water followed by drying. They are dried inside the drying oven at 100°C till the glassware's dry up completely.

Autoclave

Autoclave is the heart of a microbiology laboratory. It is used not only to sterilize liquid materials such as prepared media and saline (diluents) solutions, but also to sterilize glassware's, when required. It has an identical working principle as a domestic stress cooker. The most temperature that may be obtained through boiling water in an open field is 100°C (boiling point of water). This temperature is sufficient to kill simplest the non-spore formers, but it is tough to kill the spore-forming bacteria at this temperature, as they break out via forming warmth resistant spores. It takes a very long time to kill the spores at this temperature.

Alternatively, water is boiled in a closed box, because of increased pressure inside, the boiling factor elevates, and steam temperature raises beyond 100°C. This excessive temperature is needed to kill all the microorganisms including the heat resistant spore-formers. Steam temperature will increase with an increase in steam strain.

In running a general vertical autoclave, sufficient water is poured into it. If water is just too less, the bottom of the autoclave receives dried at some stage in heating, and further heating damages it.

If it has an in-built water heating element, water level should be maintained above the element. On the other hand, if there is too much water, it takes a long time to reach the required temperature.

Fig. 4.2.4: A Conventional Vertical Autoclave

The substances to be sterilized are protected with craft paper and organized on an aluminum or timber body saved on the bottom of the autoclave, otherwise, if the substances stay half-submerged or floating, they tumble all through boiling and water may enter. The autoclave is closed flawlessly airtight simplest retaining the steam release valve open. Then, is heated over flame or via the in-built heating element. Air in the autoclave has to be allowed to escape completely via this valve. When water vapor is visible to escape via the valve, it is closed. Temperature and strain inside are going on increasing. The pressure increase is determined on the pressure dial. Usually, sterilization is accomplished at 121°C (a pressure of 15 pounds per rectangular inch i.e., 15 psi) for 15 minutes. The required time is taken into consideration from the point, when the specified temperature-pressure is attained. After the desired time (15 minutes), heating is discontinued and the steam release valve barely opened. If opened immediately, because of the surprising fall in pressure, liquids might also spill out from the containers. Gradually, the steam release is opened greater and extra, to allow all steam to getaway. The autoclave is opened only after the stress drops again to everyday atmospheric strain (zero psi). The warm sterilized substances are eliminated through maintaining them with a piece of smooth fabric or asbestos- coated hand gloves. In the case of a steam-jacketed horizontal autoclave, a boiler produces the steam. It is launched at a designated pressure, into the outer chamber (jacket).

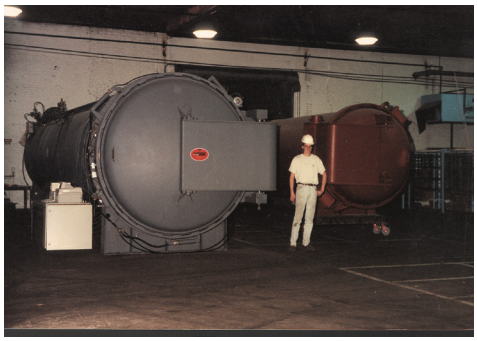

Fig. 4.2.5: A Modern Steam-Jacketed Horizontal Autoclave

The warm jacket heats the inner chamber, thereby heating the substances to be sterilized. This prevents the condensation of steam on the substances. Now, steam under stress is released from the jacket into the internal chamber and air is authorized to break out from it.

Then, its steam release valve is shut. The steam under pressure in the inner chamber reaches temperatures in an extra of 100°C, that could sterilize the materials kept inside it. The autoclave additionally has an automatic shutting device i.e., except temperature and stress come down close to room conditions, the door can't be opened.

Besides the strain dial, it additionally has a separate temperature dial to indicate the temperature internal of the internal chamber. Moreover, the autoclave continues the temperature and strain automatically and switches off after the set time of sterilization.

Microbiological Incubator

The profuse boom of microbes is obtained within the laboratory by developing them at suitable temperatures. This is executed with the aid of inoculating the preferred microbe into an appropriate culture medium and then incubating it on the temperature best for its boom. Incubation is achieved in an incubator (Figure 6), which maintains a constant temperature specifically appropriate for the growth of a selected microbe. As most of the microbes pathogenic to man develop profusely at frame temperature of an ordinary human being (i.e., 37°C), the same old temperature of incubation is 37°C.

Fig. 4.2.6: A Conventional Microbiological Incubator

The incubator has a thermostat, which keeps a steady temperature, set according to requirement. The temperature studying at the thermostat is approximate. Accurate temperature can be seen at the thermometer fixed on the incubator. Exact temperature, as in keeping with requirement, is ready by way of rotating the thermostat knob with the aid of trial and error and noting the temperature on the thermometer.

Most of the contemporary incubators are programmable, which do not need trial and error temperature settings. Here, the operator units the desired temperature and the required period.

Fig. 4.2.7: A Bacteriological incubator

The incubator automatically upholds it accordingly. Moisture is provided by placing a beaker of water in the incubator throughout the growth period. A moist environment retards the dehydration of the media and thereby, avoids spurious investigational results.

BOD Incubator (Low-Temperature Incubator)

Some microbes are to be grown at lower temperatures for specific determinations. The BOD low-temperature incubator, which can maintain temperatures from 50°C to as low as 2-3°C is used for incubation in such cases.

Fig. 4.2.8: A Conventional BOD Low-Temperature Incubator

The steady desired temperature is set via rotating the knob of the thermostat. Rotation of the thermostat knob actions a needle on a dial displaying approximate temperature. Exact required temperature is obtained, via rotating the knob finely via trial and errors and noting the temperature on the thermometer constant at the incubator.

Most of the modern BOD incubators (Figure 4.2.9) are programmable, which do not want trial and blunders temperature settings. Here, the operator units the desired temperature and the required period. The incubator mechanically keeps it accordingly.

Fig. 4.2.9: A Modern BOD Low-Temperature Incubator

Distilled Water Plant

Water is used for the preparation of media and reagents. If the media are prepared for the usage of faucet water, the chemical impurities present in it could intervene with the boom of the microorganisms in the media. Moreover, the higher is the bacteria content of the media, the longer is the time required for their sterilization and more is the risk of survival of some bacteria and ultimately leading to contamination.

Distilled water, though not completely bacteria-free, contains much less microbes. That is why; it's far preferred within the practice of microbiological media. The manufacture of distilled water by Liebig condenser is a time-taking process, in most laboratories, it is ready by using 'distilled water plants. Usually, a distilled water plant is made of metallic or brass. It is likewise called distilled water still.

It has one inlet to be linked to the water faucet and outlets, one for distilled water to drop into a container and the other for the drift outlet of hot cooling water into the sink. The still is established at the wall. It is heated by in-built electric heating elements (immersion heater).

The still works efficiently, while the water in-glide is so adjusted that, the temperature of the cooling water flowing out from the still into the sink is neither too excessive nor too low i.e., warm water has to glide out. The distilled water can also incorporate strains of metals corroded from the steel or brass box.

To get metal-unfastened distilled water, the glass distillation device is used and still better is quartz distillation apparatus. However, for a microbiology laboratory, a metallic or glass distillation equipment is sufficient. For precision analyses, double or triple distilled water is used.

Ultrapure Water Purification System

For accurate analytical works, nowadays, rather than the use of double- or triple-distilled water, micro-filtered water is used. In the case of distilled water, there is a risk that, few risky substances present within the water get volatilized for the duration of heating of the water and finally get condensed into the distilled water collected.

Thus, there can be strains of such substances inside the distilled water. To conquer this, ultrapure water is used. Here, water is authorized to bypass through very fine microscopic pores, which hold the microscopic suspended particle including the microbes. Then, the water passes through two columns of ion change resins. The anion change resin adsorbs the captions present inside the water, whilst the caption trade resin adsorbs the anions. The water that comes out is extremely pure.

Utilization of Accessory tools and equipment's of the laboratory are explained below in brief:

- **Homogenizer**

  For microbiological analysis, liquid samples are directly used, whereas stable samples need to be blended thoroughly with a diluent (usually physiological saline), a good way to get a homogenous suspension of microorganisms. This suspension is believed to contain microorganisms homogenously. The mixing of stable samples and diluents is completed using a homogenizer, wherein a motor rotates an impeller with sharp blades at excessive pace within the closed homogenizer cup containing the sample and the diluents. It has a speed regulator for controlling the speed of rotation of the impeller.

  In some laboratories mixing is finished manually via sterilized pestle and mortar. In contemporary laboratories, a disposable bag is used, internal in which the strong sample and liquid diluents are placed aseptically and mixed mechanically utilizing the peristaltic movement of a device at the bag. This gadget is called a stomacher.

- **pH meter**

  It is a tool for determining the pH of liquid media, liquid samples, and buffers. It has a glass pH electrode. When now not in use, it should be kept half of immersed in water contained in a small beaker and ideally be covered with the aid of a bell jar to avoid dust accumulation within the water and lack of water through evaporation.

  Before use, the meter is calibrated using two ideal buffers of recognized pH. Usually buffers of pH 4.0, 7.0, and 9.2 are available commercially. The tool is switched on and left for 30 minutes to heat up. The temperature calibration button is turned around to the temperature whose pH is to the measured.

  Then, the electrode is dipped into the buffer (pH 7.0). If the analysis is not 7.00, the pH calibration knob is circled until the analysis is 7.00. Then, the electrode is dipped in every other buffer (pH 4.0 or 9.2). If the analysis is the same as the pH of the buffer used, the instrument is running properly. Otherwise, the electrode is activated by way of dipping in 0.1 N HCl for twenty-four hours. After calibration, the pH of samples is decided with the aid of dipping the electrode into them and noting the studying.

  Every time, earlier than dipping into any solution, the electrode ought to be rinsed with distilled water. The samples should no longer incorporate any suspended sticky materials, which may form a coating on the tip of the electrode and decrease its sensitivity. Here, every other 'temperature electrode' is likewise positioned into the solution in conjunction with the pH electrode, which measures the temperature of the answer and routinely corrects the impact of temperature variations.

  Sophisticated pH meters have a solo gel electrode. Such electrodes have slight threat of breakage, as they may be completely enclosed in a hard-plastic casing excluding at the tip. The tip has both pH and temperature sensors. Moreover, they are easy to maintain, as they do now not require frequent dipping in distilled water, due to the fact the electrode tip is closed with a plastic cap containing saturated answer of potassium chloride, when not in use. However, in the practice of microbiological media, pH is decided with the aid of narrow-variety pH papers and is adjusted to the desired pH by including acids or alkalis as required.

- **Hot Plate**

  A hot plate is used to heat chemicals and reagents. The hot plate is made of an iron plate, which is heated by an electric heating component from below. The required degree of heating is obtained by a regulator.

- **Shaking Water Bath**

  Sometimes, heating at very specific temperatures is required. Such specific temperatures cannot be acquired in an incubator or oven, wherein temperature fluctuates, even though slightly. However, precise temperatures may be maintained in a water bath, which gives a stable temperature.

  A water bath consists of a field containing water, which is heated by way of electric powered heating elements. The required water temperature is acquired via increasing or reducing the fee of heating through rotating the thermostat via trial and error.

  In a shaking water bath, the substance is heated at the desired temperature and at the identical time, it is shaken constantly. Shaking is done by a motor, which rotates and moves the containers backward and forward in each rotation. The rate of shaking is again controlled with the aid of a regulator. Shaking agitates the substance and enhances the price of the process.

  Most contemporary water baths are programmable and do not want trial and mistake temperature settings. A desired water temperature might be sustained over a preferred period using program design accordingly. It is used for the cultivation of bacteria in broth at a specific temperature.

- **Fridge (Refrigerator)**

  It aids as a repository for thermolabile chemicals, solutions, antibiotics, serums, and biochemical reagents at cooler temperatures and even at sub-zero temperatures (at less than 0°C). Stock cultures of bacteria are also kept in it between sub-culturing periods. It is also used for the storage of sterilized media, to prevent their dehydration.

- **Deep-fridge**

  It is used to stock chemicals and reserve samples at sub-zero temperatures.

- **Electronic Top-pan Balance**

  It is used for weighing large numbers of media and other chemicals, where accurate weighing is not of much importance.

- **Electronic Analytical Balance**

  It is used to weigh small numbers of chemicals and samples exactly and quickly.

- **Double-Pan Analytical Balance**

  It is used to weigh chemicals and samples accurately. Weighing takes more time, for which it is used in emergencies only.

4.2.2 Maintenance, Cleaning and sanitation of equipment and Glassware

Properly functioning equipment is essential for the production of reliable microbiological data. A list of equipment needed with guidelines for their appropriate maintenance and repair is depicted in table 4.2.1.

Type of Equipment	Maintenance, Cleaning and sanitation of equipment[19]
Incubators	• Spillage, if any within the incubator should be cleaned and disinfected immediately to prevent subsequent cross-contamination.

Type of Equipment	Maintenance, Cleaning and sanitation of equipment[19]
	• At least once a month, all interior surfaces should be cleaned with a mild detergent solution, rinsed, and dried thoroughly with a soft cloth. • Grease or oils may be removed with toluene, naphtha thinner, or similar solvent. • If stainless steel surfaces become discolored by iron rust, a solution of 20% nitric acid and 1.5% hydrofluoric acid or a 2-5% solution of warm oxalic acid may be used to swab the affected area. After 1-2 minutes the area should be flushed with clean water to remove all of the acid and then dried thoroughly. When using these acid solutions, the analyst's hands must be adequately protected with rubber gloves, and the room must be well ventilated. • Containers in all incubators should be labeled clearly with the analyst's name, and the date and time the material was placed in the incubator. • Materials which have been inadvertently left in incubators for an unusually long time should be removed, autoclaved, and discarded.
Water baths	• The cover should fit securely on the water bath to prevent excessive moisture evaporation. • The primary maintenance task is to prevent or retard damage caused by corrosion. The baths should be inspected frequently since uncontrolled corrosion products will eventually damage the water pump as well as other components. • If more than two weeks will intervene between uses, the baths should be drained, washed with a mild detergent, and dried thoroughly with a soft cloth. • When the baths are in use, a commercial corrosion inhibitor may be used in the water. • Only distilled water should be used in the baths.
Refrigerators and freezers	• Exteriors should be cleaned with a damp cloth at least monthly. • The freezing compartment of the refrigerator should be defrosted every 3 months and all interior surfaces should be cleaned. • The freezer should be defrosted every 6 months and all interior surfaces cleaned. • An alarm system indicating excessively high temperatures should be kept in working order for both refrigerators and freezers. • All containers placed in the refrigerators and freezers should be labeled with the following information: identity of material, name of person responsible, and date that the material was placed in the refrigerator or freezer.

[19] Manual on Food Quality Control "Quality Assurance in the food control microbiological laboratory" 14/12-Food and Agricultural Organization of the United Nations.
(http://www.fao.org/3/a-t0451e.pdf)

Type of Equipment	Maintenance, Cleaning and sanitation of equipment[19]
Autoclave	• Maintenance tasks may be categorized according to their frequency of execution: daily, weekly, monthly, and quarterly. Two tasks should be performed on a daily basis. First, the daily temperature record should be removed from the printer mechanism and stored or filed appropriately. Second, the interior of the sterilizing chamber must be cleaned daily. • The interior surfaces are cleaned with a mild detergent solution, rinsed with tap water, and dried with a lint-free cloth. • As the sterilizer operates through each phase, the control panel should be observed closely. If any lights are out, a qualified service technician should be contacted. • On a monthly basis a few drops of heavy machine oil should be placed on the chamber door hinge pins. • Several tasks are performed on a quarterly basis. o First, the door post grease fitting is lubricated with a high-temperature grease. o Second, the door gasket should be examined. If it is brittle or cracked, it should be replaced. o Third, the chamber and steam generator safety valves should be checked. • After allowing the chamber and steam generator to reach operating pressure, safety valves should be checked for leakage. A qualified technician should replace the leaking safety valve. o The fourth task involves the cleaning and descaling of the steam generator according to the manufacturer's instructions
Hot air ovens	• Maintenance of the hot air oven is minimal. On a monthly basis the interior surfaces should be cleaned with a mild detergent solution, rinsed with tap water, and dried
Balances	• Maintenance by the analyst is minimal, limited to replacing a defective bulb and cleaning the protective cover and weighing pan. If two or more balances are being cleaned simultaneously, the analyst should be certain not to interchange the pan supports and weighing pans of different balances.
Blenders	• Blending is perhaps the most common procedure in test sample preparation. Often, an unavoidable consequence of blending food is spillage. Whenever spillage occurs, the exterior of the blender base should be disinfected immediately to prevent contamination of other test samples or work areas. Following disinfection, the exterior of the blender base should be washed with a warm detergent solution and rinsed to prevent accumulation of dried material.
Microscope	• The microscope stand should be cleaned, as needed, with a piece of linen or chamois leather. Enamel surfaces may be cleaned with a moistened cloth. Light patches on the object stage can be removed with liquid paraffin or acid-free petrolatum. Lenses must be cleaned after each use with lens paper and a commercial lens cleaner. Objectives should not be dismantled for cleaning.

Table 4.2.1: Maintenance Requirements of major equipment of microbiology laboratory

Maintenance and Cleaning Requirements of laboratory Glassware

Laboratory glassware should be made of low alkali borosilicate glass.

The following requirements are essential for maintain glassware in proper condition[20]:

- With each use, glassware should be examined, and items with chipped edges or etched inner surfaces should be discarded. In particular, the tips of pipets should be carefully examined since a chipped tip will result in inaccurately delivered volumes.
- The mouths of dilution bottles should also be inspected for chips that could lead to leakage or spillage of bottle contents while the analyst is making dilutions.
- Plastic caps or closures for dilution bottles or test tubes must be treated, when new, to remove toxic residues. They should be autoclaved twice while they are submerged in distilled water, or exposed to two successive washings in a warm detergent solution. Because acid or alkali residue may remain on glassware after cleaning, the pH of random batches of glassware should be checked by adding a few drops of 0.04% bromothymol blue and observing the color reaction. This indicator dye is yellow (acid) to blue-green (neutral) to blue (alkaline) in the pH range of 6.5 to 7.3. (The 0.04% bromothymol blue solution is prepared by adding 16 ml 0.01 N NaOH to 0.1 g bromothymol blue and diluting to 250 ml with distilled water).
- In addition to the pH reaction, washed glassware should be checked annually for any bacteriostatic or bactericidal substances which may have adhered to the surface. The procedure is detailed in Annex III.
- Results should be reported in a bound record book containing the following information: date, name of detergent used for washing glassware, source and lot or control number of presterilized petri dishes, manufacturer and lot number of plate count agar, microbiological counts, and name of analyst.
- Sterility of laboratory glassware should be tested on a routine basis. Sterilized petri dishes may be spot-checked by pouring plate count agar into randomly selected plates, incubating the solidified plates, and examining them for growth.
- Items such as sampling utensils, dilution bottles, and pipets may be checked for sterility by rinsing with Butterfield's phosphate buffer and filtering the buffer rinsing through a membrane. The membrane filter is placed on a nonselective medium and incubated under conditions prescribed by the method.
- Sterilized test tubes may be checked by adding fluid thioglycolate broth and observing growth after incubation. All volumetric glassware should meet the specifications established by the American Public Health Association (APHA).
- The etched calibration marks on dilution bottles, and the markings on graduate cylinders should be checked with a cylinder certified by the National Bureau of Standards (NBS).
- Disposable plastic ware may be used, provided that toxicity testing and accuracy of graduated markings are randomly, but routinely, determined.

[20] Manual on Food Quality Control "Quality Assurance in the food control microbiological laboratory" 14/12-Food and Agricultural Organization of the United Nations.
(http://www.fao.org/3/a-t0451e.pdf)

UNIT 4.3: Maintaining Hygiene and Sanitation at Work Area

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the process of cleanliness in working area to keep it free from microbes to carry out microbiological analysis.

4.3.1 Introduction

Cleaning and sanitizing are two one-of-a-kind actions, and each requires its personal precise tools and products.

- Cleaning gets rid of floor soil and different materials however generally does now not dispose of pathogens.
- Sanitization follows cleansing and decreases or removes the variety of pathogens that are on that floor, bringing them to levels which are safe and healthful.

The entire cleansing and sanitation technique start with cleaning, then requires rinsing followed by sanitization and air drying. When it involves laboratory sanitation, the care and attention that must be given to cleaning and sanitation are even greater and crucial. It is vital that everything within the lab is clean, but whenever food comes into contact with a surface, that surface have to be both cleaned and sanitized. This will ensure food safety and minimizes foodborne infection in addition to cross-infection.

The Microbiology lab consists of following areas[21]:

- **General Microbiology Lab –** Microbiology entry air lock, Microbiology general corridor, Microbiology Sterilization area, Media preparation area, Washing area, Media decontamination area, Microbiology office, Incubator room & Glassware storage room.
- **Sterility testing area –** Change rooms, Sterility Testing room, Sterile Buffer Room, etc.,
- **MLT Section –** MLT A/L & Change room, MLT room and Subculture room.

A large challenge of microbiology is searching for ways wherein human beings can avoid or put off microbial infections. To deal with this, microbiologists use a class of biosafety ranges. A biosafety level is the extent of the bio-containment precautions required to isolate risky biological marketers in an enclosed facility.

- **Biosafety Level 1:** This stage is with minimal potential chance to risk laboratory employees and the environment with pathogenic microbes.
- **Biosafety Level 2:** This level is just like Biosafety Level 1 and is suitable for work but pose slight potential threat to employees and the environment. It includes various bacteria and viruses that cause only slight ailment to humans or are difficult to contract through aerosol in a lab.
- **Biosafety Level 3:** This level is applicable to clinical, diagnostic, teaching, research, or production centers wherein work is performed with indigenous or distinguished marketers that may result

[21] SOP for cleaning and Sanitation in Microbiology Lab.
(https://www.pharmaguideline.com/2010/01/sop-for-cleaning-and-sanitization-of.html)

severe or probably lethal ailments after inhalation. It includes numerous microorganisms, parasites, and viruses that can cause severe to fatal disease in human beings, but for those diseases' treatments exist and patient can be cured (e.g., Yellow fever).

- **Biosafety Level 4:** This stage is reserved for work with dangerous and uncommon microbes that pose a high individual danger of aerosoltransmitted laboratory infections. The exposure will lead to fatal sickness in human beings for which vaccines or other remedies are not available, such as Bolivian and Argentine hemorrhagic fevers, Marburg virus, and the Ebola virus. Very few laboratories are biosafety degree 4.

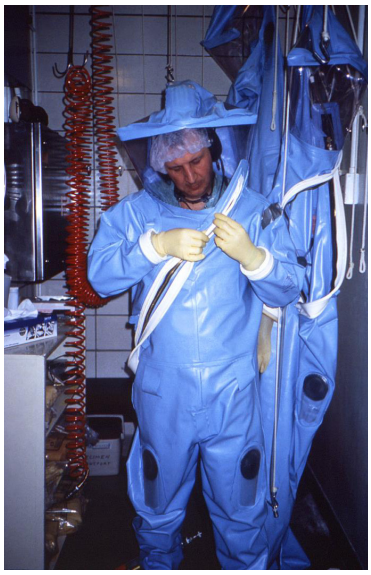

Fig. 4.3.1: Microbiologist wearing Positive pressure suit in biosafety stage 4 laboratory.

The Sanitation procedure at the Work Area will ensure the sterile environment needed for

- preventing harmful diseases;
- and providing accurate results.

The SOP for Cleaning and sanitation procedure is described below.

4.3.2 Procedure for General Microbiology lab

It is the responsibility of food microbiologist to ensure cleanliness and sanitation of general microbiology lab through monitoring and following the Standard Operating Procedure (SOP).

The steps for ensuring cleanliness are as follows:

- Remove dust from all surfaces of doors, window glasses, walls, incubator surfaces, grills, external surfaces of equipment like ovens, autoclave, refrigerator, weighing balance, pH meter, water bath, Tables etc.
- Sweep the floor to remove the dust using lint-free dry mop followed by wiping the floor with the floor cleaning solution.
- Dilute disinfectant solution in another bucket as per respective SOP.
- Wipe the cleaned surfaces twice; first with mopping cloth wetted with purified water and then with dilute disinfectant.

- Clean the drains, sinks and wash basins with purified water daily once followed by flushing with disinfecting solution.
- Clean and sanitize the media preparation table and washing area table with 70% Iso-propyl alcohol (IPA) solution.
- Empty the waste bins twice daily and clean the bins with water and disinfectant solution.
- Remove the dust from the ceiling, shelves, ducts, lights, fixtures, racks etc., using vacuum cleaner monthly.
- Record the details of cleaning in cleaning and sanitization of microbiology lab (Annexure No.-IV)

List of Disinfectant to be used:

- Lysol – 2.5% v/v
- Domex-2.5% v/v
- Savlon-2.5% v/v

Frequency of cleaning

- Twice/ day.

4.3.3 Procedure for Sterility testing area & MLT section

The steps for cleaning and disinfection in sterility testing area and MLT section is as recommended:

- Clean and disinfect the Garment cabinet and the used garment cabinet present in the Change rooms of the laboratory with a lint free cloth wetted with 70 % IPA.
- Clean the floor, glass surfaces, LAF hood with WFI and wipe with sterile lint free mop pads.
- Sprinkle the disinfectant on the floor and spread with sterile lint free mop pads and allow untouched for about 10 minutes.
- Wipe out the excess disinfectant with the sterile mop pads (lint free) using a long-handled SS mop.
- Follow the above steps in a sequence from testing room to change rooms.
- Sanitize the dedicated slippers with the same disinfectant as used for the floor daily by dipping them in disinfectant and allowing the contact period of 10 minutes. After completions of the contact period dip in WFI, spray 70% IPA and allow drying.
- Clean the autoclave door, Garment cabinet, pass box daily with 70% IPA solution.
- Clean all the high-touch surfaces, trolleys and SS furniture daily with the disinfectant.
- Change the disinfectants every week and use in rotation as mentioned below.

List of Disinfectant to be used:

- Triple 100 1% v/v
- Combatan DS 1% v/v
- Protasan DS 1% v/v

Sequence of rotation:

- On weekly rotation; one disinfectant for a weekly

Frequency of cleaning

- Twice/day.

4.3.4 Procedure for Sanitation of drain point

The following steps should be followed:

- Clean and flush the drain with water;
- Fill the cup of the drain with disinfectant or Flush the drain with disinfectant as per SOP;
- Record the information for procedure followed for sanitation.

4.3.5 Decontamination of microbiology Laboratory

Some key Steps for Reducing Contamination in the laboratory are mentioned below:

- Wipe the desktop with a disinfectant (e.g., Amphyl® or 10% chlorine bleach) before and after each lab period. Never assume that the class before you disinfected the work area. An appropriate disinfectant will be supplied. Allow the disinfectant to evaporate; do not wipe it dry.
- Never lay down culture tubes on the table; they always should remain upright in a tube holder. Even solid media tubes contain moisture or condensation that may leak out and contaminate all it contacts.
- Cover any culture spills with paper towels. Soak the towels immediately with disinfectant, and allow them to stand for 20 minutes. Report the spill to your instructor. When you are finished place the towels in the container designated for autoclaving.
- Place all nonessential books and papers under the desk. A disorderly lab table is an invitation for an accident that may contaminate your expensive school supplies.
- When pipetting microbial cultures, place a disinfectant soaked towel on the work area. This reduces contamination and possible aerosols if a drop escapes from the pipette and hits the tabletop.

Fig. 6.1.1: An Autoclave Bag

- Non-reusable items (such as plastic Petri dishes) are placed in an autoclave bag for decontamination. Petri dishes should be taped closed before autoclaving.

4.3.6 Precautions

The following precautions should be ensured by food microbiologist during the process of cleaning and sanitation:

1. Handle the disinfectant carefully to avoid contact with skin and eyes. Use the most effective confirmed disinfectants;
2. Do not use expired disinfectant solutions;
3. Rotate the disinfectants use to avoid the improvement of resistance by microorganisms; generally, rotate the disinfectant once in per week sequentially, with tested disinfectants;
4. Wherever suitable use vacuum cleaner. Ensure the vacuum cleaners are in a clean and dry condition before use;
5. Use separate utilities for cleaning of the specific area to avoid contamination.

Abbreviations used in this unit:

- SOP: Standard operating procedure
- MLT: Microbial Limit Test
- V/V: Volume by Volume
- SS: Stainless steel
- LAF: Laminar Air Flow
- IPA: Isopropyl Alcohol

Exercise

1. **Write basic objectives of a microbiological research laboratory.**

_____

_____

_____

_____

2. **What are the five functional zones of a microbiological laboratory?**

_____

_____

_____

_____

3. **What is an autoclave and enlist its principle of working?**

_____

_____

_____

_____

4. **Briefly write about:**

a) Quebec colony counter

_____

_____

_____

_____

b) Laminar flow chamber

_____

_____

_____

_____

(iii) pH meter

_____

_____

_____

_____

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सत्यमेव जयते
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Corporation
Transforming the skill landscape

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5. Microbiological Analysis

Unit 5.1 - Culture Media Preparation

Unit 5.2 - Sterilization Using Autoclave

Unit 5.3 - Sampling for Microbiological Assay

Unit 5.4 - Preparation of the work space (Laminar Air Flow Cabinet)

Unit 5.5 - Aseptic Sample Inoculation

Unit 5.6 - Pure Culture Maintenance

Unit 5.7 - Reporting Microbiological Test Results

Unit 5.8 - Microbiological Food Safety Standards and Regulations

FIC/N7610

Key Learning Outcomes

At the end of this module, you will be able to:

1. Discuss weighing of required chemicals, solvents in calibrated instruments, prepare liquid and solid culture media (nutrient broth and nutrient agar) following SOP.
2. Illustrate destruction of microbes from used culture media following SOP.
3. Demonstrate transferring prepared broth, culture media, solvent etc. in glass wares, plug with cotton plug, wrap with paper and prepare for sterilization using autoclave
4. Demonstrate preparing of solid culture media such as slopes/slants, plates from nutrient agar in sterile area
5. Illustrate sampling requirement and procedure following SOP
6. Demonstrate taking swab test samples from employees' hand and cloth for evaluating personnel hygiene, on equipment and machineries in the production line, in the premises for evaluating sanitation and collect air samples and its labelling procedures following SOP
7. Prepare the work space (Laminar Air Flow Cabinet) or lab bench by wiping with disinfectant, clean glass ware, tools and equipment dilute samples following SOP
8. Record compiling of results of microbiological tests and prepare microbiological data
9. Analyze microbiological data and compare with food safety standards of the organization, national and international regulations
10. Demonstrate inoculating samples aseptically in labelled liquid and solid culture media (through suitable techniques such as broth inoculation, pour plate, direct plating, streak plate, spread plate, membrane filtration, etc.), as applicable, following SOP
11. Demonstrate adjusting controls of all equipment
12. Explain out serial dilution of sample in sterile media and plating them in sterile condition for counting microbes, following SOP
13. Illustrate counting the micro- organisms and colonies under the microscope and record counts
14. Perform test to identify the type and characteristics of microbes from the colonies of microbes grown in the petri plates plated through serial dilution
15. Discuss preserving of pure culture through refrigeration, paraffin method, freeze drying etc., maintaining the parameters like temperature, anaerobic condition, pressure etc., following SOP
16. Demonstrate compiling the results of microbiological tests and prepare microbiological data
17. Illustrate analyzing of microbiological data and compare with food safety standards of the organization, national and international regulations

UNIT 5.1: Culture Media Preparation

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss broth, culture media, solvent preparation etc. in glass wares, plug with cotton plug, wrap with paper and prepare for sterilization using autoclave.
2. Demonstrate serial dilution technique.

5.1.1 Introduction

Microbiological analysis of food products is the use of biological, biochemical, molecular or chemical methods for the estimation, identification or enumeration of microorganisms in a material (e.g., food, drink, environmental or clinical sample). It is often applied to disease borne/food spoilage microorganisms. Finished-product testing remains a vital part of any food manufacturing quality control approach. In products in which microorganisms can survive and grow like high moisture food products, routine microbiological analysis is important to confirm that manufacturing control mechanisms are effective. It is also necessary for the checking of raw material specifications, or for examining customer grievances.

For every microbial analysis, the foremost and most important part is culture media preparation because microorganisms need vitamins, a source of energy and sure environmental conditions so one can grow and reproduce. In the original environment, microbes have adapted to the habitats most suitable for their needs. In the laboratory, however, those requirements ought to be met by using tradition media. A culture medium is largely an aqueous way to which all the necessary vitamins have been added. Culture media is the food used to develop and control microbes. Depending on the sort and mixture of vitamins, different categories of media can be made.

Key Points

- Culture media carries the vitamins needed to grow microbes.
- Culture media can vary in lots of ingredients permitting the media to pick out for or against microbes.
- Glucose or glycerol are often used as carbon resources, and ammonium salts or nitrates as inorganic nitrogen sources in subculture media.

Key Terms

- Culture: The technique of growing a bacterial or different organic entity in an artificial medium.
- Lysogeny broth: Lysogeny broth (LB) is a nutritionally-rich medium; in most cases used for the growth of microorganism.

5.1.2 Microbiological Cultures

Culture medium or growth medium is a liquid or gel designed to support the boom of microorganisms. There are one of a kind styles of media suitable for developing specific sorts of cells. Here, we will speak microbiological cultures used for growing microbes, inclusive of microorganism or yeast.

Nutrient Broths and Agar Plates

These are the maximum common increase media, even though specialized media are once in a while required for microorganism and cellular tradition boom. Some organisms, termed fastidious organisms, require specific environments due to compound nutritional requirements. Viruses, for example, are obligate intracellular parasites and require an increase medium containing dwelling cells. Many human microbial pathogens also require the usage of human cells or mobile lysates to develop on a media.

The most common increase media nutrient broths (liquid nutrient medium) or LB medium (Lysogeny Broth) are liquid. These are frequently blended with agar and poured into Petri dishes to solidify. These agar plates offer a stable medium on which microbes can be cultured. They remain strong, as very few microorganisms are capable of decompose agar. Many microbes can also be grown in liquid cultures produced from liquid nutrient media without agar.

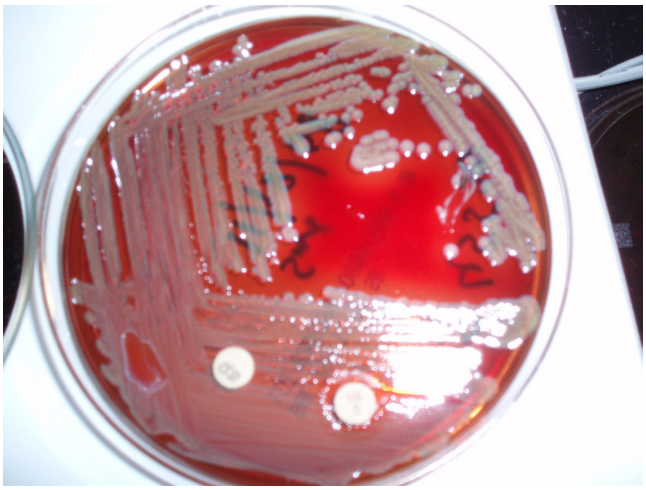


Fig. 5.1.1: Microbial pathogen growing on blood-agar plate

Red blood cells are used to make an agar plate. Different pathogens which can use pink blood cells to develop are proven on those plates. On the left is staphylococcus spp. and on the right is streptococcus spp.

Defined v/s Undefined Media

A defined medium can have known portions of all ingredients. For microorganisms, it offers trace factors and vitamins required by way of the microbe and mainly a defined carbon and nitrogen source. Glucose or glycerol are often used as carbon assets, and ammonium salts or nitrates as inorganic nitrogen resources. An undefined medium has a few complicated ingredients, which includes yeast extract, which consists of a mixture of many, many chemical species in unknown proportions.

There are many one-of-a-kind forms of media that may be used to develop specific microbes, and even sell positive cell processes; together with wort, the medium which is the boom media for the yeast that makes beer. Without wort in certain conditions, fermentation cannot occur and the beer will not comprise alcohol or be carbonated (bubbly).

Defined Culture Media

1. **Nutrient media–** A supply of amino acids and nitrogen (e.g., beef/yeast extract). This is an undefined medium because the amino acid supply consists of a lot of compounds with the exact structure being unidentified. These media incorporate all the elements that most microorganism need for growth and are non-selective, so they are used for the overall cultivation and maintenance of bacteria kept in laboratory.

2. **Minimal media–** Media that incorporates the minimal nutrients possible for colony boom, generally without the presence of amino acids, and are often utilized by microbiologists and geneticists to grow "wild kind" microorganisms. These media also can be used to choose for or against the increase of unique microbes. Usually, a fair quantity of statistics needs to be known about the microbe to decide its minimum media requirements.
3. **Selective media–** If a microorganism is resistant against a certain antibiotic, including ampicillin or tetracycline, then that antibiotic can be delivered to the medium that allows you to prevent other cells, which do now not possess the resistance, from growing.
4. **Differential media–** Also called indicator media, are used to differentiate one microorganism kind from another growing on the identical media. This kind of media uses the biochemical characteristics of a microorganism growing in the presence of specific vitamins or indicators (which include neutral red, phenol pink, eosin y, or methylene blue) additional to the medium to visibly indicate the defining traits of a microorganism. This sort of media is used for the detection and identification of microorganisms.

These few examples of media types provide some indication which are most effective; there are an innumerable of different forms of media that can be used to grow microbes. Different types and purpose are listed below in the table 5.1.1

Media	Purpose
Complex	For heterotrophic organisms
Defined	• Grow particular heterotrophs • Mandatory for chemoautotrophs, photoautotrophs and for microbiological assays
Selective	Suppress unwanted microbes while ensuring the growth of desired microbes
Differential	Helps to distinguish colonies of specific microbes from others
Enrichment	Similar to selective media but intended to increase the number of target micro-organisms to a measurable level without disturbing the rest of the bacterial population
Reducing	For growth of obligate anaerobic colonies

Table 5.1.1 Culture Media and its Purpose

Complex Media

Complex media contains protein hydrolysate which are products of amino acids, peptides and proteins in culture media. It is the most vital source for nitrogenous nutrients. They are most often obtained by enzymatic digestion or acid hydrolysis of herbal products, including animal tissues, milk, plant life or microbial cultures. The number of available proteins hydrolysate, also known as peptones, is considerable and can sustain the growth of most commonplace organisms. For the enzymatic digestion frequently papain, pepsin, trypsin or a combination of enzymes of the pancreatic juice are taken. Below is a list of regularly used expressions and the definitions.

Term	Explanation
Trypsin digested	Protein hydrolysate was produced by protein digestion with trypsin
Peptic digested	Protein was digested by pepsin

Term	Explanation
Pancreatic digested	Protein was digested by a mixture of enzymes of the pancreatic juice
Proteose Peptone	A mixed enzymatic digestion of animal proteins which contains peptides with the higher molecular weight.
Tryptone	Casein which was tryptic digested
Tryptose	A mixed enzymatic digestion of animal proteins which contains many different peptides including those of higher molecular weight (proteoses).

Table 5.1.2 The Protein Hydrolysates in Complex Media

Luria Broth as shown here is made with yeast extract, as yeast extract isn't completely chemically defined Luria Broth is consequently an undefined media.

Chemically described media ranges from serum-free media which is made up of bovine serum albumin or human serum albumin with both a chemically defined recombinant version (which lacks the albumin related lipids) or synthetic chemical which includes the polymer polyvinyl alcohol that can reproduce some of the functions of serums.

Selective and Differential Media

Selective media permits for the increase of particular organisms, whilst differential media is used to differentiate one organism from any other.

Fig. 5.1.2: Undefined Media

Key Points

- Selective media normally selects for the increase of a desired organism, stopping the growth of or altogether killing non-favored organisms.
- Differential media takes benefit of biochemical properties of target organisms, regularly main to a visible trade when increase of target organisms are present.
- Differential media, in contrast to selective media, does no longer kill organisms. It shows if a target organism is present.

Key Terms

- Recombinant: This term refers to something formed by way of combining existing factors in a brand-new combination. Thus, the phrase recombinant DNA refers to an organism created inside the lab by using including DNA from another species.

- Gene: A unit of heredity; a phase of DNA or RNA that is transmitted from one era to the next. It contains genetic information consisting of the collection of amino acids for a protein.
- Allele: One of some of alternative kinds of the identical gene occupying a given position on a chromosome.

There are many forms of media used in the studies of microbes. Two kinds of media with comparable implying names however very different features, referred to as selective and differential media, are defined as follows.

Selective media are used for the boom of most effective decided on microorganisms. For example, if a microorganism is immune to a positive antibiotic, including ampicillin or tetracycline, then that antibiotic may be brought to the medium in order to prevent different cells, which do not own the resistance, from growing.

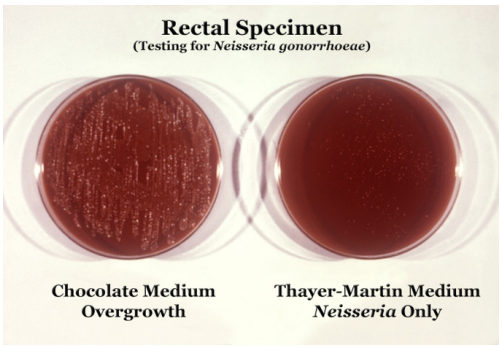


Fig. 5.1.3: Non-selective versus selective media

The non-selective media on the proper allows of the boom of numerous unique bacterial species and is overgrown with bacteria (whitish lines). While the plate on the right selectively only permits the microorganism Neisseria gonorrhoeae, to grow (white dots).

- Eosin methylene blue (EMB) that consists of methylene blue – toxic to Gram-fine bacteria, allowing handiest the boom of Gram poor bacteria.
- YM (yeast and mold) which has a low pH, deterring bacterial boom.

Differential media or indicator media differentiate one microorganism type from another growing on the equal media. This type of media uses the biochemical traits of a microorganism developing within the existence of specific nutrients or indicators (which includes neutral crimson, phenol purple, eosin, or methylene blue) brought to the medium to visibly indicate the defining traits of a microorganism.

This form of media is used for the detection of microorganisms and via molecular biologists to stumble on recombinant lines of microorganism.

- Blood agar (utilized in strep tests), which incorporates bovine heart blood that turn out to be transparent inside the presence of hemolytic. Aseptic Technique, Dilution, Streaking, and Spread Plates

Sterilization:

Before inoculation with the favored microorganisms, microbiological media and all substances entering touch with it need to be sterile.

During any subsequent dealing with of the bacterial cultures, unwanted or contaminant organisms must be excluded using aseptic techniques.

Sterilization implies the complete destruction of all microorganisms together with spores, this is performed by the usage of heat, chemical substances, radiation, filtration.

- **Heat:** Denatures and coagulates vital proteins. There are various forms of heat sterilization.
- **Red heat:** Inoculating wires or loops are sterilized by way of protecting them in a Bunsen flame until they're red hot.
- **Moist heat:** Bacteria are more effortlessly destroyed via moist warmness (steam) than dry warmness. Usually used for the sterilization of tradition media, aqueous solutions and the destruction of discarded cultures. Air have to first be removed on the way to gain the 121 °C necessary for a success sterilization.

  This is completed by means of the use of an autoclave (the technical model of a pressure cooker), which follows automated cycles of heating underneath stress for the specified time.
- **Dry Heat:** Usually employed for substances which can both be corroded by using steam or must stay dry earlier than use. These consist of metal devices, glass petri dishes, flasks and pipettes and cotton wool. In practice, dry warmth sterilization calls for longer time intervals and better temperatures than steam sterilization, e.g., Steam sterilization 121°C for 15mins or dry heat sterilization 160°C for one hundred twenty minutes.
- **Chemical:** Usually employed for delicate equipment along with optical units and electrical devices which could be damaged by warmness. Due to the toxicity of the chemical substances used, this is not the most popular form of sterilization.

  Chemicals employed encompass: gaseous ethylene oxide, which alkylates amino, sulfhydryl, carboxyl and hydroxyl companies of microbial cell compounds; formaldehyde, used as a fumigant; and hydrogen peroxide vapor used in packaging.
- **Radiation:** Employed for warmness-sensitive materials and for environmental samples consisting of soil and sediment in which structural modifications because of heat need to be avoided. Initiates the excitation of atoms which in nucleic acids leads to deadly mutations.
- **UV:** UV light cannot penetrate materials so is used particularly for surface remedies e.g., Laminar glide benches, and air and water.
- **Ionizing Radiation:** Radiations can penetrate samples, causing ionization within cells. Gamma radiation generated through a 60 Co a-source is used to sterilize complex matrices along with soil and foodstuff. Microorganisms show accelerated resistance to radiation below anoxic conditions (2-5X) and additionally in frozen samples.
- **Filtration:** Filtration sterilization operates through the exclusion instead of destruction of microorganisms. It is safe for the user and is employed for sensitive beverages and gases. Three varieties of filters are currently in use:
  - **Depth Filters:** These are made from columns filled with fibrous substances consisting of glass wool or cotton wool. The twisting and turning fibers entrap particles and so act as filters; they display little resistance to flow and are used particularly for gases or as pre-filters for membrane
  - **Membrane Filters:** Their effectiveness relies upon on the scale of the membrane pores and the electrostatic sights present. The most generally used filters in microbiology are generally manufactured from cellulose acetate or cellulose nitrate. Size of filter pores required to screen out:
    - Yeast 0.45 -1.2 µm
    - Bacteria 0.2 µm
    - Viruses and mycoplasmas 0.01-0.1µm

  Membrane filtration is usually employed for heat-sensitive substances, e.g., vitamin solutions; the filters are heat-sterilized before use.

- **Nucleation Track (Nucleopore) Filters:** These filters consist of very tiny polycarbonate films which have been preserved with nuclear radiation and then etched with a chemical to create very uniform vertical holes. They are employed for the same material as membrane filters but have the disadvantage that they are more easily clogged.

Media Supplements

Substance	Solubility in Water at 25°C	Comments/ Sterilization
Biotin	22 mg/100 ml	pH of 0.01% sol. = 4.5 acidic solutions can be heat-sterilized
Cysteine*	Soluble	Neutral slightly alkaline solution is oxidized to cystine pK_1, 1.71 pK_2 8.33 pK_3 10.78
Dextrin	soluble in 3 parts boiling water	
Ehrlichs reagent Fructose	Soluble Soluble	
Fuchsin	1 g/7 ml	
Galactose		a) soluble in 0.5 parts water, freely soluble in hot water b) soluble in 1.7 parts water at 17°C
Glucose	1 g/1 ml	pH of 0.5 M aq. solution = 5.9
Glycerol	Miscible	
Glycogen	Soluble	with opalescence
Lactose	21.6 g/100 ml	a) 1 g/5 ml b) 1 g/2.2 ml at 15°C
Maltose	Soluble	Melting point 102-103°C
Mannitol	Soluble	
Niacin	Soluble	Stable to autoclaving at 120°C for 20 mins
Ribose	Soluble	
Citric acid	soluble 59.2 % at 20°C	pH of 0.1 N solution = 2.2
Sorbitol	soluble Up to83%	Melting point 100/112°C
Starch	insoluble	
Sucrose	1g/0.5ml	
EDTA (disodium salt)	Soluble	Used to complex iron in media

Table 5.1.3 Most commonly used Media Supplements, Methods of Sterilization, Solubilities

The preparation of media and the ingredients used is annexed at annexure No. V.

5.1.3 Aseptic Technique

Key Points

- Colony streaking results in to the isolation of individual colonies, which might be a collection of microbes that got here from one unmarried progenitor microbe.
- Spread plates permit for the even spreading of bacteria onto a petri dish; allowing for the isolation of person colonies, for counting or similarly experiments.

Key Terms

- Colony: A bacterial colony is described as a seen cluster of bacteria developing at the floor of or inside a strong medium, presumably cultured from a single cellular.
- Bunsen burner: A small laboratory gas burner whose air supply can be managed with an adjustable hole.

What is aseptic technique?

Aseptic approach or sterile approach is used to keep away from infection of sterile media and system during mobile way of life. Sterile approach must always be hired when working with stay cell cultures and reagents/media with a view to be used for such cultures. This approach involves the usage of flame to kill contaminating organisms, and a standard mode of operation that minimizes exposure of sterile media and device to contaminants.

Serial Dilution

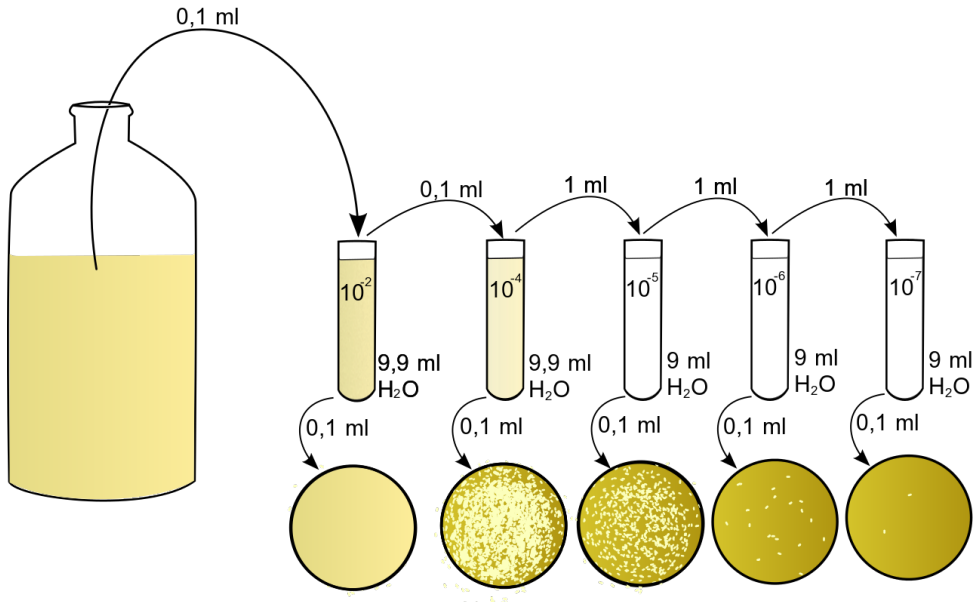


Fig. 5.1.4: Serial Dilution

A serial dilution is the step-wise dilution of a substance. Usually, the dilution at each step is constant, resulting in a geometric progression of the attention in a logarithmic fashion. A ten-fold serial dilution will be 1 M, 0.1 M, 0.01 M, 0.001 M.

Importance of serial dilution

Serial dilutions are used to as it should be creating highly-diluted solutions as well. A subculture of microbes can be diluted in the same fashion. For a ten-fold dilution on a 1 mL scale, vials are packed with 900 microliters of water or media, and one hundred microliters of the stock microbial answer are serially transferred, with thorough mixing after every dilution step. The dilution of microbes is very important to get to microbes diluted enough to anticipate a spread plate (defined later).

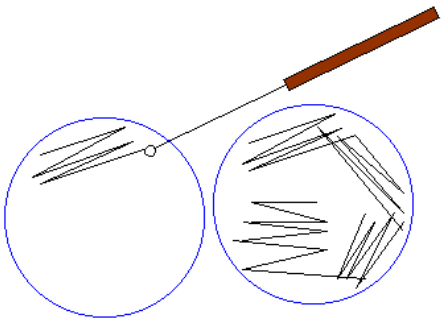


Fig. 5.1.5: Streak plate

Streak plates technique

In microbiology, streaking is a technique used to isolate a pure strain from an unmarried species of microorganism, frequently microorganism. Successful streaks lead to formation of colonies of microbes. Samples can then be taken from the resulting colonies and a microbiological subculture can be grown on a brand-new plate in order to identify, study, or test the organisms.

How it is done?

The streaking is done using a sterile tool, consisting of a cotton swab or generally an inoculation loop. This is dipped in an inoculum such as a broth or patient specimen containing many species of microorganism. The sample is spread throughout one quadrant of a petri dish containing a boom medium, typically an agar plate which has been sterilized in an autoclave. Choice of growth medium used relies upon on which microorganism is being cultured, or selected for. Growth media are normally kinds of agar, a gelatinous substance derived from seaweed.

UNIT 5.2: Sterilization Using Autoclave

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the procedure of sterilization.
2. Demonstrate preparing of solid culture media such as slopes/slants, plates from nutrient agar in sterile area.

5.2.1 Introduction

Sterilization refers to any method that eliminates all sorts of microbial organisms consisting of fungi, microorganism, viruses, spore forms, etc. present at the surface, contained in a fluid, or in a compound which include biological lifestyle media.

The autoclave kills microorganisms by the use of saturated steam under pressure. The use of moist heat eliminated all microorganisms, including heat-resistant endospores which is executed with the aid of heating the materials at temperatures above the boiling point of water.

5.2.2 Sterilization by Autoclaving

The autoclave is essential for sterilizing most microbiological media. It must be of sufficient size to sterilize media without crowding. The use of a vertical type, or a top loading, autoclave is not generally recommended because of unavoidable crowding and difficulty in adjusting and maintaining an adequate sterilization temperature. The use of a horizontal type, or side-loading, autoclave is always preferable, particularly in laboratories that handle large workloads.

The autoclave must be able to maintain an internal temperature of 121°C under a pressure of 1 bar (15 psi); it should be equipped with a calibrated thermometer to measure the temperature within the sterilizing chamber; it must be equipped with a pressure gauge and safety valves that are connected directly to a saturated steam supply line; and it must be able to reach the desired temperature within 30 minutes. The autoclave should also be equipped with a temperature recorder to provide a permanent record of the sterilizing cycle.

Need for Autoclaving

The autoclave should be used primarily for sterilizing media and solutions. Sterilizing pipets and other calibrated glassware in the autoclave are not recommended because accumulated moisture will affect the delivery capacity of the calibrated glassware. To make sure, sterilization is a success microbiologist should ensure:

- Air inside autoclave have to be evacuated in order that the chamber fills with steam;
- Articles need to be positioned in the autoclave so that steam can without difficulty penetrate them;

Fig. 5.2.1: An Autoclave

Similar to pressure cookers, steam sterilizer autoclaves work quickly and effectively due to their excessive temperature. The machine's temperature and unique shape make it simpler to preserve the warmth interior to much longer periods.

The autoclave's chambers are typically within the form of a cylinder due to the fact cylindrical shapes are more prepared to deal with the high pressure this is needed for the sterilization method to work. For safety reasons, there is an outside lock and a safety valve that stops the autoclave steam sterilizer's pressure from getting too high.

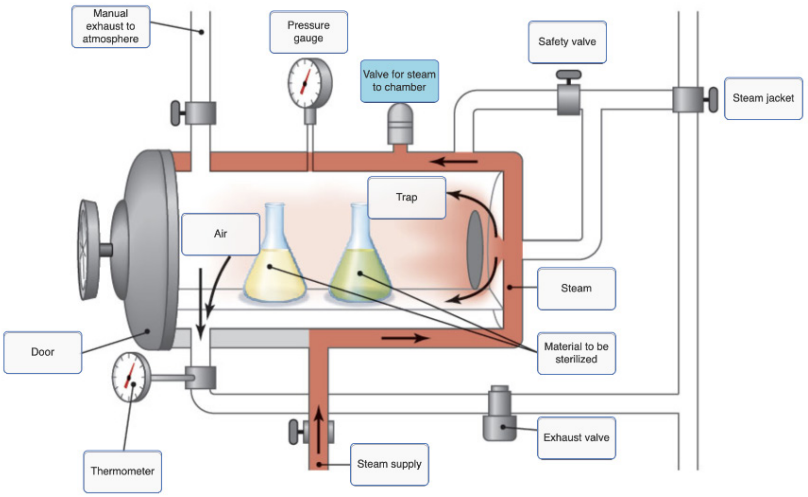


Fig. 5.2.2: Schematics of an Autoclave

After closing of the autoclave sterilizer chamber, a vacuum pump gets rid of all of the air from inside the tool. During the sterilization manner, steam is constantly entering the autoclave to thoroughly kill all dangerous microorganisms. Once the desired time of sterilization has elapsed, the chamber could be exhausted of stress and steam permitting the door to open for cooling and drying of the stuffing.

When microbiological media is made, it carefully has to be sterilized because of microbial infection from air, glassware, hands, etc. Within a few hours there could be thousands of microorganisms reproducing within the media so it has to be sterilized fast before the microbes start the use of the nutrients up. The sterilization manner is a 100% effective, and guarantees that the medium will be sterile unless exposed to contaminants.

Mechanism of sterilization

Steam enters into a jacket surrounding the chamber. When the strain from the steam is at a sure point inside the jacket, a valve permits the steam to enter the chamber. The pressure will pass up over 15 pounds per rectangular inch (psi): at this point the timer begins to matter down commonly for 15 minutes, relying on the form of media. The high pressure in a closed container allows the temperature to go above the best temperature one ought to get through simply boiling, around 121°C. Therefore, the parameters for sterilization with an autoclave are 121°C at >15 psi for 15 mins. Fifteen minutes is the thermal death time for maximum organisms (besides some sincerely hardy spore formers).

The prepared media is sent in special ways, depending at the form one is making. Broths and agar deeps are allotted into tubes and then sterilized. Agar slant tubes are sterilized and then the rack is tilted to permit the agar to solidify in a slanted fashion.

Fig. 5.2.3: Types of Autoclaves

Agar medium to be poured into plates is sterilized in a flask, and then poured afterward. Not all media or solutions may be sterilized through an autoclave. Certain high-protein solutions such as urea, vaccines, and serum will denature in the acute warmth, and so they'll should be filter-sterilized without heat.

Procedure

- Place the fabric to be sterilized within the pressure chamber and fill the cylinder with sufficient water;
- Close the lid and placed on the electrical heater;
- Adjust the protection valve to the specified pressure;
- After the water boils, permit the steam and air mixture to flee through the discharge faucet until all the air has been displaced
    - This will be tested by passing the steam-air mixture liberated from the discharge faucet into a pail of water through a connecting rubber tube.

- When the air bubbles stop coming back within the pail, it indicates that everyone the air has been displaced by steam.

- Close the discharge faucet. The steam pressure rises within and once it reaches the required set level (e.g., fifteen pounds (lbs.) per square measure in most cases), the protection valve opens and excess steam escapes out;
- Count the holding amount from now of your time, that is regarding quarter-hour in most cases;
- After the holding amount, stop the electrical heater and permit the autoclave to chill till the gauge indicates that the pressure within is adequate the air pressure;
- Open the discharge faucet slowly and permit the air to enter the autoclave;
- Open the lid of the autoclave and take away the sterilized materials.

5.2.3 Performance Check-Autoclave

Modern autoclaves have devices to keep up correct pressure and record internal temperature throughout operation. No matter the presence of such a tool, autoclave pressure ought to be checked sporadically and maintained.

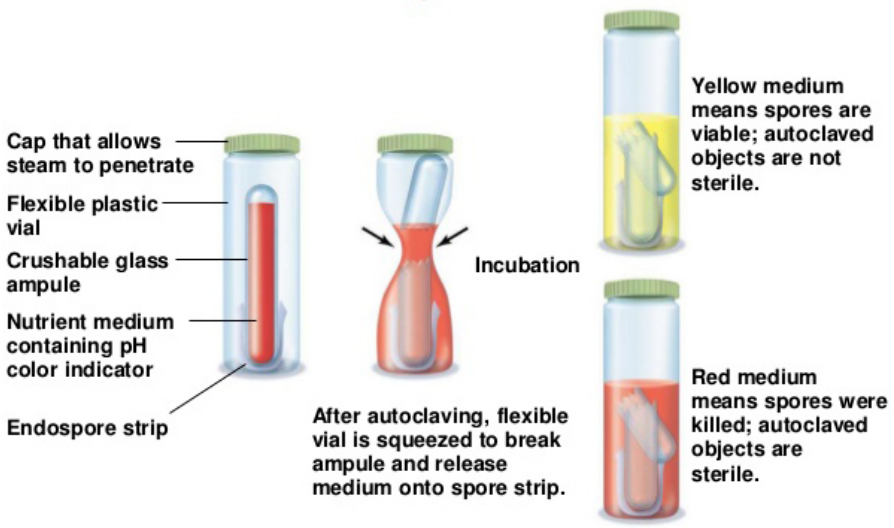


Fig. 5.2.4: Sterility Controls

Several strategies are there to confirm that autoclave reach the correct level of sterility

The proper functioning and working of the autoclave may be ensured by either physical and/or microbiological means.

It is suggested that a service contract specialist make thermocouple readings at various locations within the sterilizing chamber on an annual basis. The food microbiologist, however, should also use a microbiological indicator, such as a

- Bacillus Stearothermophilus spore ampule;
- a maximum registering thermometer to certify sterility conditions of the autoclave with each use;
- Commercially available tape, indicating sterility, should also be used with each load.

UNIT 5.3: Sampling for Microbiological Assay

Unit Objectives

At the end of this unit, you will be able to:

1. Explain sampling, control and storage requirements of samples, disposal of test material following SOP.
2. Demonstrate the sampling plan following SOP.
3. Explain environmental sampling of the laboratory by swab technique.
4. Discuss the test methods to be followed for sample testing.

5.3.1 Introduction

Sampling is a defined procedure whereby a part of the substance material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis) the sample may not be representative but is determined by availability.

5.3.2 Sampling and Sample Handling

Sampling for testing or analysis is a process of taking a representative portion from a material or product to test (e.g., by physical measurements, chemical analysis, microbiological examination), typically for the purposes of identification, quality control, or regulatory assessment. The sampling is a significant role in testing activities as it reflects the ultimate test results. It is not mandatory that all the laboratories shall be involved in sampling activities. However, the laboratory involves in sampling shall maintain at least the following[22]:

- The laboratory policy & declaration on sampling.
- The laboratory should have authorized personnel / sampler with adequate knowledge, training etc on sampling.
- The laboratory shall maintain the sampling plan & procedure in respects of the products / materials that shall include selection, withdrawn & preparation of samples during sampling. The same shall be based on appropriate statistical method / regulatory guidelines / references.
- Work instruction shall be maintained for the personnel involve in sampling activities.
- The laboratory should have all facilities like tools, equipment's / instruments etc requires for various sampling.
- The laboratory shall maintain the relevant data & operation related to sampling, procedure use, location, date / time of sampling, identification of sampler, other specific requirements like environmental conditions, transportation, statistics the sampling procedures are based upon etc and documents shall be maintained.
- All incoming samples shall receive through the receiving section maintained and supervised by laboratory responsible person. On receiving section, the laboratory responsible personnel initially

[22] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

checked the relevant overall criteria like sample identity/labelling, mode of transportation, condition of the sample including packaging, sample quantity, verification of fees (whenever necessary), parameter to be tested etc against the customer declaration / requirements. Any abnormalities / deviation / doubts from the normal condition, suitability of the sample for tests etc, the same shall be clarified from the customer / laboratory responsible personnel before accepting the samples for registration / testing. In case microbiological test samples, the same shall be received in the sterilized container/sample box etc. The laboratory documentation system shall include all relevant information such as customer details, date of receipt, condition of the sample on receipt, sample quantity, transportation, parameters to be tested, observation/remark (if any) etc.

- The laboratory shall maintain a system on traceability of all accepted samples and the same shall be maintained throughout the retention of the sample in the laboratory without any confusion.
- The laboratory must have all infrastructures, facilities for storage and preserve the samples depending on the physical, chemical and microbiological properties to maintain the sample integrity, security, avoid loss / damage, deterioration etc. The laboratory must have proper documented system on retention & disposal of the tested / remnant / reference samples. The retained samples may also use for retesting and the internal quality assurance purpose. Wherever necessary the specific storage like deep freezer, refrigerator etc shall be provided and during storage the environmental conditions shall be maintained, monitored & documented.
- The laboratory must have documented system, procedures, instructions & facilities for conditioning and preparation of sample according to the standard method or laboratory protocol to maintain the homogeneity, avoid loss / damage of the test sample.
- The laboratory should ensure to maintain a proper documented system procedure for handling of test items including sample receiving, storage, transportation, retention / disposal, integrity, avoid and prevent loss/damage of the test samples.

General Principles[23]:

- The identity, homogeneity and integrity of the materials being handled by the laboratory must be ensured throughout the time they are under the control of the laboratory e.g., from sample receipt to data report and authorized disposal of the surplus material.
- The analytical data report must reflect the composition of the received material as a whole.
- The sampling procedure should describe the selection, sampling plan, withdrawal or preparation of sample from a substance, material or product to yield the required information. If the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with appropriate sampling data and shall be included in all documents containing test and /or calibration results.
- The laboratory shall have the procedure for recording relevant data and operations relating to sampling that forms part of the testing and calibrations that is undertaken. These records shall include the sampling procedure used, the Identification of the sampler, environmental conditions (if relevant) and diagrams and other equivalent means to identify the sampling location as necessary.

Sample Classification

Samples may be conveniently classified under two broad divisions:

1. **Formal samples –** These are samples taken to determine if the food complies with national or local laws or regulations and

[23] FSSAI Manual on "General Guidelines on Sampling".
(https://old.fssai.gov.in/Portals/0/Pdf/Draft_Manuals/GENERAL_GUIDELINES_ON_SAMPLING.pdf)

2. **Informal Samples –** These are samples taken for the purpose of monitoring or as part of survey work.

Formal follow-up samples can be taken if informal samples receive adverse laboratory reports. Formal or informal sample are also taken under others such as follow-up to a consumer complaint.

Sample Receipt and Assignment:

Receipt and identification of a sample have to be clear and unambiguous for the quality assurance to be maintained. The laboratory register of test materials should be of a type where papers are numbered and cannot be removed. Entries on computer-based registers must be protected against deletion and/or alteration. A back-up copy must be produced and stored separately from the original.

When a sample is received for analysis, there must be a system to track the sample throughout its initial stage, analysis and later reserve storage. This is usually embodied in a record-keeping system, which is keyed to a unique identification number assigned to the sample at the time of sampling. This number can be sequential (i.e., 00001 to 9999) or can be devised to give information (i.e., 024-95-07) the 24th sample taken in 1995 under sampling programme No. 7) The record must show the movement of a sample, its receipt, assignment to a laboratory person for analysis, return to the sample and eventual dispersal. One of the administrative staff should be given this record – keeping function and closely supervised by the laboratory Head. It is preferable to use a card system rather than a logbook as cards are more flexibly handled. There are certain items of information, which should be on each card:

1. Sample number
2. Product name
3. Date Sampled
4. Date received at the laboratory
5. Type of sample (Survey, Complaints etc.)
6. Method of storage (dry, refrigeration, freezing etc.)
7. Storage location (coded for easy finding)
8. Date assigned for analysis
9. To whom assigned (the analyst should initial to show receipt)
10. Date retuned (from analysis)
11. From whom returned (maybe different from the original analyst)
12. Reserve storage method and location
13. Final disposal of samples, method and date.

Example of a typical sample record is depicted below

Example of a Sample Record

EXAMPLE OF A SAMPLE RECORD

PRODUCT:

Lab No: Product Code:

Date Received:

Storage Conditions: Storage Location:

Security Classification:

Sample Description:

Transfer Information:

Name Date out Location Analysis Date returned

References to Files, Records, Certificates of Analysis and Results

Number Location Subject Classification

Records Officers Name: Signature:

Date:

Fig. 5.3.1: Sample Record (Source[24]: Food and Agricultural Organization "Quality Control Manual")

Sample Collection

Important points to consider during sample collection:

- No. of batches/ lot: A representative statistical sampling strategy should be made for batches and lots based on the volume of material available on-site.
- No. of batches or lot are decided as per the Investigations Operations Manual Sample Plan.
- Each lot that is to be examined must be clearly defined. In case of random sampling the items are collected in such a way that all possible combinations have same probability of being collected. If the lot is heterogeneous, stratified sampling may be a solution.

[24] Manual of Food Quality Control. "Quality Assurance in the food control chemical laboratory" 14/14-Food and Agricultural organization of united Nations, Food and Nutrition Paper.

- Protocol for labelling and sealing: Labelling and sealing should be appropriate to maintain integrity and traceability of the sample. The identity of the sample should be evident from the reference stated on the drawn sample container.
- Representative number of subsamples should be made with the sample number, collection date and your written initials. Similarly identify any outer packaging, labels or circulars.
- Do not use tape on very small containers such as ampoules, which must be snapped or broken to remove the contents for analysis. Tape wrapped around the container may interfere with assay. Do not use permanent type markers when identifying subs in absorbent containers if the ink may penetrate into the product thus contaminating the sample. Diamond or carbide tipped stylus pencils may be used to mark tin, glass, etc. Do not use diamond or carbide tipped stylus to mark products in glass under pressure (i.e., carbonated beverages). Transparent tape such as Scotch Magic Transparent tape accepts ball point ink and may be used on glossy items such as glass, plastic, tin, etc. Glass, such as bottles, vials and ampules, may be identified by using a very fine pointed felt or nylon marking pen and covering the identification with transparent tape for protection.
- Sealing the edges: All the samples should be sealed immediately post sampling. A tamper evident seal should be used like wax, adhesives etc.
- Manner of packing: Packing of the sample should be done taking care to maintain the integrity and homogeneity of the sample. Packing should avoid pilferage and should be tamper evident. Clean inert container should be used offering adequate protection from external contamination and protection against damage to the sample in transit. The container should be sealed in such a manner that unauthorized opening is detectable and sent to lab. as soon as possible. Precautions should be taken against leakage and spoilage. Storage conditions should also be maintained.
- Define category of analysis: The category of analysis for foods should be done according to the requirement for regulatory or monitoring purpose.
    - Chemical
    - Microbiological
    - Physical
    - Sensory
- Final parts of food which are perishable should be kept refrigerated or in a frozen state, as necessary.

Control and Storage[25]:

The storage of test materials is of major importance if the analytical data produced is to reflect and be traceable to the original sample. Deterioration of test materials invalidates any results. Therefore; test materials must be stored so as to ensure their integrity, safety, legality and stability. The laboratory must guard against deterioration, contamination and loss of identity. Special care will be needed where trace analysis is involved in order to ensure that extraneous materials do not contaminate the test materials and equipment.

There are three basic forms of storage - room temperature (dry room), refrigeration and freezing. The QA programme should specify the conditions to be used. There are also problems associated with the type of container in which food can be stored. Foods that contain fats and oils should not be stored in copper or metallic vessels and foods that easily desiccate such as fruits need to be stored in ways, which avoid loss of water.

[25] FSSAI Manual on "General Guidelines on Sampling".
(https://old.fssai.gov.in/Portals/0/Pdf/Draft_Manuals/GENERAL_GUIDELINES_ON_SAMPLING.pdf)

Perishable, unfrozen food must be maintained at $0^{O}C – 4^{O}C$ and frozen food kept preferably at $-18^{O}C$ or below. All perishable items should be examined within 36 hrs. of collection. Perishable samples that have been examined within 36 hrs after being sampled should be frozen, canned. Dry non-perishable foods maybe stored at room temperature before analysis.

The test material could also be dried and stored pending analysis, if analysis will not be affected by drying. Special conditions apply to test materials, which are to undergo microbiological examination as well as chemical analysis. If a test material is to be stored frozen and a number of separate analyses are to be performed, it is preferable to sub-sample before freezing.

All test materials when stored must be properly and indelibly labelled so that identification is not lost. The most effective method of labelling maybe to place the label in its own plastic bag, inside the test material container, but separated from the food by a suitable layer.

The sample is then stored until it can be matched with a suitable test note containing all the above information and any other relevant information required for analysis and interpretation of the results. The test note should preferably be of the type that incorporates enough space for the test results and observations. The sample and the test note should (when matched if they arrive at different times) be clearly and indelibly marked with a registration number and passed to the analyst. From this point onwards, the analyst will identify everything pertaining to that sample with the laboratory number.

The Analytical Sample (Test Portion):

Before removing the test portion (s) for analysis, the analyst must be certain that all records are in order, integrity has been maintained containers are intact and sealed (if any), unbroken.

Any ambiguity in the analytical requirement must be resolved, e.g., with canned pickle in oil, is the analysis to be done on the pickle, oil or the whole contents of the can.

For analysis, the analyst first removes a test portion. If the test material comprises more than one item (fruit, vegetable etc.) the test portion should contain material from each item – usually achieved by combining a number of items and removing a portion. After the test portion has been removed, the remaining test material is returned to the storage.

Referral of the Test Material:

The reference materials are generally used for, to develop and validate accurate method of analysis ensuring traceable measurement results at the working level, to calibrate measurement system and to demonstrate the accuracy of results, assure the long-term adequacy and integrity of measurement quality assurance programme and monitor the lab performance, use in inter laboratory comparison and proficiency testing programme.

The laboratory shall ensure to maintain the reference standards, which are certified by the competent body having traceability to a national/international system like National Institute of Standards and Technology (NIST) etc. These shall be procured for all the microbiological parameters tested by the lab and shall be procured from with traceable and authorized sources (like Microbial Type Cell Culture (MTCC) in India, American Type Culture Association (ATCC) in USA, National Collection of Type Cultures (NCTC) in UK, New Zealand Reference Culture Collection (NZRCC) in NZ. Generally, the reference strains are received in lyophilized stage or deep-frozen stage. If the reference strain has been thawed, they shall not be refrozen.

The laboratory should establish and document system for handling and effective maintenance of cultures and their appropriate usage. On occasions it may be necessary to pass a test material to another laboratory for some specialized analysis or because of some analytical facility not being available with the laboratory or because of overload of work. Unless the other laboratory is a part of the same QA

programme or the two laboratories are accredited by the same (or equivalent schemes), this referral would mean that the test portion sent for that analysis ceases to be quality assured by the parent laboratory. This should be made clear in the analysis report to the customer.

The certificate provided by the supplier/manufacturer shall be maintained in the laboratory for records.

- The reference standards having high purity, critical characteristics and require to store in special condition and hence its, to be stored in appropriate special condition as per the requirements. The substances are to be kept in sealed vial and shall be stored in dry place, away from heat, sunlight & moisture.
- The reference standard solutions are required for sample analysis, quantification and Quality control (QC) checks. The laboratory shall be prepared the standard solution as needed like stock / primary, intermediate & working solution and wherever applicable the purity shall be considered during preparation. The standard solutions shall be kept in screw capped glass vials, standard volumetric flasks/stoppered conical flask (transparent/amber coloured) in air-conditioned room / refrigerate / deep freezer depending upon storage condition & requirements.
- The standards shall be prepared from bulk reference standard materials received from the market as A grade material. The selection criteria for the bulk material intended to accept as working standard in assay and purity of substances. For accepting the material to be taken as working standard the molecule must be subjected to chemical characterization. First the standard stock solution to be prepared from which different working standard is made. The preparation of standards is generally carried out in regular interval as per the requirement / laboratory protocol and the records of those are to be maintained and labelled with concentration & date of preparation.
- The preparation of working standard is generally carried out during analysis/ whenever necessary and records of these are to be maintained. The intermediate checks of the standards shall be checked in regular interval to ensure the performance, stability & integrity of the standards and records of those are maintained with Quality Control Chart / Levey-Jennings Chart etc.
- It is the responsibility of the laboratory to maintain the critical characterization, performance, stability & integrity of the standards through proper handling, storage etc & same shall be ensured by the intermediate checks in regular interval / as per the laboratory protocol.
- For some reference standards the shelf life / expiration date may not declared by the reference standards providing organization, in those cases the following shelf life may be considered when the standards are stored un opened at recommended temperature
    - Room temperature items, which are not temperature sensitive and usually are stabled for five years from the date of receipt.
    - Refrigerated items usually are stabled for two years from the date of receipt.
    - Freezer items usually are stabled for one year from the date of receipt

However, it is the primary responsibilities of the laboratory to ensure the performance, stability & integrity of the standards through intermediate checks in regular interval / as per the laboratory protocol.

Reagent solution/standard solutions shall be prepared in established manner, for preparation of reagents the testing personnel refers to be relevant reference. After their preparation, those are to be stored in appropriate storage condition i.e., protected from light, tightly stoppered, refrigerated etc. Wherever, it is recommended reagents are to be prepared freshly. All the reagents/solutions bottles shall be properly labelled with name, date of preparation, concentration etc.

All reference standards shall be kept under responsible person to maintain proper storage, transport, security, integrity, mishandling etc and the relevant records are also to be maintained. The utmost care & protection shall be taken during handling & preparation of standards to avoid cross contamination & health hazard.

Use of reference strains

The reference microbial stains are used for Quality control; internal quality control and performance of culture media in terms of productivity, selectivity, performance evaluation and interpretation of result. The reference cultures are received either on slant form or in lyophilized forms in vials.

Revival of reference cultures

On receipt the reference cultures, requires to revive in the laboratory. Some key points are mentioned below:

- The active cultures shall be sub-cultured on to recommended medium and incubated at temperature specified. For lyophilized culture the outer surface of the vials is disinfected, wrapped with thick cotton wool and neck of the culture vials is broken.
- The contents should be transferred into 3 to 5 ml of recommended broth medium and mixed properly.
- The suspension is to be streaked on the recommended agar plate followed by incubation at specified temperature.
- Reference cultures to be checked for its purity, homogeneity, and typical morphology. Subsequently they have to check for characteristic reaction in selective medium and biochemical reactions. Whenever necessary, serological test as per analytical procedure is also to be carried out to check the pure culture.
- Sub-culturing from original stock in regular intervals as working culture for routine use and records to be maintained. The intermediate checks on the purity and biochemical characterization also to be checked.
- All the working cultures have to be properly located with name, date etc. & to be kept under proper storage condition.

Test Material Disposal:

Sample disposal is relatively a simple matter. The only problem arrives when there is a hazard involved in the destruction or the sample remains must have specific treatment e.g., a sample of groundnut heavily contaminated with aflatoxin. Reserve portions of microbiology samples containing pathogenic microorganisms and/or microbial toxins should be autoclaved before disposal. Large masses of dry food should be autoclaved in smaller (0.5 - 1kg) amounts to ensure that adequate penetration of steam during autoclaving will kill all viable pathogenic organisms. About 1 liter of water should be added to each 500 g amount of dry food to ensure adequate generation of steam during the sterilization cycle. If necessary, the dry reserve sample may be kneaded with added water to dissolve or disintegrate large clumps of solid material. The register should therefore have a column in it for details of when, how and where the test material was disposed.

5.3.3 Sampling Plans, Procedure and Guidelines, as per FSS Guidelines for Microbiological Analysis

Sampling plans are required which ensure that fair and valid procedures are used when food is being controlled for compliance with a particular commodity standard. Since numerous, yet often complex, sampling plans are available it is the purpose of these guidelines to help those responsible for sampling to select sampling plans that are appropriate for statistical inspections under specifications laid down in standards. No sampling plan can ensure that every item in a lot conforms. These sampling plans

are nevertheless useful for guaranteeing an acceptable quality level. These guidelines contain the elementary principles of statistical control at reception, which complete the basic recommendations mentioned above.

Basic recommendations for the selection of sampling plans

- **Nature of the control**
  - Characteristic applicable to each individual item of the lot
  - Characteristic applicable to the whole lot (statistical approach)
- **Nature of the characteristic to control**
  - Qualitative characteristic (characteristic measured on a pass/failed or similar basis, i.e., presence of a pathogen micro-organism)
  - Quantitative characteristic (characteristic measured on a continuous scale, for example a compositional characteristic)
- **Choice of the quality level (AQL or LQ)**
  - In accordance with the principles laid down in the FSSA Manual and with the type of risk: critical/ non-critical non-conformities.

  The Acceptable Quality Level (AQL) for a given sampling plan is the rate of non- conforming items at which a lot will be rejected with a low probability, usually 5 %. The Acceptable Quality Level (AQL) is used as an indexing criterion applied to a continuous series of lots which corresponds to a maximum rate of acceptable defective items in lots (or the maximum number of defective items per hundred items). This does not mean that all the lots having a rate of defective items greater than the AQL will be rejected at the control, but this means that the higher the rate of defective items exceeds the AQL, the greater is the probability of rejection of a lot.
- **Nature of the lot**
  - Bulk or pre-packed commodities
  - Size, homogeneity and distribution concerning the characteristic to control
- **Composition of the sample**
  - Sample composed of a single sampling unit
  - Sample composed of more than one unit (including the composite sample)
- **Choice of the type of sampling plan**

  Sampling plan needs to be specified. Single sampling plans for inspections of percent non-conforming items by attributes can be used. Sampling should be done considering the no. and nature of parameters to be assessed. Attribute sampling plan can be used when evaluating isolated lots. Variable method can be used if less no. of parameters is to be assessed. Sampling plan for lots moving in international trade are to be selected by attributes indexed by limiting quality level. For microbiological assessment, inspection by two or three class attributes is to be done. Acceptance sampling plans for statistical quality control
  - for the control of the average of the characteristic
  - for the control of per-cent non-conforming items in the lot
    - Definition and enumeration of non-conforming items in the sample (attribute plans)
    - Comparison of the mean value of the items forming the sample with regards to an algebraic formula (variable plans).
  - Convenience (or pragmatic, empirical) sampling plans (The two flow-charts in the following page sum up a systematic approach for the selection of a sampling plan)

Types of single sampling plans

- Single sampling plans for inspections of percent non-conforming item
- Principles of inspection by attributes of percent non-conforming items

A sampling plan for inspection by attributes is a method for evaluating the quality of a lot which operates by classifying each increment of the sample as a conforming or nonconforming characteristic or attribute, depending on whether the standard specification is complied with or not. This characteristic is either qualitative (for example the presence of a blemish on fruit) or quantitative (for example the sodium content of a dietary food, classified as conforming or non-conforming in relation to a limit noted). The number of increments having the nonconforming attribute are then counted and if the acceptance number set by the plan is not exceeded the lot is accepted, otherwise it is refused.

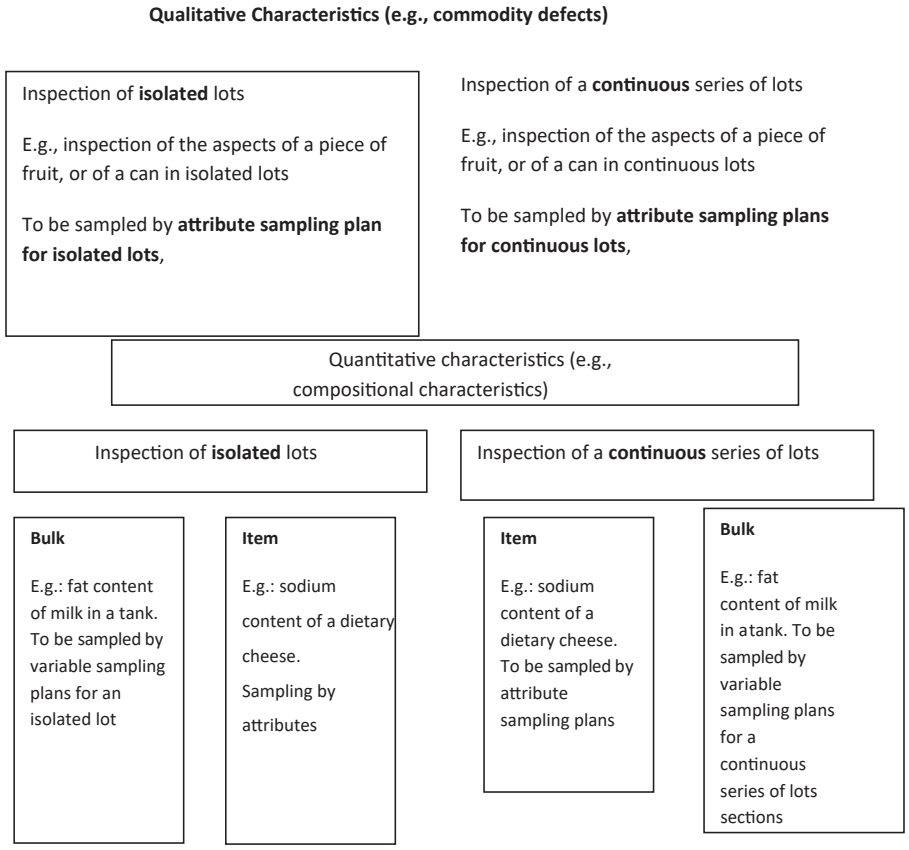


Fig. 5.3.1: Flow Chart for chemical and physical characteristics

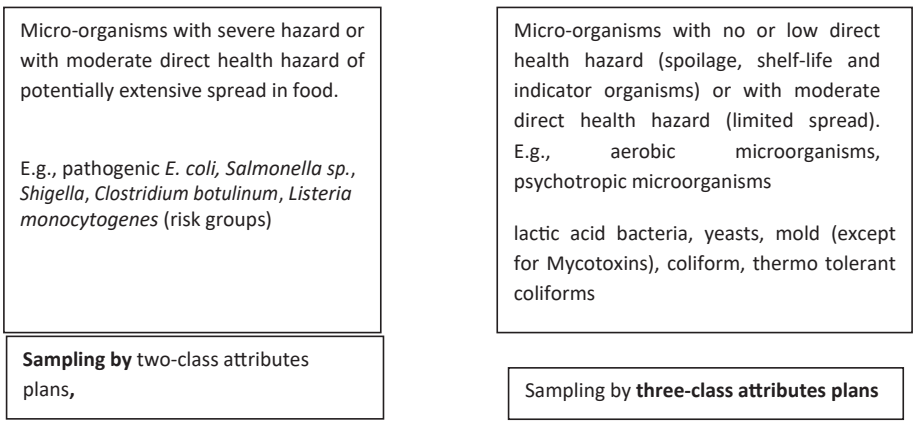


Fig. 5.3.2: Flow Chart for microbial characteristics

Comparative advantages and disadvantages of attribute plans and variable plans

When it is possible to implement either an attribute plan or a variable plan, for example for the inspection of the sodium content of a dietary cheese, the selection must be made after having consulted in particular the following Table 5.3.1 on the comparative advantages and disadvantages of the plans.

	ADVANTAGES	DISADVANTAGES
ATTRIBUTES PLANS	No condition on the mathematical law of distribution of the variable inspected; Greater simplicity of processing the results on the sample.	Less effective than variables plan for a same sample size of n increments (the LQ is higher); more costly than variables plans because the collected sample requires more increments than those required, for the same efficacy, by a variable plan.
VARIABLES PLANS	More effective than attributes plan for the same sample size of n increments (the LQ is lower); for the same AQL they are less expensive than attributes plan because the sample collected requires fewer increments than those required, for a same efficacy.	They cannot be used in all cases because to validate the calculation formulas the mathematical law of distribution of the inspected variable must necessarily follow or approximately follow a normal law.

Table 5.3.1: Comparison of attribute and variable sampling plans

Two and Three Class Attributes Plans for Microbiological Assessments

Two-class Attributes Plans

Two-class attributes plans provide a simple means of inspection where the sampling plan is defined by two values, n and c. The value of n defines the sample size in terms of the number of items; and the value c denotes the maximum number of nonconforming items permitted in the sample. When undertaking a microbiological assessment, a maximum concentration of micro-organisms permitted in any item is denoted by m; any item contaminated at a concentration greater than m is considered to be nonconforming.

For a given value of c, the stringency (probability of rejection) of the plan will increase as n increases.

The application of a two-class attributes plan can be summarized as follows :

Set the value of m, n and c

↓

Collect the sample with n items

↓

Inspect each item in the sample

↓

Accept the lot if: number of defective items ≤ c

Three-class Attributes Plans

Three class attributes plans are defined by the values n, c, m and M (see below); and are applied to situations where the quality of the product can be divided into three attribute classes depending upon the concentration of micro-organisms within the sample:

- Unacceptable quality, with a concentration of micro-organisms above the value, M (which must not be exceeded by any items in the sample).
- Good quality, where the concentration must not exceed the value, m.
- Marginally acceptable quality. Marginal items have a concentration which exceeds m, but which is less than M (such concentrations are undesirable but some can be accepted, the maximum number acceptable being denoted by c).
- The value m is the concentration of the micro-organism which is acceptable and attainable in the food under inspection, as reflected by Good Commercial Practice (GCP). For 3-class plans, m will be assigned a non-zero value.

The value M is a hazardous or unacceptable level of contamination caused by poor hygienic practice, including improper storage. There are several approaches to choosing the value of M:

- As a 'utility' (spoilage or shelf-life) index, relating levels of contamination to detectable spoilage (odor, flavor) or to an unacceptably short shelf-life;
- As a general hygiene indicator, relating levels of the indicator contaminant to a clearly unacceptable condition of hygiene;
- As a health hazard, relating contamination levels to illness. A variety of data may be used for this purpose including, for example, epidemiological, experimental animal feeding and human feeding data.

The values m and M may be independent of each other. The choice of values for n and c varies with the desired stringency (probability of rejection). For stringent 'cases', n is high and c is low; for lenient 'cases' n is low and c is high. The choice of n is usually a compromise between what is an ideal probability of assurance of consumer safety and the work load the laboratory can handle. If the concentration of micro-organisms in any item of the sample is greater than M, the lot is directly rejected.

The application of a three-class attributes sampling plan may be summarized as follows:

Set the values of m, M, n, c

↓

Collect the sample with n items

↓

Inspect each item in the sample

↓

Accept the lot if: number of marginally defective items (i.e., a concentration of micro- organisms between m and M) ≤ c, immediately reject the lot if the concentration of micro-organisms in any item >M and/or the number of marginally defective items > c.

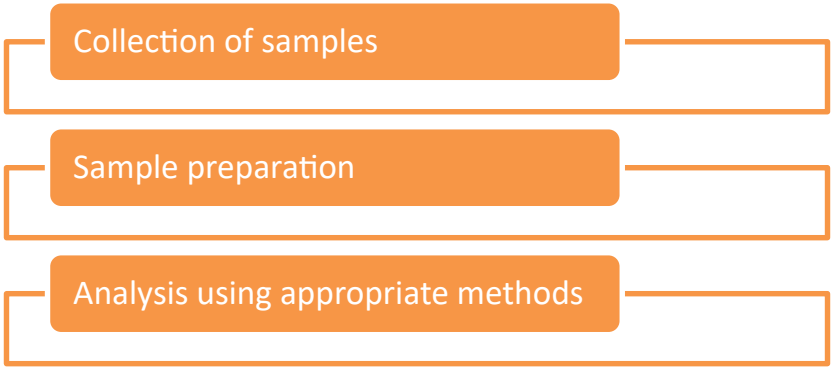
The Application of Two and Three-class Attributes Plans for microbiological analysis

Two and three-class attributes plans are ideally suited for regulatory, port-of- entry, and other consumer-oriented situations where little information is available concerning the microbiological history of the lot. The plans are independent of lot size if the lot is large in comparison to sample size. The relationship between sample size and lot size only becomes significant when the sample size approaches one tenth of the lot size, a situation rarely occurring in the bacteriological inspection of foods.

When choosing a plan, one must consider:

The type and seriousness of hazards likely to be caused by the microorganisms; and the conditions under which the food is expected to be handled and consumed after sampling.

The reliability of the analytical data thus collected depends on many factors, the main factor being the sampling. Present analytical methods include an analysis of only a few grams of the food sample. So, a sample must be as representative of the population as possible. The study of food items includes three main activities:



The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results for microbiological analysis

2-Class Sampling Plan (where n, c and m are specified)	3-Class Sampling Plan (where n, c, m and M are specified)
• Satisfactory, if all the values observed are ≤ m • Unsatisfactory, if one or more of the values observed are >m or more than c values are > m	• Satisfactory, if all the values observed are ≤ m • Acceptable, if a maximum of c values is between m and M and the rest of the values are observed as ≤ m • Unsatisfactory, if one or more of the values observed are >M or more than c values are > m

Table 5.3.2 Interpretation of Results

Test methods for collected samples

1. The laboratory shall normally use only standard methods as prescribed in DGHS (Director General of Health Services-India) Manual, BIS (Bureau of Indian Standards) specifications, AOAC (Association of Official Agricultural Chemists) test method manual or any other international publications like USFDA (United States Food Drug Administration), BAM (Bacteriological Analytical Manual), American Public Health Association (APHA) Compendium of Methods for the Microbiological Examination of Foods.

2. Where standard methods are prescribed and followed, the laboratory is expected to maintain current versions of the standard methods (reference texts) and up-date laboratory bench methods in accordance with these. Although full validation is not required, a laboratory must verify that it can properly operate the method, and can demonstrate (where specified) the limits of detection, selectivity, repeatability and reproducibility. Laboratories shall pay attention to the limitations, concentrations range and sample matrix specified in the test standards.
3. The use of commercial test systems (kits) shall normally be avoided unless absolutely necessary. In case these are used, they shall require further validation if the laboratory is unable to source the validation data. When the manufacturer of the test kits supplies validation data, the laboratory will only perform secondary validation (verification). Laboratories should retain validation data on commercial test systems (kits) used in the laboratory. These validation data may be obtained through collaborative testing, from the manufacturers and subjected to third party evaluation. If the validation data is not available or not applicable, the laboratory should be responsible for completing the primary validation of the method.
4. The validation of microbiological tests methods should be carried out as per the guidance provide in National Accreditation Board for Testing and Calibration Laboratories (NABL).

The following general points should be kept in mind while choosing test methods[26]:

- The laboratory shall use only official methods depending on the requirement of the test, its sensitivity and nature of the commodity which is being tested and quality/safety factors to be determined.
- In case of non-official method, validation of the methods as per set norms is a must and their range of detection/quantification, Limit of Detection (L.O.D)/ Limit of Blank (L.O.Q) limitations etc. must be established.
- Selection of method is very important depending upon the requirement of the test and customer requirement.
- Estimation of uncertainty of measurement should be available for each method in context of the food commodity and test to be done.
- External calibration of the equipment is a must annually or depending upon its use. However, in case of any equipment being used very frequently, internal calibration facility should be available and done regularly with a record thereof. Refer Annexure-II for calibration procedure of microscope which is the soul of microbiology laboratory.
- Glass apparatus should be calibrated.
- In case of standard chemicals required in testing, whose purity can alter the result should be certified reference material with proper traceability.
- In case of recovery and PPM level extraction from a food commodity, percentage recovery must be established for each food and the contaminant/constituent which have to be determined and the calculation should take care of such recovery.
- Sometimes official methods do not prescribe the interfering material in the test method, limitations, its sensitivity, range of detection and qualification, capability of the equipment's being used, due to change of the sophisticated equipment as prescribed in the method for a particular model/ technology. Hence it is necessary to establish the suitability of such methods for their particular test and equipment, etc. before giving the results. Obviously, the method needs to be validated internally for its particular use using particular equipment.

[26] FSSAI Manual on "General Guidelines on Sampling".
(https://old.fssai.gov.in/Portals/0/Pdf/Draft_Manuals/GENERAL_GUIDELINES_ON_SAMPLING.pdf)

- Standard solution should be stored at required temperature and condition and its strength should be checked regularly and record thereof should be maintained.
- Calculation should be done and rounded off while reporting the results to the required level of standard.
- SOP as far as possible should be available for test method along with the protocol.
- Method should be available while performing any test to follow exactly the test method prescribed. No short cuts should be followed and tests should not be done on a memory basis alone.
- Purity of the solvents, water being used and other chemicals should be checked regularly and a record thereof should be maintained.
- In case of any controversy or marginal results, only reference methods should be used.
- In case of micro biological analysis standard culture must be available to establish the confirmation of the microbes. SWAB testing must be done for inoculation room and media preparation room regularly to ensure that it is not contaminated.
- The results should be recorded commensuration with the calibration of the glass apparatus etc. e.g., in case of a burette, the result should be reported only to the displayed capabilities of the burette.
- Special precaution should be taken for pipetting and ejecting the solution from the pipette. The solution should not be blown by air through mouth.
- All the apparatuses specially glass should be contamination free and should be cleaned and rinsed thoroughly before use. No chemicals should be used after its expiry or otherwise if it looks like deteriorated or decomposed.

Environmental sampling of the laboratory by swabbing technique

Environmental sampling program will help in the detection of unacceptable microbial infection in a timely manner. Over the last decade environmental monitoring has changed from basically random sampling, using imaginary grids over a manufacturing area and checking out factors within each grid, to modern strategies which might be focused on risk evaluation to determine the most suitable methods for monitoring. Sampling packages need to consist of the gathering of samples in the course of production on an ordinary basis from work surfaces in a randomized way in order to mirror the differing working conditions. In addition, samples need to be taken from those websites after sanitizing and from web sites which may also function harbors of resident organisms.

Sampling ought to not handiest be conducted on food contact surfaces, but the evaluation of non-food touch surfaces including conveyor belts, rollers, walls, drains and air is equally as essential as there are many ways (aerosols and human intervention) wherein microorganisms can migrate from non-food touch surfaces to food. The results of those samples should be tabulated as soon as to be had and in the sort of manner that they can be compared with preceding results for you to spotlight trends.

General considerations

The environment to which the samples, extracts from them, personnel and equipment are subjected must be checked to ensure that quality of results is not affected. Thus, records will be checked to show that:

- Samples are received, stored, handled and analyzed under environmental conditions that will not adversely affect analyses;
- Temperature, humidity and light controls are adequate in sensitive areas to protect samples, extracts from them, personnel and equipment;
- The results of environmental sampling in laboratory areas are recorded.

Normally, microbiological monitoring of the environment involves analysis of laboratory surfaces and air for the presence of microorganisms. Laboratory surfaces may be tested to determine cleanliness of the same work area over a prolonged period or of different work areas at any given time, the needed frequency of housecleaning, effectiveness of disinfectants on workbenches and needed frequency of workbench disinfection, and efficiency of laminar flow hood. Monitoring of air is performed to determine efficiency of air filters and needed frequency of changing them, and any possible sources of environmental contamination of samples.

The enumeration of microorganisms on laboratory surfaces may be determined either by the swab method (Annex I) or the replicate organism direct agar contact (RODAC) method (Annex I). The RODAC method is especially adapted for sampling flat, impervious surfaces. It should not be used on irregular surfaces or on surfaces with cracks or crevices. It is optimally used on flat surfaces that have been cleaned and sanitized or disinfected. Heavily contaminated surfaces will result in overgrowth on the RODAC plates. Microbiological quality of the air should be monitored at least biweekly to be certain that the laboratory environment is not a significant source of contamination.

One simple, yet effective, approach for monitoring air quality is referred to as the sedimentation procedure or the "fallout" plate technique. Plates of a nonselective medium, e.g., plate count agar, are exposed to the environment at various sites throughout the laboratory. The actual choice of sites may be based on such factors as flow of pedestrian traffic or relative magnitude of analytical activity. After a 15-minute exposure, plates are closed and incubated at 35° for 48 hours. Plates are counted and results are written in a hard-bound record book. Plates exhibiting more than 15 colonies indicate that the microbiological quality of the air may be unsuitable for performing laboratory analyses. In this event, laboratory work should be suspended, all laboratory surfaces disinfected, and the microbiological quality of the air reevaluated before normal laboratory operations are resumed. For laboratories desiring a more sophisticated approach, there are various types of environmental air sampling devices, e.g., sieve samplers, split samplers, and centrifugal samplers, discussed in detail in the American Public Health Association's (APHA) Compendium of Methods for the Microbiological Examination of Foods (Vol 2).

How to Collect Swab Samples for Microbiological Environmental Testing?

Horizontal techniques for sampling strategies from surfaces the usage of touch plates and swabs does however provide a preferred platform for the important steps that should be considered within the development of testing processes. The key factors of this well-known that have to be taken into consideration include:

1. Moistened swabs have to be employed for all sampling of surfaces;
2. The answer used to moisten swabs should neutralize any detergents and sanitizers employed;
3. Swab moisturizer solution have to preserves the integrity of the pattern i.e., Bacterial numbers must stay constant until the pattern accrued onto the swab may be evaluated;
4. Wherever feasible the scale of the location sampled should be greater than 100cm^2;
5. The analysis of the samples for particular pathogens is done via transferring the swabs into the ideal enrichment broth;
6. After enrichment switch a sample to the proper agar plate medium for the goal organism being sought;
7. Report the target microorganism as presence or absent;
8. The contact plate approach (which includes dip slides, Replicate Organism Detection and Counting (RODAC) plates and 3M Petri film™) shall not be used for the precise detection of pathogenic microorganisms.

Refer Annexure-I for more details

Detection of Target Microorganisms

As mentioned above, the exam of environmental swabs for specific food pathogens isn't always defined in any specific popular techniques, however the general precept that the analysis of the samples for particular pathogens can be done by using shifting swabs into the right enrichment broth may be carried out to any precise pathogen being sought.

Method		24 Hours	48 Hours
USDA FSIS (Food Safety and Inspection Service)		UVM (University of Vermont Medium) Broth	Fraser Broth
Health Canada 2002)	No. HFLP-38,	PALCAM (Polymyxin Acriflavin Lithium-chloride Ceftazidime Esculin Mannitol) Broth	UVM2 Broth
USFDA (BAM) Association of Official Analytical Collaboration (AOAC)/ Food and Drug Administration (FDA)		LEB (Luria Broth)	LEB

Table 5.3.5 Culture media suitable for the selective enrichment of Listeria spp.

Evaluation of the Results from Environmental Microbiological Testing

Following sampling and microbiological evaluation a chain of consequences will be to be had that offer an illustration of the overall stages of hygiene inside the processing environments evaluated. This body of statistics gives a valuable tool for maintaining and improving the fine and protection of merchandise. In addition, the detection of precise pathogens which includes Salmonella and Listeria is important in making sure food safety for the consumer.

It isn't always unusual for food manufacturers most effective to react to unacceptable consequences while those pathogens seem while final food products are evaluated but, it's miles important (specially in high threat products) that on-going environmental sampling practices are implemented and performed. The evaluation of samples and sampling plans and the test data generated over prolonged periods should result in modifications in take a look at sample frequency and location, which in turn need to lead to enhancements in cleansing and sanitizing practices.

Example of Path-Check Hygiene Pathogen Detection is discussed in detail below

Path-Check Hygiene Pathogen Detection

The Path-Check Hygiene Pathogen Detection product variety is various microbiological environmental monitoring merchandise that integrate all of the requirements of the Indian standards of Organization (ISO) Standard, ISO 18593:2004(E) Microbiology of food and animal feeding stuffs – Horizontal strategies for sampling strategies from surfaces using touch plates and swabs and the pathogen isolation, and detection strategies employed in pathogen isolation and detection strategies.

Storage and Shelf Life

The Path-Chek Hygiene Detection Broths need to be saved at 2 - 8°C when now not in use.

The pre-moistened sample swabs need to be stored at 4 - 25°C. Both components have to not be used after the expiry date printed on the carton label. Preservative Efficiency of Neutralizing Buffer

Eight species of usually encountered environmental microorganism and food pathogens microorganism had been grown overnight on Tryptone Soya Agar plates and suspended in 10 ml Ringers technique to an approximate turbidity of Browns Opacity Standard No 1. 0.1 ml of those dilutions have been

transferred into the 100 ml neutralizer. Six sponges had been inoculated with 5ml neutralizer for each type of bacteria. The sponges have been incubated at 22^{O}C throughout the take a look at.

A semi-quantitative total possible counting method changed into used to check the range of microorganism surviving in the neutralizer. Bacterial ranges had been tested at 0, 24, 48, 72 and 168 hours.

Discussion

All of the organisms in this check maintained regular numbers up to 24 hours when stored at 22^{O}C. Beyond 24 hours a sluggish decrease within the numbers of organisms recovered came about with all species examined, however S. aureus changed into the most effective organism to suffer great reductions in numbers.

The outcomes display that the swab neutralizing buffer is able to preserve the viability of the bacteria used in the test while also stopping over growth.

(Source: FSSAI)

UNIT 5.4: Preparation of the work space (Laminar Air Flow Cabinet)

Unit Objectives

At the end of this unit, you will be able to:

1. Prepare the work space (Laminar Air Flow Cabinet) or lab bench by wiping with disinfectant, clean glass ware, tools and equipment dilute samples following SOP

5.4.1 Working of LAF

All the microbiological analysis is carried out in the sterile or aseptic workspace. Laminar Air Flow (LAF) is widely used for the purpose. It is an enclosed bench designed to avoid contaminations.

Air from the room passes via the HEPA (High Efficiency Particulate Absorbing) filters and is fed into the working chamber by means of a unidirectional vertical descending go with the flow. The Hoods have to be grew to become on about 10-20 minutes before getting used to kill the germs. It is essential to exchange off this light throughout use as it is able to purpose mutations and can supply any uncovered skin sunburn and might cause cataracts too. It is required to wipe down the cupboard floor with ethanol earlier than and after use and it's also required to maintain the hood free of muddle as viable because this could intervene with the laminar flow air pattern.

Fig. 5.4.1: The Laminar Air Flow (LAF) Cabinet

The process of laminar air flow can be defined as airflow where an entire frame of air flows with steady, uniform velocity.

Laminar Flow Cabinets work by the usage of in-glide laminar air drawn through one or greater HEPA filters, designed to create particle-unfastened operating surroundings and provide product protection. Air is taken via a filtration system and then exhausted throughout the work surface as part of the laminar flows manner. Commonly, the filtration machine contains a pre-filter and a HEPA filter out. The Laminar Flow Cabinet is enclosed on the sides and consistent superb air stress is maintained to save you the intrusion of infected room air.

5.4.2 Components of the Laminar Hood

- A Blower
- High Efficiency performance Air filter
- A Plenum Chamber (Pressurized housing containing air at positive pressure)

5.4.3 Important parameters to make sure that the hood works efficiently

- the HEPA filter has to remove all airborne materials
- the air speed in the working area has to be about 0.5

5.4.4 Need of Laminar Hood

- It offers clean air to the working area.
- It offers a constant flow of air out of the work area to avoid room air from ingoing.

The air that flows out from the Hood, removes contaminants brought into the work area by personnel. The most important part of a laminar glide hood is a High Efficiency Particulate Air clear out (HEPA). Room air is taken into the unit and passed through a pre-filter out to cast off gross contaminants (lint, dirt etc.). The air is then compressed and channeled up in the back of and via the HEPA filter out in a laminar waft fashion. The HEPA clear out removes nearly all the bacteria from the air.

5.4.5 Types of laminar flow hoods

Laminar Flow Cabinets can be produced as both horizontal and vertical cabinets. There are many different types of cabinets with a variety of airflow patterns for different purposes.

- Vertical Laminar Flow Cabinets
- Horizontal Laminar Flow Cabinets

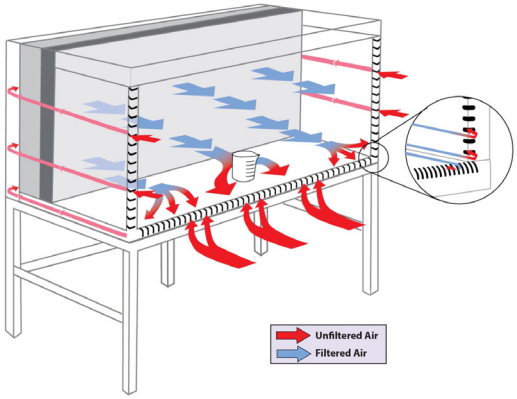


Fig. 5.5.2: Line diagram of horizontal laminar air flow bench

- **Horizontal Laminar Flow Cabinets**

  Horizontal Laminar Flow Cabinets acquire their name because of the route of air flow which comes from above however then changes route and is processed throughout the work in a horizontal route. The steady float of filtered air affords material and product protection.

- **Vertical Laminar Flow Cabinets**

  Vertical Laminar Flow Cabinets function equally nicely as horizontal Laminar Flow Cabinets with the laminar air directed vertically downwards onto the running vicinity. The air can leave the working area through holes in the base. Vertical drift cabinets can offer extra operator protection.

5.4.6 Cleaning and Sanitation of Workspace

Cleanliness and air filtration are extremely important in maintaining sterility levels in a cleanroom or laboratory. Proper cleaning and maintenance will result in accurate results. If cleaning procedures are not followed, contamination may deliver incorrect results. Laminar flow hood cleaning should be conducted regularly and by food microbiologist.

1. Cleaning Equipment required for preparation of workstation:
   - 70% ethanol (Most effective in killing microbes)
   - Avoid using soap and water
   - Laboratory-grade wipes
   - Biohazard trash bags
   - Lint-free cleanroom cloths
   - Laboratory gowns or coats should be worn
   - Gloves, face, and eye protection
2. Vertical Laminar Flow Hood Cleaning Steps
   - Start by cleaning the back wall of laminar flow hood
   - Clean the side walls, use a sweeping motion from left to right moving from top to bottom
   - And lastly, clean the work surface. Food microbiologist should begin working at the back of the unit and followed by working in front area.
3. Horizontal Laminar Flow Hood Cleaning Steps
   - Start by cleaning the laminar flow hood ceiling
   - Clean the side walls, use a sweeping motion from left to right moving from top to bottom
   - And lastly, clean the work surface. Food microbiologist should begin working at the back of the unit and followed by working in front area.
4. Cleaning Tips
   - A new cloth should be used for each wall
   - Always clean from back to front, top to bottom
   - Overlap each swipe
   - Do Not attempt to clean the filter
   - Filters should be replaced every 3-5 years

5.4.7 Biosafety Precautions should be taken for the Laminar Hood

The key precautions while working with the LAF are mentioned below:

- Large objects should not be placed near the back of the hood, as they may contaminate everything downstream and disrupt the laminar flow pattern of air too.

- All calculations should be done before entering the hood and waste or other items should never enter the hood.
- Hands should be cleaned with ethanol
- Do not touch your hair, face or clothing while working.
- Excess dust should be cleaned from items before introducing them into the hood.
- Hair should be tied up while working
- Do not work with the cabinet UV light source illuminated.
- The cabinet must be on for at least 5 minutes before starting biohazard work.
- The researcher should wear a closed-front lab coat and gloves and the gloves should overlap the lab coat
- All the required materials should be placed in the hood before initiating work to minimize in-and-out.
- Do not overload the working area or block front, side, or rear air grills which will restrict air flow.
- While operating the Laminar, the lab entry door must be kept closed and traffic minimized
- Do not use electric fans in the room while working this will seriously affect the airflow.
- Clean the hood with an appropriate disinfectant at the end of each operation.

UNIT 5.5: Aseptic Sample Inoculation

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss aseptic inoculation of the samples for microbial growth.

5.5.1 Introduction

This unit describes the methods of inoculating tradition media and sub-culturing of organisms and the usage of aseptic techniques. To method specimens satisfactorily following considerations are recommended:

- the first-rate of specimens taken and the transport conditions when in transit to the laboratory;
- the need to method specimens within suitable time scale for organism viability and medical want;
- the protection elements of specimen processing;
- the specimen kind and its anatomical origin;
- the requirement for pre-treatment before inoculation (for example, centrifugation, homogenization and dilution as is the case with acid rapid bacilli (AFB) scientific samples inclusive of sputum;
- the selection of primary isolation media;
- the incubation temperature and atmosphere.

5.5.2 Understanding Flaming technique in microbiology

Flaming Technique

Holding the loop inside the flame of the Bunsen burner kills all contaminating organisms, for this reason microbiologist needs to sterilize the loop. The loop must glow pink-hot for a few seconds. After flaming, make sure to slightly cool the loop before picking up organisms from the inoculum plate. When transferring an inoculum from a plate, cool the loop through touching at the very peripheral of agar. When shifting from a broth, the red-hot loop will make a sizzling noise as quickly as microbiologist insert it into the subculture. The loop will automatically cool as soon as it touches with the broth periphery, but wait a one or seconds before doing away with the loopful of inoculum from the tube. (The hot loop may additionally create aerosols while it touches the media containing microorganisms. It will cause some of the broth and microorganism to boil briefly, creating a microorganism-containing aerosol. This airborne microorganism has the chances of moving into the respiratory tract or into the frame parts. If you hear a hissing sound while you place the heat sterilized loop into the broth culture indicates that the loop isn't always cooled sufficiently).

Flaming the Mouth of the Test Tube

Passing the mouth of a tube through the flame of a Bunsen burner creates a convection modern-day which forces air out of the tube. This prevents airborne contaminants from entering the tube. The warmth of the Bunsen burner also causes the air round your work location to rise, reducing the hazard of airborne microorganisms contaminating your cultures.

Agar Slants

Cultures are frequently transferred to agar slants, further to broth tubes and agar plates. An agar slant is a contains strong agar organization of a slant in the test tube. When inoculating an agar slant, draw the loop containing the inoculum very lightly over the floor in a zigzag formation at the same time as being cautious not to interrupt the floor. A needle can be used in place of a loop to inoculate an agar slant through stabbing the needle containing the inoculum into the agar

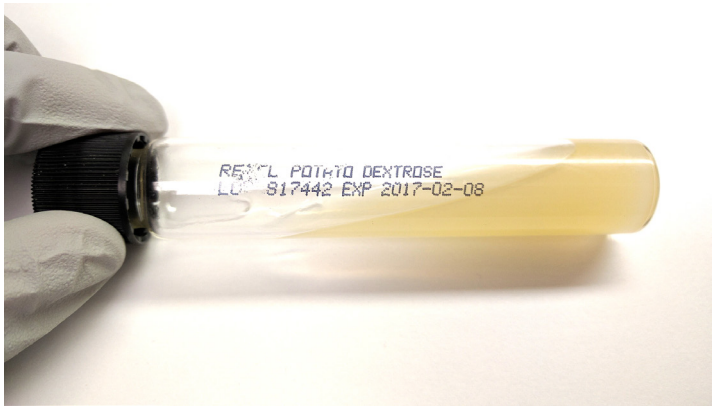


Fig. 5.5.1: Inoculation of culture into agar slant

Principle

Aseptic method is an essential and vital laboratory skill within the discipline of microbiology. Microbiologists use aseptic techniques for a number of approaches which include transferring cultures, inoculating media, isolation of pure cultures, and for appearing microbiological tests. Proper aseptic technique prevents infection of cultures from foreign bacteria inherent within the surroundings. For example, airborne microorganisms (together with fungi), microbes picked up from the researcher's body, the lab bench-top or different surfaces, microbes found in dust, as well as microbes discovered on unsterilized glassware and equipment, etc. may additionally potentially infected cultures, hence interfering with the lab results. Using right aseptic technique can significantly limit or even eliminate the danger of infection. In addition, aseptic approach is of utmost importance to keep pure inventory cultures at the same time as transferring cultures to new media. Aseptic method is also important for isolation of a single species of microorganism from a mixed subculture to reap a natural way of life. Furthermore, proper aseptic technique prevents microbes used in the laboratory from accidentally being launched into the surroundings and/ or infecting people operating in the laboratory. This is especially relevant whilst pathogens are being handled.

UNIT 5.6: Pure Culture Maintenance

Unit Objectives

At the end of this unit, you will be able to:

1. Explain different tests to identify the type and characteristics of microbes
2. Discuss preservation of pure culture through refrigeration, paraffin method, freeze drying etc. maintaining the parameters like temperature, anaerobic condition, pressure etc., following SOP

5.6.1 Introduction

Quite often, huge collections of microbial cultures are used in a laboratory for number of reasons. Microbiologist need microbial cultures for further references, comparisons, re- examinations, etc. So, it's far crucial to hold them well for in addition use. Maintenance and upkeep of microbial way of life is a major task. The basic principle in retaining the cultures is to keep the morphological and physiological characteristics of the organism intact.

Pure culture, in microbiology, a laboratory lifestyle containing a single species of organism. A pure subculture is normally derived from a mixed way of life (one containing many species) by way of moving a small pattern into new, sterile increase medium in such a manner as to disperse the person cells across the medium floor or through thinning the sample many folds before inoculating the brand-new medium. Both strategies separate the character cells so that, after they multiply, every will form a discrete colony, which may additionally then be used to inoculate more medium, with the guarantee that simplest one form of organism could be present. Isolation of a pure lifestyle may be enhanced through offering a blended inoculum with a medium favoring the boom of one organism to the exclusion of others.

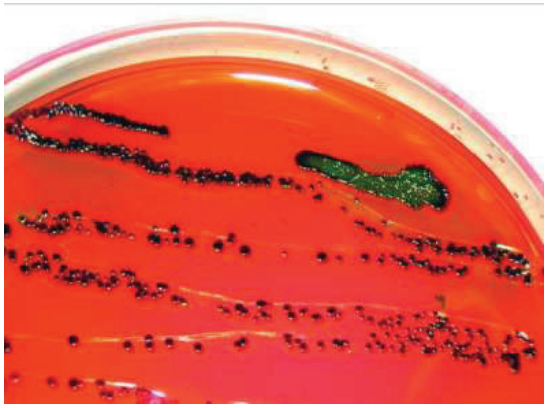


Fig. 5.6.1: Escherichia coli bacteria grown in pure culture on EMB (eosin methylene blue) agar

5.6.2 Importance of Maintenance and Preservation of Microbial Cultures

Microbial lifestyle renovation pursuits at maintaining a microbial pressure alive, uncontaminated, and without variation or mutation, as like authentic isolate. Many varieties of work require readily available microorganisms. The delays incurred in acquiring them from different resources or seeking to re-isolate them from their natural habitat can be unacceptable. Sometimes it's far not possible to achieve the

identical isolate again. Sometimes repeated attempts of re- isolation of the identical organism have been failed.

Importance of maintenance and Preservation of Pure Culture

The efficient exercise of microbiology is based on using cultures of microorganisms. Authentic reference lines are required for evaluation with laboratory isolates, for control cultures in standard strategies of analysis, and for use in research and teaching. The amazing boom in number and size of industrial fermentations has accentuated the cost of maintaining collections of microorganisms, particularly of production lines, assay organisms and associated species.

Considerable paintings have been dedicated to finding methods of keeping cultures in a lively and strong condition. Industrially important microbes also are preserved for use in numerous industrial processes. The upkeep of bacterial inventory cultures to keep viability and biochemical or virulence traits is an imperative requirement for the continuity of microbiological research.

Easy access to actively growing cultures is a demand of maximum microbiological laboratories. Cultures are required commonly on an everyday foundation for first-rate analysis, comparative testing, inoculum for bioassays and for numerous other reasons.

5.6.3 Methods of Pure Culture Maintenance and Preservation

Once a microorganism has been remoted and grown in pure culture, it turns into important to keep the viability and purity of the microorganism by way of keeping the pure culture free from contamination. Normally in laboratories, the natural cultures are transferred periodically onto or into a sparkling medium (sub culturing) to allow continuous increase and viability of microorganisms. Since repeated sub culturing is time consuming, it becomes difficult to keep a large range of pure cultures effective for an extended time. In addition, there is a chance of genetic modifications in addition to contamination. Therefore, it's far now being replaced through some modern-day methods that do not need frequent sub culturing. These strategies include refrigeration, paraffin technique, cryopreservation, and lyophilization (freeze drying).

Different Preservation Techniques

Many preservation techniques had been used to preserve microorganisms. The techniques which have been advanced and used can be divided into 3 categories:

- Continuous growth
- Dehydration
- Frozen storage

These categories can be in addition subdivided. The objective of maintenance techniques is to keep the viability and genetic stability of the tradition by means of lowering the organism's metabolic fee thereby extending the period between subcultures. Continuous growth includes all techniques that permit the organism to develop and metabolize at some point of life. There are numerous factors to be considered that is required in subcultures. These include manipulation of microbial boom by limiting carbon, nitrogen and strength resources, reducing the temperature, or preventing dehydration. Other than this, dehydration or drying may be used to hold organisms: strategies encompass air-drying, desiccation in or above a desiccant, or drying in a vacuum either from the liquid or frozen state. Frozen garage or cryopreservation is storage at a temperature in which the organism is frozen to reduce or completely save you metabolism and physical change. Success of the maintenance depends on the use of the proper medium and cultivation process and on the age of the subculture on the time of renovation. The

approach of upkeep is mainly of types: short- term preservation and long-term maintenance. Short-term techniques include specially the serial transfer of organisms to sparkling medium, storage at low temperature, preservation of spores of spore formers in dry sterile soil etc. long-term strategies are now broadly used and use either freeze drying or ultra-freezing in liquid nitrogen (-196^{O}C). It is important to understand that there's no universal method of maintenance this is successful for all microorganisms. Taxonomic group of microorganisms respond in another way to special renovation strategies.

The preservation techniques used replicate the one-of-a-kind biological houses of the various groups of microorganisms which includes microorganism, viruses, fungi, algae and protozoa, and their responses to modifications in their environment. Most protection techniques reap a discount in metabolic price by means of withholding nutrients, water and oxygen, via decreasing the garage temperature or by means of a mixture of these.

The choice of upkeep technique relies upon on the nature of the microorganism, availability of device and skilled employees and on the renovation objective. For instance, the preference may be influenced via the anticipated length of preservation, the range of cultures and their destiny use. Other factors can be considered are ease of transportation, frequency of use of cultures and maintenance costs. All preservation strategies observe an essentially comparable protocol with wonderful stages:

- Culture purity check;
- Preparation of the ampoules (labeling, sterilizing);
- Growth of the culture;
- Suspension of the cells in preservation medium;
- Dispensing of cell suspension into ampoules;
- Preservation (by method of choice);
- Ampoule stock storage;
- Update ampoule stock records;
- Ampoule recovery and testing (viability, purity, genetic stability).

Regular Subculture

Periodic modification on fresh, sterile media can maintain microbial subculture. The subculture preserved in this manner is maintained by way of alternate cycles of active growth and garage periods acquired through series of subcultures. Subculture is a familiar method to all working towards microbiologists; its miles called basic abilities of aseptic approach without any special gadget. The frequency of switch varies with the organism. For instance, a lifestyle of E. Coli needs to be transferred at month-to-month intervals. After increase for 24 hours at 37^{O}C, the slants can be saved at low temperature for 20- 30 days. To maintain the cultures viable, it's miles important to use the ideal boom medium and a right storage temperature. The frequency of subculture can be reduced if developing it on a medium containing minimal vitamins lowers the metabolism of the organism. Several elements are taken into consideration while preserving a microbial culture via using subculture method. Solid media need to be selected in desire to liquid as there's a higher danger of contamination in liquid media. Slope cultures are often used for preservation however oxygen touchy microorganism may benefit from stab subculture. After sub culturing the tubes should be sealed properly. Cotton wool plugged tubes are not adequate, as media will quick dry out and cultures will be lost. Sub culturing has many disadvantages, a number of them are noted below:

- Change of characteristics- Sub culturing can cause exchange of characteristics, i.e., characteristics can be lost, reduced, or intensified. Changes probably occur most regularly amongst strains wherein intervals between transfers are short.
- Contamination - This occurs regularly, particularly when massive numbers of cultures are concerned and the concentration of the man or woman doing switch lags.

- Mislabeling- Cultures may be classified with the incorrect name or variety. Labels may emerge as distorted and unrecognizable.
- Loss of cultures- This situation occurs once in a while and is probably extra not unusual with delicate organisms. Temperature fluctuations in incubation or refrigeration system make a contribution to the opportunity of loss.

Various methods of preservation are described below:

Paraffin Method

This is a completely simple and cost-effective technique of preserving cultures of bacteria and fungi for longer time at room temperature. In this method sterile liquid paraffin is poured over the slant subculture of microbes and stored upright at room temperature. The layer of paraffin prevents dehydration of the medium and ensures anaerobic conditions. It slows the metabolic interest by reduced growth via reduced oxygen tension. Cultures also can be maintained by way of protecting the agar slants with a layer of sterile mineral oil about half of inch above the surface of the slant. The oil ought to be above the tip of the slanted floor. Mineral oil blanketed cultures are stored at room temperature or ideally at 0-5^{O}C. Some microorganisms were preserved satisfactorily for greater than 15-20 years by using this technique. While preserving the cultures in oil following points should be considered:

- Unless the oil is properly above the uppermost degree of the medium, the medium tends to dry out, break away the wall of the tube and flow to the surface of the wall, in which the even the organisms are commonly observed dead.
- The high-quality of the oil is very essential, as any rancidity or poisonous substance is harmful to the organisms.
- It is best to sterilize the oil within the hot air oven at 150^{O}C to 170^{O}C for one hour; for all through autoclaving moisture becomes combined with the oil, giving it a milky appearance.

Storage in Soil

Various fungi such as Fusarium, Penicillium, Alternaria, Rhizopus, Aspergillus etc. proved successful for storage in sterile soil. Soil storage involves inoculation of 1 ml of spore suspension into soil (that has been autoclaved twice) and incubating at room temperature for 5-10days. This initial growth period allows the fungus to use the accessible moisture and slowly to become dormant. The bottles are then stored at refrigerator. Spraying few soil particles on a suitable medium retrieves culture.

Storage in Silica Gel

Both bacteria and yeast can be kept in silica gel powder at low temperature for a period of up to 1-2 years. In this method, finely powdered, heat sterilized and cooled silica powder is mixed with a thick suspension of cells and stored at low temperature. The basic principle is quick drying at low temperature, which allows the cell to remain workable for a long period.

Storage at Refrigerator or Cold Room Storage

Live cultures on a culture medium can be successfully stored in refrigerators or cold rooms, when the temperature is kept at 4^{O}C. At this temperature range the metabolic activities of microbes slows down greatly but do not altogether stop. As a result, bacterial metabolism will be very slow and only less quantity of nutrients will be utilized. This method cannot be used for a very long time because toxic products get accumulated which can kill the microbes. Refrigerator or cold room storage is of use only for short time preservation of cultures.

Storage by Freezing

Freezing is a common process for storage of bacteria. Thus, thick bacterial suspensions can be frozen at a temperature of - 30^{O}C. Metabolic rates are reduced by dropping the temperature and in the extreme case of storage in liquid nitrogen at -196^{O}C, are considered to be brought to nil. Freezing and thawing is a well- known technique for actually disrupting cells. Moreover, as water is removed during freezing as ice, electrolytes become increasingly concentrated in unfrozen water, and this too may be harmful, since electrolyte concentrations outside cells become very different from inside those cells, leading to osmotic stress. Cultures can be preserved very effectively if frozen in the presence of a cryoprotectant, which reduces damage from ice crystals. Glycerol or dimethyl sulphoxide (DMSO) are commonly used as cryoprotectants. The simplest way to preserve a culture is to add 15%(v/v) glycerol to the culture and then to store it at -20^{O}C or -80^{O}C in a freezer.

Cultures can be preserved for a number of years in glycerol, at a temperature of -40^{O}C in a freezer. In this method, about 2 ml of glycerol solution is added on to the agar slant culture. Shaking can emulsify the culture. Emulsion is then transferred to ampoules, with each ampoule having 5 ml of the culture. These ampoules are placed in a mixture of industrial methylated spirit and carbon dioxide and frozen rapidly to -70^{O}C. Ampoules are then removed and placed directly in a deep freeze at -40^{O}C for utilization of the stock cultures. The ampoules are kept in a water bath at 45^{O}C for about a few seconds and then used for plate cultures.

The use of cryogenic storage at ultra-low temperature obtained by freezing in liquid nitrogen at -196^{O}C has proven to be a simple standardized technique for the preservation of a wide range of microorganisms and mammalian cells. Advantages of liquid nitrogen storage include little loss of viability, rapid resuscitation, readily availability as a living suspension and speed of preparation.

Disadvantages of the liquid nitrogen storage are the cost of the apparatus and regular supplies of liquid nitrogen, risk of explosion when ampoules are brought into room temperature, loss of large numbers of cultures if careful monitoring of liquid nitrogen levels is not carried out and possible contamination of the liquid nitrogen in the storage container if an ampoule break.

Storage of cultures by Freeze Drying

Freeze-drying is the most widely used technique for maintaining bacterial cultures. Freeze drying is also called lyophilization. When bacterial cultures or virus suspensions are dried and kept in the dry state under suitable conditions. If such materials are dried from liquid state, a high salt concentration is produced in the later stages of drying; this causes denaturation of proteins, death of organisms and deterioration of serum. Freeze-drying or lyophilization whereby the culture or serum is dried swiftly in vacuo from the frozen state largely avoids the problem. The substance is frozen by a suitable method and at that point dried by sublimation of the ice. Freeze drying is a multistage process; it begins with freezing, a temporary stop to metabolic activity, then continues with the removal of water without thawing (sublimation), and ends with a dried product. The dried product is sealed either below vacuum or underneath an inert gas, can be stored at room temperature with no further metabolic movement until water and nutrients are reinstated.

Freezing must be very rapid, with the temperature lowered to well below 0^{O}C (e.g., to -20^{O}C), since slow freezing would prolong exposure to the denaturing influence of the suspending salt solution. The liquid should be frozen in a shallow layer with a large surface available for evaporation. Freeze drying involves several steps. These are the following:

- Pre-drying requirement for cultures: The type of culture media used is a vital criterion in the freezedrying for some microbes, the pre-drying culture and maintenance may be the identical or different. The pre-drying media should have a rich concentration of microbes. The age of the culture is another important criterion because the cultures that have reached the optimum growth phase survive better than the cultures that are still in the growth phase.

- Ampoule preparation: The ampoules used in the preservation of the culture should be made of neutral glass and appropriately disinfected. After plugging with the cotton wool, they must be sterilized with an autoclave for 20 minutes under 20 lbs. pressure.
- Harvesting the culture: Cultures grown on agar slants must be harvested for 3-5 days after incubation. Suspending fluid like horse serum, glucose, nutrient broth should be put to use for harvesting culture. The suspensions should be directly transferred to the ampoules.
- Primary Drying: Special centrifuges are used for this primary drying. The primary drying procedure is allowed to proceed between 2.5 to 4 hours during which, more than 90% of free water is removed. Air is then allowed to slowly enter into the vacuum chamber. The centrifuge head is then removed from the machine and the ampoules are plugged again with cotton wool.
- Secondary drying: The ampoules are then transferred to a secondary dryer, which consists of high grade P_2O_5 contained in a tray, to which is attached a vacuum pump. The ampoules are left on this dryer for 18-20 hours upon which the moisture content is reduced to 1%. The ampoules are checked for upkeep of vacuum, and sealed with flame. The culture in the ampoule is now a light powdery substance. The ampoule can be deposited at $4^{O}C$.

Two types of commercial freeze-dryer, the centrifugal and shelf are in common use. In the former freezing is brought about by evaporation that occurs when the vacuum is applied, and the cell suspension is centrifuged during initial freezing to increase the surface area and prevent frothing. For large culture collections, the centrifugal method has advantages in minimizing the likelihood of cross contamination as ampoules may be plugged after filling and sealed under vacuum on a manifold at the end of secondary drying stage. Lyophilized cultures need to be rehydrated according to the manufacturer's directions and maintained viable through frequent transfers or freezing procedures. One of the chief advantages of freeze-drying is that the ampoules are predominantly suitable as a means of distributing cultures because the viability and integrity of the ampoules resist the changes in pressure and temperature in the airmail services. A disadvantage of freeze-drying is the relatively high capital cost of commercial equipment.

Some strains, which are sensitive to freeze-drying, can be preserved by drying from the liquid state rather than the frozen state. A number of methods for drying suspensions of bacteria for preservation purposes have been developed which are useful in laboratories that cannot afford the expensive equipment used for storing at very low temperatures or for freeze drying, or in which preservation of cultures is performed infrequently. Some of the following procedures of drying method are mentioned below:

- Paper Disc: A dense suspension of bacteria is mounted on thick sterile absorbent paper, which are then dried under vacuum in a desiccator over phosphorus pentoxide.
- Gelatin Disc: Bacteria are prepared for a thick suspension and added to the nutrient gelatin. Drops of the gelatin bacterial suspension are placed on sterile waxed paper or on a Plastic Petri dish and then dried under vacuum in a desiccator over phosphorus pentoxide.
- Pre dried Plugs: Thick bacterial suspensions are prepared and drops are placed on sterile cellophane or on pre-dried peptone, starch, or dextran plugs before drying in a vacuum in a desiccator over phosphorus pentoxide.
- L- Drying: Using a vacuum pump and desiccant and a water bath to control temperature, thick bacteria in small ampoules are dried from the liquid State. L-drying is also used for mycorrhizal vesicular fungi. In this process the suspensions of the species are dried from the liquid state under vacuum without freezing. There are several techniques for L- drying:
    - The material dries by rapid evaporation before freezing can occur by using small volumes of suspension distributed over a large surface area.
    - Freezing can be avoided by limiting the flow of water vapor from the drying material, either by inserting cotton plugs into the ampoules or by regulating the vacuum through a valve.
    - Immersion of the ampoules into a water bath will hold enough heat input to the suspensions to prevent them from freezing under vacuum.

5.6.4 Preservation Programme

The consent of a culture is not complete until it has been successfully preserved or arrangements are made for its routine maintenance if no adequate long-term preservation method is available. It is required to preserve new strains after the least possible subculture to ensure minimum risk of change. Existing stocks of preserved cultures are routinely subjected to viability checks and survival assessment. Initially new cultures are checked after one or two weeks of preservation and then it is preserved for long term. Another important aspect of any preservation program is ampoule stock control. Ampoules are regularly taken from stocks for use or distribution.

5.6.5 Quality Control

Quality control is essential in a culture collection and an effective quality control program must be established to ensure viability, purity and genetic stability are achieved in the preservation program. Industrial collections may collect cultures into broadly based taxonomic groups and place more emphasis on a particular metabolic characteristics or other property. Strains selected for use in a biotechnological process usually have a unique set of characters and productive efficiency. Quality control testing is essential to ensure that these characters, which have been selected or developed, are preserved in as stable and reliable state as possible. As per USP, cultures of microorganisms should be maintained weekly or monthly transfers to fresh agar slants or stabs, which are kept under refrigeration at 2-8^{O}C.

5.6.6 Shipment of Cultures

Culture collections and indeed many microbiologists, are often required to supply cultures on request. Various local, national or international bodies regulate the distribution of cultures and culture collections must build these constraints into their management procedures. Microbiologists who use the local and international postal services should be thoroughly conversant with the postal and quarantine regulations governing the shipment of cultures. This applies particularly to cultures, which may pose a threat to human, animal or plant health if properly not handled. In general, it is desirable to send freeze-dried cultures in ampoules. If it is necessary to send actively growing cultures these should be sent as agar slope cultures in screw capped glass or plastic bottles. Broth cultures should be sent only in screw capped bottles or tubes. Loosely capped tubes of broth cultures or petri dish cultures should not be sent on the post. One should also be concerned with the moral and ethical implications of dispatching cultures, which may have a harmful effect on health, economics, and ecology of the recipient nation.

For disposal of cultured media refer module

UNIT 5.7: Reporting Microbiological Test Results

Unit Objectives

At the end of this unit, you will be able to:

1. Record compiling of results of microbiological tests and prepare microbiological data
2. Analyze microbiological data and compare with food safety standards of the organization, national and international regulations
3. Analyze implications of test results with respect to food safety standards and draw conclusions
4. Demonstrate adjusting controls of all equipment
5. Illustrate counting the micro- organisms and colonies under the microscope and record counts

5.7.1 Introduction

The laboratory report is a condensed version of the data appearing in worksheets and laboratory notebooks. It must contain all the information normally necessary for the customer to utilize the result it contains.

General requirements in preparation of the reports[27]

- The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods;
- The results shall be reported, usually in a test report, and shall include all the information intended by the requirements of the regulatory testing and necessary for the interpretation of the test or calibration results and all information required by the method used. The food testing laboratories working under regulatory regime are required to report as per the requirements of the regulation, which specifies the information required to be contained in the test report and covers all essential information like Unique identification number, Description of the sample, Physical appearance, Label, Quality Characteristics, Name of method of test used, Result, Prescribed standard, Signature and date. Other essential information like dates of start of test and completion of test, deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions, shall be available in other records like observation work book, etc. For ease and consistency in reporting the labs should establish product wise report format in line with the regulatory requirements;
- Opinions and interpretations - When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.
- When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.
- **Electronic Reporting:** In the case of transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, (delete the requirements of this criteria shall be met) issuing laboratory must ensure what is transmitted electronically is what is received by the customer. While sending reports as email attachment laboratories need to consider whether customers will have the appropriate software and version to open attachments without corruption.

[27] FSSAI Guidelines. "Guidance document for Setting up of a regulatory food analysis laboratory". (https://fssai.gov.in/upload/uploadfiles/files/Guidance_Document_Food_Laboratory_16_02_2018.pdf)

- **Transmission:** Laboratories should verify (at least initially, and periodically thereafter is recommended) the integrity of the electronic link e.g., by asking the customer to supply a copy of what was received and comparing it with what was transmitted. It is also important that the laboratory and its customer agree as to which part of the electronic transfer system they are responsible for and the laboratory must be able to demonstrate data integrity at the point the data comes under the control of the customer. The laboratory should document what this check involves and record when it has been carried out.
- **Security:** Laboratories should avoid sending test reports in an electronic format that can be readily amended by the recipient. Examples would be in word processing or spreadsheet software. Where possible, reports should be in an image format e.g., the image format option for pdf files. Where this is not possible e.g., the customer may wish to transfer the reported results file into a larger database, then laboratories are recommended to indicate these electronic reports have an interim status and are followed-up by a hard copy (or more secure) final report. Laboratories must retain an exact copy of what was sent. This may be a hard copy (recommended) or non-editable electronic copy. These copies must be retained securely and be readily available for the time specified in the laboratory's documented policies.
- **Signatures:** All reports (whether hard copy or electronic) must not be released to the customer until authorized by individuals with the authority to do so. For electronic reports there must be a clear audit trail with a positive authorization record to demonstrate this is the case. Where this is managed through password access levels in the laboratory's electronic system, appropriate procedures should be in place to prevent abuse of password access.
- **Amendments to test reports and calibration certificates -** After a test report is already released by the laboratory and an amendment is required to be issued then it shall be made only in the form of a further document, or data transfer, which shall clearly state that the amendment is a Supplement to the previously issued test report and shall also include the test report identification number. In case the amendment to the report is substantial and relates to test results reported, then it may be desirable to issue a fresh test report. The fresh test report may have new identity created by prefixing the old report number with a letter —R. It shall also contain reference to the old number stating that it replaced the old test report.

The sampling report should include the following:

- reason for sampling;
- the origin of sample;
- the sampling method;
- Name, Address of the Laboratory;
- Name, Address of the customer;
- Certificate/Report Number;
- Page Identification (Page X of Y);
- Sample received details (Dates, Names of deliverable, receiver);
- Unambiguous identification of sample / test material (Description, Laboratory Number etc.);
- Analysis conducted, Methods, Procedures any deviation from standard practices;
- Preparation of test material, taking of test portions;
- Results;
- Uncertainty of measurements;
- Comments on significant of findings (if expected by the customer);
- Date of report;
- Authorizing signature.

The other important points which have to be looked into while report preparation for microbial analysis is as follows:

- Any deviation from the specified sampling procedure to be reflected in report.
- The reporting of test results for the microbiological parameters shall be strictly as per the reporting requirements specified in the relevant test method. Further the results shall be reported in the same units as the specified requirements for the food product/matrix tested.
- In microbiological testing if the result of the enumeration is negative, it should be reported as not detected for a defined unit or less than the detection limit for a defined unit. Qualitative test results should be reported as detected/not detected in a defined quantity or volume.

As per the Manual of Methods of Analysis of Food for Microbiological Testing, the tests performed and their interpretation is reported in the following manner:

5.7.2 Aerobic Mesophilic Plate count

Expression of Result

Aerobic (Mesophilic) Plate Count = 19000 CFU/g or 1.9x104 CFU/g or

If plates from all dilutions have no colonies and inhibitory substances have not been detected, the result is expressed as less than 1 x 101 CFU per g or ml.

If plates from the lowest dilutions contain less than 30 colonies, record the actual number and calculate as above but express results as CFU per g or ml.

For statistical reasons alone, in 95% of cases the confidence limits of this test vary from ± 12% to ± 37%. In practice even greater variation may be found specially among results obtained by different microbiologists. (Corvell and Morsettle, J. Sci. Fd. Agric., 1969, vol. 20 p 573)

5.7.3 To Determine and Confirm Aciduric Flat Sour Spore Formers in Foods

The organism of this group is Bacillus coagulans. It is responsible for spoilage of canned products.

Expression of Result

Aciduric flat sour spore formers = X/g

5.7.4 Detection and Determination of Bacillus cereus in Foods, and Beverages

Reporting

After confirmation, the number of B. cereus colonies is multiplied by the reciprocal of the dilution that the countable plate represents (It should be noted that the dilution factor is 10-fold higher than the sample dilution since only 0.1 ml was plated) and report as B. cereus/gram.

Expression of Results

Bacillus cereus= Present/Absent

5.7.5 Detection and Determination of Anaerobic Mesophilic Spore formers (Clostridium perfringens)

Expression of Result

Clostridium perfringens = present/absent

5.7.6 Detection, Determination and Confirmation of Coliforms, Fecal coliforms and Escherichia coli in Foods and Beverages

Interpretation

Escherichia coli= x MPN/g

5.7.7 Direct Microscopic Count in Tomato Puree, Sauce, Paste, Chutney

Expression of Results

Mold Hyphae positive fields = % Microscopic Bacterial Count = 106 per cc Yeast and Bacterial spores = 1/60 mm^3

5.7.8 Fermentation Test (Incubation test)

To determine commercial sterility of processed canned foods.

Interpretation of Data

The development of swelled containers may indicate microbial activity. Growth must be confirmed by demonstrating excessive microorganisms by direct smear or by sub culturing or abnormal product (pH, texture, odor, discoloration, evolution of gas).

Swelling may also be due to overfilling; low filling temperatures, improper vacuum closing procedures, incipient spoilage and chemical swells.

Expression of Results

Incubation test Negative/positive when incubated at $30^{o}C/35^{o}C$ for a period of 10 days.

5.7.9 Rope Producing Spores in Flours

Expression of Results

Rope spores = /g

5.7.10 Detection and Confirmation of Salmonella species in foods

Expression of Results

Salmonella = Present/Absent per 25 g

5.7.11 Detection and Confirmation of Shigella species

Expression of Results

Shigella = Present / Absent per 25g of sample

5.7.12 Detection, Determination and Confirmation of Staphylococcus aureus

Expression of result

Staphylococcus aureus = x/g

5.7.13 Detection and Confirmation of Sulfide Spoilage Spore formers in Processed Foods

Expression of Result

Spores of sulfide spoilage/g

5.7.14 Detection and Determination of Thermophilic Flat Sour Spore formers

Expression of Result

Thermophilic flat sour bacteria = x/g

5.7.15 Detection and Determination of Pathogenic Vibrio's in Foods

Results

Test for pathogenic Vibrio = Positive/ Negative

5.7.16 Estimation of Yeasts and Molds in Foods and Beverages

Reporting

Yeast and Mold count = x/g

5.7.17 Detection and confirmation of Listeria monocytogenes in Food

Expression of results

Based on the observations and interpretation of the results report presence or absence of L. monocytogenes in test portion specifying the mass in grams or milliliters of the sample taken.

L. monocytogenes =present or absent/ g or ml.

5.7.18 Bacteriological Examination of Water for Coliforms

Expression of Results

Coliforms = x MPN/250 ml or 100 ml

Expression of Result

Coliform count = x cfu/g

5.7.19 Bacteriological Examination of Water for Detection, Determination and Confirmation of Escherichia coli

Expression of Result

Escherichia coli = present/ absent in 250 ml or 100 ml.

5.7.20 Bacteriological examination of water for presence of Salmonella and Shigella

Expression of Result

Test for Salmonella = present or absent/250 ml Test for Shigella = present or absent/ 250 ml

5.7.21 Bacteriological examination of water for Detection and Confirmation of Clostridium perfringens

Expression of Results

Clostridium perfringens = present or absent/50 ml

5.7.22 Bacteriological Examination of water - Bacillus cereus

Expression of Result

Bacillus cereus = present absent/250 ml

The protocols to be followed for these tests are given in the manual and are to be followed as per the instructions and references given there.

Refer Practical's for more details

UNIT 5.8: Microbiological Food Safety Standards and Regulations

Unit Objectives

At the end of this unit, you will be able to:

1. Express analyzing of microbiological data and compare with food safety standards of the organization, national and international regulations

5.8.1 Introduction

To distinguish food of acceptable quality from food of unacceptable quality requires the application of what are known as microbiological criteria. Three different types of microbiological criterion have been defined by The International Commission on Microbiological Specifications for Foods (ICMSF).

- A microbiological standard is a criterion specified in a law or regulation. It is a legal requirement that foods must meet and is enforceable by the appropriate regulatory agency.
- A microbiological specification is a criterion applied in commerce. It is a contractual condition of acceptance that is applied by a purchaser attempting to define the microbiological quality of a product or ingredient. Failure of the supplier to meet the specification will result in rejection of the batch or a lower price.
- A microbiological guideline is used to monitor the microbiological acceptability of a product or process. It differs from the standard and specification in that it is advisory rather than mandatory.

The ICMSF have also specified what should be included in a microbiological criterion as set out below:

- A statement of the food to which the criterion applies. Clearly ingredients differ of their origin, composition, and processing; will gift different microbial habitats; and will consequently pose different spoilage and public fitness problems.
- An assertion of the micro-organisms or toxins of issue. These may cover both spoilage and health aspects, but selections on what to include have to be realistic and based totally on a legitimate under standing of the microbial ecology of the food in question.
- Details of the analytical strategies to be used to detect and quantify the micro-organisms/pollutants. Preferred techniques for standards or specifications would be the ones elaborated by global bodies, even though less touchy or much less reproducible techniques may be used for simplicity and speed in confirming compliance with guidelines.
- The wide variety and length of samples to be taken from a batch of food or from a source of difficulty including a point in a processing line.
- The microbiological limits appropriate to the product and the wide variety of sample outcomes which must conform with those limits for the product to be acceptable. In this regard, it must be remembered that for positive food- borne pathogens along with Staphylococcus aureus or Clostridium perfringens, their mere presence does not necessarily indicate a hazard and specification of some numerical limits is necessary.

These last two points can present the greatest problem. In applying the microbiological criterion, it is assumed that the analytical results obtained are an accurate reflection of the microbiological quality of the whole batch of food. The justification of extrapolation is will depend upon the accuracy and precision of the tests used and on how characteristic the samples were that were tested.

Micro-organisms are seldom distributed uniformly through a food. When micro-organisms are spread in a food material, in the course of its production some may die while some may be unable to grow and others may find themselves in microenvironments in which they can multiply.

5.8.2 Principles for the Establishment of Microbiological Criteria for Foods

These Principles are intended to present guidance on the establishment and alertness of microbiological standards for ingredients at any point in the food chain from primary production to final consumption. The protection of foods is principally confident via manipulate at the supply, product layout and method manage, and the utility of Good Hygienic Practices at some point of production, processing (which includes labelling), handling, distribution, storage, sale, practice and use, alongside the software of the HACCP system. This preventive method offers more manipulate than microbiological testing because the effectiveness of microbiological examination to evaluate the safety of food is limited. Guidance for the status quo of HACCP primarily based structures is specified in Hazard Analysis and Critical Control Point System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3-1997).

Microbiological standards ought to be established in step with these standards and be primarily based on scientific analysis and advice, and, wherein sufficient statistics are available, a chance analysis suitable to the nutrition and its use. Microbiological standards need to be evolved in a transparent style and meet the requirements of fair trade. They ought to be reviewed periodically for relevance with respect to rising pathogens, converting technologies, and new understandings of science.

Definition of Microbiological Criterion

A microbiological criterion for food defines the acceptability of a product or a food lot, primarily based on the absence or presence, or quantity of microorganisms including parasites, and/or amount of their pollution/metabolites, in step with unit(s) of mass, volume, region or lot.

Components of Microbiological Criteria for Foods

A microbiological criterion consists of:

- a statement of the microorganisms of challenge and/or their pollution/metabolites and the cause for that concern;
- the analytical techniques for their detection and/or quantification;
- a plan defining the number of subject samples to be taken and the dimensions of the analytical unit; microbiological limits considered suitable to the food at the desired factor(s) of the food chain;
- the number of analytical units that have to conform to those limits.

A microbiological criterion should also state:

- the food to which the criterion applies;
- the point(s) inside the food chain in which the criterion applies; and
- any actions to be taken whilst the criterion is not met.

When making use of a microbiological criterion for assessing products, it is essential, a good way to make the high-quality use of cash and manpower, that most effective appropriate tests be carried out to those foods and at those points in the food chain that provide maximum benefit in offering the purchaser with a food this is safe and appropriate for consumption.

5.8.3 Purposes and Application of Microbiological Criteria for Foods

Microbiological standards can be used to formulate design necessities and to signify the desired microbiological repute of raw substances, elements and end-merchandise at any stage of the food chain as appropriate. They may be applicable to the exam of ingredients, together with raw materials and elements, of unknown or unsure beginning or whilst other manner of verifying the efficacy of HACCP based totally systems and Good Hygienic Practices are not available. Generally, microbiological criteria may be carried out to outline the distinction between desirable and unacceptable raw substances, components, products, lots, by regulatory authorities and/or food enterprise operators. Microbiological standards may also be used to decide that tactics are constant with the General Principles of Food Hygiene (CAC/RCP 1-1969).

Application by Regulatory Authorities

Microbiological criteria can be used to define and check compliance with the microbiological requirements.

Mandatory microbiological standards shall follow to those products and/or factors of the food chain where no other more effective equipment are there, and where they may be anticipated to improve the diploma of safety offered to the consumer. Where those are suitable, they shall be product type precise and handiest carried out at the factor of the food chain as specified inside the regulation.

In situations of non-compliance with microbiological standards, depending on the assessment of the chance to the consumer, the factor within the food chain and the product kind specified, the regulatory manage movements can be sorting, reprocessing, rejection or destruction of product, and/or further research to determine appropriate movements to be taken.

Application by a Food Business Operator

In addition to checking compliance with regulatory provisions microbiological criteria can be carried out with the aid of food enterprise operators to formulate design requirements and to look at end-products as one of the measures to verify and/or validate the efficacy of the HACCP plan.

Such standards will be unique for the product and the degree within the food chain at which they will follow. They may be stricter than the standards used for regulatory functions and must, as such, no longer be used for criminal action.

Microbiological standards are not normally suitable for monitoring Critical Limits as defined in Hazard Analysis and Critical Control Point System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3-1997). Monitoring procedures need to be capable of stumble on loss of control at a Critical Control Point (CCP). Monitoring need to offer this data in time for corrective moves to be taken to regain control before there's a need to reject the product. Consequently, online measurements of physical and chemical parameters are often favored to microbiological trying out because consequences are regularly to be had more swiftly and at the manufacturing site. Moreover, the establishment of Critical Limits may want other considerations than those defined in this report.

5.8.4 Microbiological Aspects of Criteria

Microorganisms, Parasites and their Toxins/Metabolites are of in a Particular Food

For this purpose the document includes:

- bacteria, viruses, yeasts, molds, and algae;
- parasitic protozoa and helminths;
- Their toxins/metabolites.

The microorganisms included in a criterion ought to be widely usual as relevant as pathogens, as indicator organisms or as spoilage organisms to the unique food and technology. Organisms whose significance in the specified food is doubtful needs to not be blanketed in a criterion.

The mere finding, with a presence-absence check, of microorganisms recognized to motive foodborne illness (e.g., Clostridium perfringens, Staphylococcus aureus and Vibrio parahaemolyticus) does no longer always imply a danger to public fitness.

Where pathogens can be detected directly and reliably, consideration ought to be given to trying out for them in preference to testing for indicator organisms. If a check for a trademark organism is applied, there have to be a clear statement whether or not the take a look at is used to suggest unsatisfactory hygienic practices or a health hazard.

Microbiological Methods

Whenever feasible, handiest methods for which the reliability (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in numerous laboratories have to be used. Moreover, desire have to accept to strategies which have been demonstrated for the commodity involved preferably in terms of reference strategies elaborated via international organizations. While techniques have to be the most touchy and reproducible for the motive, methods for use for in-plant trying out might often sacrifice to some degree sensitivity and reproducibility in the interest of velocity and simplicity. They ought to, however, had been proved to provide a sufficiently dependable estimate of the statistics needed.

Methods used to determine the suitability for intake of extraordinarily perishable food, or ingredients with a short shelf-life, have to be chosen wherever feasible so that the outcomes of microbiological examinations are available earlier than the food are fed on or exceed their shelf-life.

The microbiological strategies specified ought to be affordable in regards to complexity, availability of media, equipment etc., ease of interpretation, time required and costs.

Microbiological Limits

Limits utilized in criteria ought to be primarily based on microbiological records suitable to the food and have to be applicable to a number of similar products. They ought to consequently be based totally on information gathered at diverse manufacturing institutions operating under Good Hygienic Practices and making use of the HACCP system.

In the status quo of microbiological limits, any changes within the microflora possibly to occur all through storage and distribution (e.g., lower or increase in numbers) must be taken into account.

Microbiological limits need to think about the hazard associated with the microorganisms, and the situations beneath which the food are expected to be dealt with and consumed. Microbiological limits ought to additionally take account of the probability of choppy distribution of microorganisms within the food and the inherent variability of the analytical procedure.

If a criterion calls for the absence of a particular microorganism, the dimensions and variety of the analytical unit (in addition to the wide variety of analytical pattern units) should be indicated.

Exercise

1. **What is the preferred method of decontaminating microbiological waste and reusable equipment's?**

2. **Differentiate between defined and undefined media.**

3. **Define:**

   i) Protein hydrolysates

   ii) Recombinant

   iii) Nucleation track filters

4. **What is the role of different media components?**

   (i) Glucose

   (ii) Agar

(iii) EDTA

(iv) Phosphate

(v) Microbiological Criterion

5. **Explain key points and procedure of aseptic technique.**

6. **What do you mean by biosafety level? Explain types of biosafety levels.**

7. **Describe different indicators to check the effectiveness of sterilization by autoclave.**

8. **How to collect swab samples for microbiological environmental testing?**

9. **Enlist Biosafety Precautions that should be taken for the Laminar Hood.**

10. What is HEPA filter?

_____

_____

_____

_____

11. Write the significance of flaming.

_____

_____

_____

_____

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Food Industry Capacity and Skill Initiative

6. Monitoring of Food Safety System

Unit 6.1 - Waste Disposal Practices for maintaining laboratory hygiene

Unit 6.2 - Food Safety and Hygiene Audits

Unit 6.3 - Microbiological Hazards

Unit 6.4 - Environmental Monitoring in Food Processing Units

FIC/N7611

Key Learning Outcomes

At the end of this module, you will be able to:

1. Illustrate maintaining of workplace in a clean and tidy order to meet workplace standards and waste disposal following industry standards.
2. Apply corrective action.
3. Illustrate Carrying out internal audit on housekeeping to ensure safety and hygiene system are in place.
4. Identify food safety requirements in the food products production process based on microbial analysis results of production line, premises and food product.
5. Identify microbiological hazards in production process, and its critical control point to minimize or prevent those hazards.
6. Illustrate taking swab sample of work area, materials, equipment, products and personnel routinely for microbiological analysis and discussing of reports.
7. Apply procedures after audit like different findings, reanalyzing the preventive measures based on the audit findings, and arriving at additional preventive controls to address the hazards identified.
8. Apply monitoring premises of the food processing unit, processing machineries, drainage system to ensure it meets food hygiene standards of the processing unit.
9. Apply monitoring storage area for raw materials, packaging materials, finished goods to ensure quality standards are met and food products are fit for human consumption.
10. Illustrate monitoring of personnel hygiene and health condition of employees and PPE (Personal Protective Equipment).
11. Discuss hygiene system of the organization.

UNIT 6.1: Waste Disposal Practices for maintaining laboratory hygiene

Unit Objectives

At the end of this unit, you will be able to:

1. Illustrate maintaining of workplace in a clean and tidy order to meet workplace standards
2. Discuss waste disposal practices following industry standards.

6.1.1 Introduction

There are distinct sorts of waste generated in a laboratory, and each has particular necessities for disposal.

All laboratory waste is controlled following a four-step technique that begins with figuring out and characterizing it. Next, the waste is positioned in suitable containers, relying on its classification, and is categorized or marked so that it is easily identifiable. The very last step is disposal that follows the protocol for its classification. It is crucial that the waste is managed inside its personal space in the lab. This prevents or reduces the hazard of contamination of different regions or surfaces. Laboratory waste isn't best limited to contaminates or pathogens. It may be organic waste, that's anything living along with human, animal or plant material. If the cloth is infectious or harmful, it is taken into consideration to be biohazardous waste. Glass is another sort of waste that requires unique managing. This may be lab system like slides, beakers and different containers. A more dangerous shape of laboratory waste is sharps, or needles. Each of these poses its very own risk to safety and health. Non-hazardous waste may be located in a common waste field. However, other forms of waste should meet certain safety requirements and placed in special containers. Sharps are a great example of this. A sharp is anything this is capable of puncture or cut the skin. This includes scalpels, syringes, needles, razor blades and objects that have a sharp edge, like pipe that has been reduce. The predominant difficulty is that the needle or glass will puncture handler's skin.

All materials need to be contained, and waste must be disposed of. Any chemical substances or biologicals which might be believed to be contaminated must be disposed of properly, in an approved box. Typically, a leakproof, sturdy field is required. This even manner soiled cleansing and sanitizing supplies. Health and safety should constantly be a priority.

It is the clear responsibility of the microbiologist and all analysts of the laboratory to ensure the safe and correct disposal of all wastes produced during the analysis. Waste must be categorized as to its identity, constituents, and hazards so that it may be safely handled and managed. Improper and irresponsible disposal of chemical wastes down drains or into the atmosphere is forbidden. The Aldrich Handbook provides a useful summary of the correct disposal procedure for most chemicals. 'Generated knowledge' can be used for waste characterization, such as the knowledge of waste characteristics and constituents by laboratory personnel who conducted the process, procedure, or experiment. It is essential that all the laboratory personnel accurately and completely identify and clearly label all chemical and waste containers in their respective sections/laboratories[28].

[28] FSSAI Guidelines. "Guidance document for Good Food Laboratory Practices". (https://old.fssai.gov.in/Portals/0/Pdf/GFLP_Document_06_09_2016.pdf)

6.1.2 Waste Characterization and disposal methods

Chemical Waste can take the form of solvents, aqueous solutions, dry powders, and unwanted old chemicals. The following procedure should be implemented

1. Chemicals that can be wash down drains with excess water
   - Concentrated acid after dilution and dilute acids and alkalis
   - Harmless soluble inorganic salts (including all drying agents such as Calcium Chloride ($CaCl_2$), Magnesium Sulphate ($MgSO_4$), Sodium Sulphate (Na_2SO_4), Phosphorous Pentoxide (P_2O_5)
   - Alcohols containing salts (e.g., from destroying sodium)
   - Hypochlorite solutions from destroying cyanides, phosphines, etc.
   - Fine (TLC-Thin Layer Chromatography grade) silica and alumina
2. No material on the "Red List" should ever be washed down a drain. This list is as follows:
   - Substances that do not mix or dissolve readily in water (e.g., fats)
   - Compounds of the following elements: - antimony, arsenic, barium, beryllium, boron, cadmium, chromium, cobalt, copper, lead, mercury, molybdenum, nickel, selenium, silver, tellurium, thallium, tin, titanium, uranium, vanadium and zinc.
   - Halogenated organic solvents/ organochlorine compounds (e.g., chloroform, dichloromethane, epichlorohydrin, carbon tetrachloride).
   - Toxic organic solvents (e.g., methanol, acetonitrile, xylene)
   - Organohalogen, organophosphorus or organonitrogen pesticides, triazine herbicides, any other biocides.
   - Cyanides and azides; Cyanide wastes must be placed in an appropriate waste bottle and the solution kept alkaline at all times.
   - Antibiotics
   - Formaldehyde or paraformaldehyde solutions
   - Phenol, benzene or their derivatives
   - Mineral oils and hydrocarbons
   - Poisonous organosilicon compounds, metal phosphides and phosphorus element
   - Fluorides and nitrites
3. Solvent Waste collection in individual labelled containers for:
   - Halogenated solvents (methylene chloride, tetrachloroethylene, and chlorinated fluorocarbons)
   - Nonhalogenated solvents (acetonitrile, xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, methanol, and n-butyl alcohol).
   - Soluble organic waste including most organic solids
   - Paraffin and mineral oil (from oil baths and pumps)
4. Each laboratory section should have the following waste bins preferably color coded and labelled. Ensure every bin has a lid. When the laboratory bin is ¾ full, the lid should be placed on the bin and the contents transferred to the larger solid waste bins:
   - **Controlled waste:** Items in this category includes dirty paper, plastic, rubber and wood, which will be collected by the cleaners daily.
   - **Glass:** All broken laboratory glassware including disposable test tubes, bottles etc.
   - **Bottles:** Empty reagent bottles to be collected separately. The tops/caps must be removed from all bottles put out for disposal and there should be no detectable smell of chemicals from any bottle put for disposal.
   - **Metal sharps:** Any sharp objects like can tops, pins, syringe needles, scalpel blades, razor-blades, scalpel blades. Under no circumstances must any item of glass, sharp metal or fine powder ever be put in a normal laboratory waste bin

- **Plastic ware:** All disposable plasticware including, Eppendorf vials, syringes, pipette, tips, plastic bottles etc.
- **Batteries:** All used batteries
- **Waste for special disposal** collected in labelled individual bottles
  - Mercury
  - Cyanide solutions
  - the quantity of special waste must be kept to an absolute minimum and stored under suitable conditions.
  - Should be disposed as per the regulations of the State Pollution Control Board

Biological Waste

Each individual laboratory may consult a contract with a commercial firm which is licensed by their respective State Pollution Control Board, to remove and transport biological waste to a designated disposal site for incineration.

In most cases, the ideal method of decontaminating microbiological waste and reusable equipment is the auto-clave.

- Remove all labels from tube cultures and other contaminated reusable items and place them in the designated autoclave container. This will likely be an open autoclave pan to enable cleaning the tubes and other items following sterilization.
- For safety reasons, all the disposable petri-plates used for the inoculation and enumeration of the microorganisms, should be autoclaved (steam sterilized) to inactivate the biological agents. Once autoclaved, waste can be disposed of.
- Do not pour melted agar into sink or floor drains. Allow it to cool and solidify for disposal as a bio waste and can be placed with non-hazardous waste.
- Dispose of plate cultures (if plastic Petri dishes are used) and other contaminated no sharp disposable items in the designated autoclave container. Petri dishes should be taped closed. (Note: To avoid recontamination of sterilized culture media and other items, autoclave containers are designed to be permanently closed, autoclaved, and discarded. Therefore, do not place reusable and non-reusable items in the same container.)
- Dispose of all blood product samples and disposable gloves in the container designated for autoclaving.
- Place contaminated broken glass and other sharp objects (anything likely to puncture an autoclave bag) in a sharp's container designated for autoclaving. Uncontaminated broken glass does not need to be autoclaved, but should be disposed of in a specialized broken glass container.
- Spill kits suitable for the waste handled should be available. Personnel handling the waste should be competent in using the kits. Provision for a waste storage security system should be considered especially for biological waste from BSL 3 and 4 laboratories.

Decontamination of Biological Waste

Biological waste should be decontaminated to render them non-infectious before disposing as normal waste. In general, decontamination can be achieved by disinfection or sterilization.

- **Disinfection**

  This is normally carried out by applying liquid chemicals, usually for solid surfaces and equipment. The effectiveness depends greatly on the disinfectant used and the biological organism involved. However, as many of these chemical disinfectants are hazardous, safety precautions and care must be taken in applying them.

- **Sterilization**

  There are many methods of sterilization – by heat, vapor, gas or radiation. Autoclaving using steam is most commonly used for decontamination of biohazardous waste in the laboratory. However, certain wastes are not suitable for heat sterilization as hazardous by- product might be generated from the process (e.g., ammonia fumes may be generated when autoclaving urine samples).

  Animal waste should be considered as infectious waste if it is derived from animals with zoonotic diseases or infected with agents infectious to humans. Carcasses, body parts, tissue, body fluid, excreta and bedding should be considered as infectious waste. Such waste should preferably be incinerated.

  Biological waste contaminated with hazardous chemicals should first be suitably decontaminated and subsequently handled as chemical waste. However, care must be taken to ensure that decontamination of one portion does not create a greater hazard due to the presence of the other portions. The collection, storage and transportation of the waste should be carried out using durable, leak-proof containers with a secondary container or be double bagged. The plastic bags used must be tear resistant, leak resistant and sturdy enough to withstand normal handling.

6.1.3 SOP for disposal of used culture media

It is the responsibility of microbiologist to correctly dispose of the used culture media to ensure laboratory decontamination.

Steps for disposal of used culture media/slants/test tubes/flasks/plates/pipettes

- Autoclave at 121^{O}C for 30 minutes at 15 psi pressure
- Drain the contents into the sink under running tap water
- Soak the empty tubes/flasks for 1 hour in 2.0% savlon solution
- Wash thoroughly with 0.1% teepol solution and rinse with tap water. Finally rinse with purified water and dry the glassware.

Precautions while disposal:

- Handler should wear complete PPE
- Run an empty autoclave sterilization cycle at 121^{O}C for 15 minutes at 15psi pressure
- Maintain and record the register as “Disposal Load”
- Assign separate lad number for disposal load.

UNIT 6.2: Food Safety and Hygiene Audits

Unit Objectives

At the end of this unit, you will be able to:

1. Illustrate Carrying out internal audit on housekeeping to ensure safety and hygiene system are in place
2. Perform audits by establishing clearly the scope of the audit, the responsibilities of the auditees, the quality procedures that apply to their work, previous audit history and expectations to maintain quality, encourage to cooperate fully, and carry out audit to reveal any deviations from relevant quality procedures
3. Maintain complete records of safety and hygiene audits for management review and future reference.
4. Illustrate Carrying out internal audit on housekeeping to ensure safety and hygiene system are in place
5. Identify food safety requirements in the food products production process based on microbial analysis results of production line, premises and food product

6.2.1 Terms and Definitions

Before understanding the audit process and its key components let one understand the key terms and definitions related to the audit process[29].

1. "Audit" is a systematic, unbiased and documented procedure for acquiring audit evidence and comparing it objectively to determine the quantity to which the audit criteria are fulfilled.
2. "Auditing Agency'' method an auditing business enterprise recognized by the Food Authority for project food protection audit according with FSS (Food Safety Auditing) Regulations.
3. "Food business" approach any assignment, whether for profit or now not and whether public or private, sporting out any of the activities related to any level of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients;
4. "Food Business Operator (FBO)" in terms of food enterprise method someone by means of whom the commercial enterprise is carried on or owned and is liable for making sure the compliance of this Act, rules and policies made thereunder;
5. "Food Safety" method warranty that food is suitable for human consumption consistent with its meant use;
6. "Food Safety Audit" method a scientific and functionally unbiased exam of food safety measures adopted by using manufacturing units to determine whether or not such measures and related outcomes meet with goals of food safety and the claims made in that behalf;
7. "Food Safety Management System (FSMS)" method the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified via regulation, for the food commercial enterprise;

[29] Food Safety and Standards (Food Safety Auditing) Regulations, 2018. (https://www.fssai.gov.in/cms/food-safety-and-standards-regulations.php)

8. "Risk", with regards to any article of food, approach the chance of an adverse effect on the fitness of purchasers of such food and the severity of that impact, consequential to a food chance;
9. "Risk Analysis", in terms of any article of food, manner a technique consisting of 3 components, i.e., hazard assessment, hazard management and risk communication;
10. "Risk Assessment" means a scientifically based totally technique consisting of the following steps:
    - hazard identification,
    - hazard characterization;
    - publicity assessment, and
    - danger characterization;
11. "Standard", when it comes to any article of food, manner the requirements notified by means of the Food Authority;
12. "Hazard Analysis and Critical Control Points or HACCP" is a systematic preventive method to food safety from biological, chemical, and bodily hazards in production approaches that can motive the finished product to be unsafe, and designs measurements to lessen these risks to a secure level. In this manner, HACCP attempts to avoid risks as opposed to attempting to investigate completed merchandise for the effects of these risks. The HACCP gadget can be used at all levels of a food chain, from food production and preparation processes such as packaging, distribution, etc.

It is the ethical responsibility of every food business operator to prevent customers from any harm. If the Food safety and hygiene norms are not followed then it may lead to foodborne disease outbreak. To prevent such occurrences, World Health Organization considers Food Safety and Hygiene as the paramount. According to WHO (World Health Organization), it must include these five key Food Safety principles:

- Prevent contamination of food with pathogens
- Prevent contamination of cooked food from separate raw and cooked foods.
- Kill pathogens by cooking food for the appropriate length of time and at the appropriate temperature.
- Storage of food at proper temperatures as per the specific requirements.
- Use of potable water and safe raw materials

Every organization dealing with the handling, processing, manufacturing, packaging, storing, and distribution of food by any food business operator should observe the Food Safety and Hygiene Norms. It is the duty of the food business operator and the individuals handling food in the food establishments to ensure adherence to general hygienic and sanitary practices. It means that every food business operator should follow steps which are critical to ensuring food safety in the activities of the food business. These measures ensure better Food Safety and Standards Regulations.

All kinds of Food hygiene legislation in India are developed by the Food Safety and Standards Authority of India. It is a highest organization that is managed by the Ministry of Health and Family Welfare dedicated to ensuring Food Safety and Hygiene Requirements in India. Here is a list of pre-requisite requirements on Hygienic and Sanitary Practices to be followed by all food business operators under the domain of Food Safety and Standards (Licensing & Registration of Food Business) Regulations, 2011:

- **Location and neighborhood of the food establishment:** The Food and Safety Guidelines given by FSSAI suggest that it should ideally be away from environmental pollution and industrial activities that are probable to contaminate the food through disagreeable odor, fumes, dust, smoke, chemical emissions, pollutants. These contaminants have the potential risk of contaminating food areas prone to infestation of pests or wastes. It is also imperative to note that the manufacturing sites of food articles must not have any direct contact to any residential area. Location of establishment also plays a vital role in meat and meat products. In order to get a FSSAI License to any food business

operator dealing in meat and meat products, one must ensure that the establishment is linked to a meat market and is away from vegetable, fish, and other food products.

- **Layout and design of food establishment/laboratory:** General hygienic and sanitary practices include that the floors, ceilings and the walls of the food establishment must be maintained in a comprehensive condition with no flaking and plaster. Adequate control measures must be taken to avoid insects and rodents from entering the establishment. No individual shall be permitted the sale of any article within the premises of the food manufacturing unit which is not effectively separated from the place of urinal, sullage, place of storage of foul matter, or drain.
- **Equipment and Containers:** Food hygiene guidelines suggest that all the containers used by any food establishment must be in good order and in clean hygienic conditions. These containers should be made of corrosion free materials. The main purpose is to guard the food from dust, dirt, flies, and insects. Proper cleaning and disinfecting of equipment are necessary in order to hold Food Safety and Hygiene Requirements.
- **Facilities:** Water supply facilities must be adequate in order to guarantee no risk of contamination of food articles. This means only transportable water must be used as an ingredient in cooking and processing. Facilities for washing of raw materials, washing of utensils, drainage, and waste disposal, personal facilities and toilets, air quality and ventilation, and lighting are essential to be developed in order to acquire a Food license for any food business operator.
- **Food operations and controls:** Food Hygiene System must ensure that the food establishment is cautious about obtaining of raw materials. Expiry or use by date must be carefully checked. Temperatures for high-risk food; such as milk goods, frozen food, meat, must be sustained to ensure safe storage of raw materials and food articles.
- **Sanitation and maintenance of establishment premises:** Proper cleaning and maintenance facilities, pest control systems must be guaranteed to meet Food Safety and Standards Rules. All food institutions must ensure a Food Hygiene System that carefully draws cleaning and sanitation program. Specific cleaning regularities and procedures must be customary to ensure food hygiene and sanitation. Also, pest infestations should be dealt with immediately. One must be careful of not adversely affecting the food quality in the treatment of pests.
- **Personal Hygiene:** Food Safety and Hygiene Norms must ensure personal cleanliness of the food handlers. It is the duty of the food business operators to make available all food handlers with Food Safety and Hygiene Requirements such as: protective clothing, head covering, face mask, gloves, and required footwear. These requirements must also be compulsory for those visiting the food establishments. Also, all food handlers must undertake frequent health checkups. Any illness or disease that can be transmitted through food can be dangerous. Carriers of these diseases must not be permissible in the food establishments.

While all the Food Hygiene Guidelines have been specified by Food Safety and Standards Authority of India, a food business operator must ensure that all food handlers are well aware of their roles and responsibilities in protecting food from any kind of adulteration. All food handlers must be equipped with the essential knowledge and skills relevant to food manufacturing, processing, packaging, storing, and serving. Food safety and quality must be ensured without any food quality deterioration.

Periodic valuations of the effectiveness of training, awareness of safety requirements, check to ensure Food Safety and Hygiene Requirements are being carried effectively are done by Food Safety and Standards Authority of India.

For more details refer to module Number 2.

6.2.2 Food Safety Audit

Before studying the specific character and nature of a food safety audit, let's first look at what is an audit in general. An audit is defined as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. An audit is a process where an authorized auditor officially visits a facility to assess food safety compliance. During the audit the auditor carries out an inspection of the facility, observes the food handling practices, and reviews food safety documentation (including the food safety program and monitoring).

Food Safety Audit means a systematic and functionally independent examination of sanitary & Hygiene compliances as per Schedule IV, Food safety measures (based on HACCP) and other standards (e.g., Product standards) adopted by FBO to meet the regulatory requirements.

According to the FSS (Food Safety and Standards) Act, 2006, a Food Safety Audit means, a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with the objectives of food safety and the claims made in that behalf.

Audits on licensed food business will be carried out by the auditors of agencies recognized under the Food safety and Standards (Food Safety Auditing) Regulations, 2018.

6.2.3 Audit Framework

Roles and Responsibilities

	Roles & Responsibilities
Food Authority	• Define third party audit requirements based on risk categorization • Describe the inspection frequency as described in Section 8 of the Food Safety and Standards Regulations (Food Safety Auditing) 2018 • Define the code of practice to be followed by the audit agency / auditors and the protocol for the audit management • Defines channels of contact between the various stakeholder • Audit agency performance monitoring & integrity
Audit Agency	• Employ the full criteria set out in this document, the specifications of the FSS (FSA) Regulations 2018 and the specifications of the Accreditation Authority. • Auditing agency auditors are to perform the audit and submit the report. • The audit results closed in section 7.3.7. • Presentation of timeline-compliance audit reports as specified in FSS (FSA) Regulations, 2018. • Conflict of Interest conditions should be fulfilled. o Update the Authority regarding any changes in accreditation, audit scope, auditors' detail etc.
Auditors	• Carry out the duties set out in section 10 of the FSS (FSA) Regulation, 2018. • Conduct audit in an objective, competent manner and follow the Auditing Standards to maintain confidentiality.

	Roles & Responsibilities
FBO	• The FBO is considered responsible for conducting the audit according to the business risk classification. • Conflict of interest conditions to be safeguarded when choosing the auditor / audit firm. • Other FBOs which are not identified in the risk categorization can also voluntarily participate in the third-party audit system.

Table 6.2.1 Roles and Responsibilities

Food Safety Audit Process

Process	Description
FBO will select the audit agency	• Audit agency must collect all information about FBO, scale, number of production lines / group of goods, consultancy / training details, number of food handlers, storage area (in case of storage and distribution)
	• The audit date will be agreed with the agency by FBO and the audit fee to be paid by the FBO will be determined.
The Audit agency fills in the audit Intake form in FSSAI Audit management system	• The Audit Agency must log in to the FSSAI audit portal and fill in the Audit Intake Form information of the scheduled audit.
	• The Audit Agency will log in to the FSSAI audit portal and fill out the scheduled audit details in the Audit Intake Form.
	• Date of audit, information of the auditor, man-days of audit will be listed in the intake form. The details cannot be revised after the form has been filled out. Once done, the specifics of the scheduled audit are clear to the Food Authority, the agency concerned and the FBO.
	• The department will be notifying FBO of the Audit Report at least 8 days in advance.
	• FBO will get their businesses audited as per the audit plan on the scheduled date.
• The auditor / audit agency shall carry out the audit as per the inspection checklist and shall communicate the audit score and submit the draft audit report BEFORE leaving the FBO facility. FBO must adhere to all results. In case of disagreements, the FBO can represent to the Food Authority, if any.	
• In the case of Major non-compliance, the Food Authority will be informed within 24 hours (also by email / phone) via the web portal. Information regarding the same should also be reached by the Director (RCD), the Central Licensing Authority and the Food Safety Commissioner of the State / UT concerned through web portal / mail / other means.	
• In the event of Minor Non-Conformities, the audit department must close the findings within 15 days including their rectification and follow-up. FBO will close the results and take corrective action. In the event of delay by FBO, the organization shall inform the CLA or SLA concerned by means of web portal / mail / other means for the required action at its end.	

Process	Description
•	The Final audit report is submitted to the FSSAI Audit management web page within 15 days of the audit date.

Table 6.2.2 The Food Safety Audit Process

Mandatory vs Voluntary audits and its frequency

The Food Authority shall, from time to time lay down the category or type of food businesses which shall be subject to compulsory food safety auditing, primarily based on their risk classification. The classification of food business can be done after deliberation of the major risk factors like food type, intended customer use, nature of activity of the business, volume of the business, technique of processing and or any other factors that the Food Authority may specify on this behalf. Such food businesses shall get their business audited by the standard auditing agency as per the frequency stated by the Food Authority. Food businesses which are not mandatorily subject to food safety auditing but are desirous of getting audited by the recognized auditing agency, can opt for the same.

Food businesses in which food safety audits have been satisfactorily conducted may be subject to lesser inspections by the Central or the State licensing authorities apart from for regulatory purpose. Provided that in case of any grievances against the food businesses or when it comes to the knowledge of the Food Authority that the public health and safety is at risk, the Food Authority shall have the decision to undertake frequent inspections.

The audit process involved for assessing the food safety management system of a Food Business Operator shall be based on IS/ISO 19011:2011 (Guidelines for audit in management systems).

Audit Frequency

The Audit Frequency recommended by the Food Authority for FBOs to conduct the mandatory food safety audits is as per table below. Please note that if the:

- Audit Score range is 81-100% the audit frequency is Once in 12 months
- Audit Score range is 51 - 80 % the audit frequency is Once in 09 months
- Audit Score range is <50% the audit frequency is Once in 06 months

Product ID	Product
1	Dairy products and analogues, excluding products of food category 2.0
2	Fats and oils and, fat emulsion
3	Edible ices including, sherbet and sorbets
4	Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes)
5	Confectionery
6	Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses legumes and pith
7	Bakery products
8	Meat and meat products including poultry
9	Fish and fish products, including mollusks, crustaceans, and echinoderms
10	Eggs and egg products

Product ID	Product
11	Sweeteners, including honey
12	Salts, spices, soups, sauces, salads and protein products
13	Foodstuffs intended for particular nutritional uses (e.g., Food for infant nutrition, etc.)
14	Beverages, excluding dairy products
15	Ready-to-eat savories
16	Prepared Foods (catering etc.)
99	Substances added to food

Table 6.2.3 Audit Frequency

Audit Principles

Following "The Principles of Auditing" (ISO 19011) is a prerequisite for enabling auditors, working independently from one another, to reach to the conclusions in the given scenarios. These principles are the effective tools in support of management policies and controls, to improve the performance.

Principle 1:	Integrity – The foundation of professionalism In the course of an audit, auditors are expected to conduct themselves in an honest, diligent, and responsible manner. They ought to be aware of, and comply with, any legal requirements that apply to the auditee, its business type, or its location. Auditors need to be impartial and they also need to be aware of - and resist - any attempt to influence their judgment.
Principle 2:	Fair Presentation - The obligation to report truthfully and accurately. Auditors are obliged to report on the results of audits truthfully and accurately. All communications need to be as timely, clear, complete, and objective as possible.
Principle 3:	Due professional care - The application of diligence and judgement in auditing
Principle 4:	Confidentiality - Security of information
Principle 5:	Independence - The basis for the impartiality of the audit and objectivity of the audit conclusions This principle goes hand-in-glove with the principle of fair presentation. In other words, the presentation (report) of my findings is more likely to be viewed as fair, impartial, and objective if the auditor is independent of the party/organization being audited.
Principle 6:	Evidence based approach - The rational method for reaching reliable and reproducible audit conclusions When an auditor comes up with nonconformity, he has to describe the problem clearly and concisely so the auditee understands it and can identify it for themselves. It has to be indicated where and when the problem was identified, how you identified the problem (observed, interviewed, etc.), describe the requirement that is not being met, and describe the objective evidence that led you to your finding of a nonconformity or observation.

Table 6.2.4 Audit Principles (Source: FSSAI Auditor's Manual)

Behavior Skills of Auditor

Auditors should hold personal characteristics to enable them to act in accordance with the principles of auditing. An auditor should be:

- Ethical, i.e., fair, truthful, sincere, honest and discreet;
- Open-minded, i.e., willing to consider alternate ideas or points of view;
- Diplomatic, i.e., tactful in dealing with people;
- Observant, i.e., dynamically aware of physical surroundings and activities;
- Perceptive, i.e., instinctively aware of and capable of understanding situations;
- Versatile, i.e., adjusts readily to different situations;
- Tenacious, i.e., persistent, focused on achieving objectives;
- Decisive, i.e., reaches sensible conclusions based on logical reasoning and analysis; and
- Self-reliant, i.e., acts and functions independently while interacting effectively with others.

Confidentiality Requirements

The purpose of the Confidentiality Policy is to ensure that all information relating to the FBO and/or audit process is handled in confidence. Besides, an agreement shall be in place between the audit agency and FBO, which shall be uploaded on FSSAI audit portal.

Confidential Information shall mean any information in any form emanating, directly or indirectly, including, but not limited to, product lines, management systems, methods of business operation, technical information, economic information data, specifications, know how, process information and methods of manufacture, distribution and sale relating to the development and marketing, Photos of Non-conformance etc.

Confidential Information does not include any statistics which:

- Is used in the appropriate performance of a service and/or discussed or disclosed with FBO's consent.
- At the time of disclosure is generally known by the public or thereafter becomes public knowledge.
- This policy shall not apply in any situation where disclosure is required in accordance with statute law to an official body having a legal right to require that information.

Specific business records and correspondence of a commercially sensitive nature (details of fees, letters relating to one company or person, etc.) shall be kept in confidence unless the Company has received written permission from the person(s) or entities involved, authorizing release of the information.

Declarations for Conflict of Interest, Anti-bribery Norms and Subcontracting of audits

Declarations on below subjects shall be maintained by audit agencies and shall be submitted to FSSAI as and when required.

- Conflict of Interest: As prescribed in Section 12 of FSS (FSA) Regulations, 2018, Form C of FSS (Food Safety Auditing) Regulation 2018 shall be obtained by audit agency for every audit and uploaded on FSSAI audit portal. The auditing agency shall give a declaration in Form 'C' of the agenda before accepting food safety audit of a Food Business Operator. The recognition of any auditing agency shall be suspended or cancelled immediately by the Food Authority on the event of providing false statistics on conflict of interest.
- Anti-bribery: No auditor/personnel of audit agency should have any financial interest in managing or otherwise controlling the FBO or any of its affiliate/parent/subsidiary. In case of breach, the recognition of the agency shall be suspended/cancelled.

- Subletting/Sub-contracting of audits: The entire audit work must be carried out by the auditor of the recognized auditing agency himself/ herself. In other words, the auditor shall not assign the audit work to any agency/ auditor. Any violation in this regard shall lead to de-recognition of the auditor/agency.

6.2.4 Audit Planning

Audit Duration

The Food Business Operators are broadly divided into 3 categories for calculation of audit time/duration viz.

1. Manufacturing,
2. Catering/ Quick Service Restaurants (QSR) / Restaurants, and
3. Food Retail/Warehouse/Storage.

Audit time is calculated based on number of food handlers, product groups / HACCP study, etc.

The Audit Duration recommended by the Food Authority for conducting the food safety audits for the three categories are as below:

- **Manufacturing**

Food handlers (Parameter 1)	No. of production lines/ Product group in FBO/ No. of HACCP study (Parameter 2)	On Site Man-days **
0- 50	1	0.5
51-100	1-2	1
101-300	4	1.5
301-600	6	2
601-1000	8	2.5
>1000	10+	3

Table 6.2.5 Manufacturing

For calculating the number of man-days, the parameter with the higher number of man days shall be taken into consideration. For egg: If the number of food handlers is 80(i.e., <100) and the number of production lines is 4 then the number of man-days will be 1.5 man-days (i.e., maximum of 1and 1.5 man-days).

- **Catering/ QSRI Restaurants**

Food handlers	On Site Man-days **
0-25	0.5
26-50	1
51-100	1.5
101-100	2

Table 6.2.6 Catering/ QSRI Restaurants

- **Food Retail/ Warehouse/ Storage**

Area (Sq. ft)	On Site Man-days **
<15,000	0.5
15001-50,000	1
>50,000	1.5

Table 6.2.7: Food Retail/ Warehouse/ Storage

**These are ON-SITE audit man-days prescribed and do not include reporting time.

Any change in the duration of audits should be informed to FSSAI and permission for changing the same should be taken.

Audit Fees

The Audit fee will be as per mutual agreement between the Auditing Agency and the FBO. However, the Food Authority may issue guidelines regarding the fee structure as and when required.

Competence of Auditor

The requirements for Auditing Agencies with respect to the auditor competence and qualification process are as per Food Safety and Standards (Food Safety Auditing), Regulation, 2018. All auditors conducting Food Safety Audits should meet the following minimum requirements:

Educational Specifications

Educational qualification of Auditors prescribed in Section 3(c) of the FSS (FSA) Regulation, 2018 is as follows:

Bachelor's degree in Food or Dairy or Fisheries or Oil Technology or Biotechnology or Agriculture or Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry or Hotel management or Catering technology from a recognized university;

Initial Training

- Auditor should meet the requirements detailed in the section specific specifications:
- successful completion of Accredited Lead Auditor course in Food Safety Management System;
- knowledge of the FSS Act and the rules and regulations made thereunder;
- sector specific information of hygienic and sanitary practices, processing techniques, hazards identification and analysis and control and familiarity with contaminants and allergens;

Work & Audit Experience

Auditor has a minimum of two years of full-time work experience in minimum of 10 audits (third party audits).

All audit agencies will submit the sector specific qualification (based on ISO 22000) as approved by NABCB or similar accreditation agencies. The FBO audits will be done by the auditor qualified for that specific sector.

Auditor Training (by FSSAI)

Each probable recognized food safety auditor as part of an agency must attend a training with the Food Safety and Standards Authority of India (FSSAI) on policies, procedures, reporting and other requirements. The details of the training will be available in FSSAI Website. The expenditure for this training will not be borne by FSSAI.

The training must be attended by every Food Safety Auditor before commencing any food safety audits as recognized auditor.

Audit team requirements

The agency should also ensure that the audit team complies with the following requirements:

- Familiarity with the applicable legal regulations, certification procedures and certification requirements;
- Thorough knowledge of the relevant assessment method and assessment documents;
- Appropriate technical knowledge of the specific activities for which certification is sought and, where relevant, with associated procedures and their potential for failure (Technical experts who are not auditors may fulfil this function);
- Understanding sufficient to make a reliable assessment of the competence of the organization to provide products, processes or services in its certified scope;
- Ability to communicate effectively, both in writing and orally, in the required languages;
- Free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example: providing of consulting services, training etc. to the organization; As per agreement with the audit team members it is mandatory to inform its auditing agency, prior to the assessment, about any perceived conflict of interest.

Maximum Audits per year by an Auditor

The maximum number of food safety audit work carried out by each auditor of an auditing agency as a team or individually shall not exceed 50 audits per year subject to a maximum of 100 man-days per year.

6.2.5 Audit Execution

Filling up of Audit Intake Form

An Audit Intake Form on FSSAI web portal shall be filled in once all the relevant information is collected, verified and confirmed from the interested FBO by the audit agency. Once the form is filled on portal, it cannot be changed. The Audit Intake Form shall cover

- Information about the applicant FBO
- FSSAI license number of FBO
- Product groups / HACCP Study for the FBO
- Number of employees & production area of the FBO
- Auditor Details (as assigned by agency)
- Audit date and/or scheduled timings (as mutually decided)
- Current Food Safety and Management System (FSMS) certifying agency, if any of FBO

Communication of audit plan to FBO

Audit agency will send a detailed audit plan / agenda to FBO at least 8 days in advance. The audits shall not be conducted as surprise audits, unless specified by the food authority.

The audit agenda shall cover audit Scope, objectives, criteria (i.e., Schedule IV, Food Safety Measures and Other Standards), auditor time per process / area / department, date, auditors etc.

Conducting Audit

The onsite audit should include:

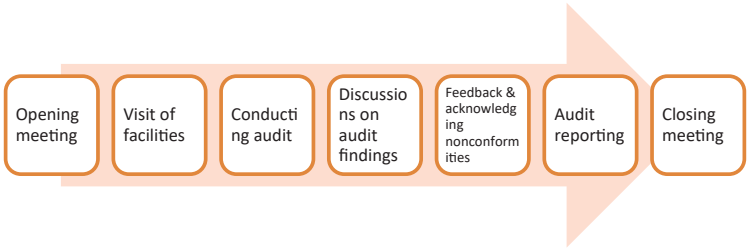

Fig. 6.2.1: Steps for on-site audits

Opening Meeting

The audit activities at site shall start with an opening meeting to be held with the auditee's management and, where appropriate, those responsible for the functions or processes to be audited. If Guides are used their role must be explained. The purpose of the inaugural meeting is to:

1. confirm the agreement of all parties (e.g., auditee, audit team) to the audit design;
2. introduce the audit team;
3. ensure that all planned audit activities can be performed.

The meeting shall be chaired by the Auditor /Audit team leader, and the following items should be considered, as appropriate:

introduction of the participants, including an outline of their roles;

1. confirmation of the scope of assessment;
2. confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the Licensee;
3. confirmation that the resources and facilities needed by the audit team are available;
4. confirmation of matters relating to confidentiality;
5. the method of reporting, including any grading of audit findings, inspection checklists etc.;
6. methods and procedures to be used to conduct the audit based on sampling;
7. confirmation that, during the audit, the Licensee will be kept informed of audit progress and any concerns;
8. opportunity for the FBO to ask questions

Conducting the audit activities:

The audit team shall conduct an onsite audit as per the requirement and audit criteria. During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes, shall be verified and recorded.

The audit criteria shall include the followings:

- Availability of valid FSSAI license
- Compliance of Schedule 4 of FSS Regulations
- Review any deviations to activities conducted at the licensed food businesses that may affect the businesses food safety risk
- Review changes to approved activities or processes
- Review of previous audit report and pending actions if any including non-conformities not addressed
- Review of enforcement action taken by the Food Authority
- Previously issued Non-conformities reviewed and discussed (Non conformities not addressed will be escalated)
- Licensed food businesses must produce evidence of corrective actions taken for all non- conformities issued
- Review of food safety plan to ensure currency and accuracy including:
  - hazard analysis and control points (as determined by legislation),
  - finished product specifications,
  - monitoring records, flow charts,
  - product testing results, and verification records.
- Inspection of the licensed food business and following of processing and manufacturing practices
- Establish Non conformities to be issued and severity
- Issue of corrective action requests
- Complete audit report and notes

The audit team shall use the inspection checklists prescribed by FSSAI for assessment of food businesses of relevant food category. The inspection checklists for various categories of food businesses are placed at Annex 5 of this manual.

The auditing agencies should not issue any Food Safety Certificates to FBOs on behalf of FSSAI and should only submit audit reports as per inspection checklists at Annex 5 of this manual. Strict action shall be taken against agencies found issuing certificates without knowledge of FSSAI.

Audit Examination

Audit examination shall cover collection of objective evidence and documenting audit observations. Evidence can be collected through interviews, examination of documentation and observation of activities. Where the deficiencies or non-conformances detected, they shall be documented clearly and concisely and shall point out the regulatory requirements that are being contravened.

During the audit process, the auditing agency shall verify the compliance not only with the food safety measures but also with the Food Safety Standards Regulations as applicable other than those which may require specific sampling and laboratory analysis of the products. The auditing agency shall check relevant documents related to laboratory reports maintained by the Food Business Operator as part of compliance with various regulations made under the Act.

Audit Conclusive report

The auditor shall report the findings of the audit to the food business subsequently the completion of the audit, wherein the food business shall be given a chance to discuss the findings and provide further information or clarification to the auditor, if necessary. The auditing agency shall submit the

audit report in the presentation specified by Food Authority to the Food Business Operator instantly after completion of the audit and also to the Central or State Licensing authority within fifteen days as the case may be clearly bringing out the findings or non-conformities or concerns and observations for improvement. The auditor may recommend any change in audit frequency of the food business operator along with justification to the Central Licensing Authority or State Licensing Authority based on the audit.

Grading of Nonconformity

The details on audit reporting and grading of Non-Conformities are as laid down in section 11 of FSS (Food Safety Auditing) Regulations, 2018. The non-conformities of the audit are broadly classified into two categories, namely,

- Major Non-Conformity- As per Section 11(2) of the regulations, when there is a serious failure in the food safety management system of the Food Business Operator, which may result in adverse health consequence perhaps even fatal, the auditor shall report such findings to the Central or State Licensing Authority within 24 hrs. The Central or State Licensing Authority after determining the seriousness of the situation shall take regulatory action against the said food business operator. Further, major non-conformity is the absence of, or the failure to implement and maintain, one or more requirements of the relevant standard under auditing, or a situation, which would, on the basis of available objective evidence raise significant doubt as to the conformity of the product sent by the company, bearing high risk severity. A major non-conformity may be an individual non-conformity or a number of minor but related non-conformities, which when considered in total are judged to constitute a major non- conformity. In case of Major Non-conformity follow up audit can be planned depending upon the severity of the Non-conformity
- Minor Non-Conformity- As per Section 11(2) of the regulations, a Minor Non-conformity is when there is a shortcoming in the food safety management system or regulatory contravention of the Food Business Operator, which may not cause any serious health consequence. In this case the auditor shall set up an appropriate timeframe of not more than 30 days for its rectification and follow up, so that the non-conformance could be rectified. Failure by food business operator to rectify the trivial non-conformity within the specified timeframe shall be raised to the Central or State Licensing Authorities, as the case may be. The auditor may recommend in writing the reasons for the change in audit frequency of the food business operator to the Central or State Licensing Authority based on the audit.

  A minor non-conformity shall be allocated to a single isolated failure in the area concerned to comply with the requirement of relevant standard under auditing or with the specified requirements the organization is subscribed to as per the scope of the standard having moderate risk, without constituting an overall system failure.

  For non-conformities as per requirement of certification and auditing, corrections (immediate disposition) and corrective actions (Appropriate actions against cause of detected nonconformities) are required to be taken.

Closing meeting (Conducted at completion of the audit):

It is important that the auditor reports the findings of the audit/ audit score to the food business at the completion of the audit so that the food business has an opportunity to discuss the findings and provide further information to the auditor if appropriate. The number of people involved and the time taken for a closing meeting will depend on the size and complexity of the food business and the number and extent of the audit findings. The main objective is to ensure that all involved in the audit have a clear understanding of the findings.

The Agenda for closing meeting may include the followings:

- advising the FBO that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty;
- the method and timeframe of reporting, including any grading of audit findings;
- the procedure for closure of nonconformities including any consequences relating to the status of the FBO's license;
- the timeframe for the FBO to present a plan for correction and corrective action for any nonconformities identified during the audit;
- Ensure all information recorded on report
- Ensure FBO is fully aware of what information will be communicated back to the Food Authority
- Ensure receiving of acknowledgement of the Nonconformities if any.
- information about the complaint handling processes.
- give opportunity for questions to the FBO.
- Discuss and resolve any diverging opinions regarding the audit findings or conclusions between the audit team and the FBO (if applicable and where possible).

Closure of Audit Findings

- **Closure of Major Non-Conformities:**

  The auditor shall report any Major Non-Conformities (as defined in section 7.3.5(1) of this manual) to the Central or State Licensing Authority within twenty four hours. through mail/ phone/ web portal etc. The auditor should ascertain that the information reaches the concerned Central licensing authority/state licensing authority (CLA/SLA) and FSSAI (Director (RCD)/ Director (FSMS)). The Central or State Licensing Authority after ascertaining the seriousness of the situation shall take regulatory action against the concerned food business operator. Once the information and other details have been shared by the auditor with concerned CLA/SLA, the next steps will be taken by CLA/SLA and the role of auditor ceases.

- **Closure of Minor Non-Conformities:**

  In the case of Minor Non-Conformity (as defined in section 7.3.5(11) of this manual), the auditor shall set up an appropriate timeframe of not more than 30 days for its rectification and follow up, so that the non-conformance could be rectified. The complete audit report after rectification of non-conformities will be uploaded by the agency on the FSSAI audit management portal. Failure by food business operator to rectify the minor non conformity within the specified timeframe shall be referred to the Central or State Licensing Authorities, as the case may be.

6.2.6 Suspension / Cancellation Policy

The suspension/ cancellation of the recognition of an auditing agency will be governed as per section 7 of the FSS (Food Safety Auditing) Regulation, 2018. The Food Authority may suspend or cancel the recognition granted to the auditing agency by an order on any of the following grounds, namely, -

- the auditing agency has been declared insolvent by a competent authority;
- the auditing agency has failed to performs its duties satisfactorily or in accordance with these regulations;
- the auditing agency has suppressed material information or committed fraud;
- the auditing agency has fails to perform satisfactorily or has become incompetent to continue to be accredited as auditing agency;

- the auditing agency has failed to provide access to their records and furnish necessary information to the Food Authority to conduct the assessment or investigation;
- the auditing agency has failed to take timely and necessary corrective measures, if any, as directed by the Food Authority;
- the recommendation of the Screening Committee on of the regarding conduct of the auditing agency; complaints received;
- the auditing agency has provided false information with regard to conflict of interest;
- any other reason that the Food Authority may specify.

Failure to declare any conflicts of interest, as under Form C of the Schedule of the Regulation, may also result in the suspension or cancellation of an auditor's recognition by the Food Authority.

6.2.7 Renewal of recognition

The auditing agencies are granted recognition for three years. At the end of their three-year recognition they have to renew their recognition as per procedure laid down in Section 6 of the FSS (FSA) Regulations, 2018. If an agency does not renew its recognition prior to the expiry of validity of their date of recognition, their recognition will be cancelled and they will not be eligible to perform food safety audits on behalf of the Food Authority.

The Food Authority before renewing the Certificate of Recognition will consider the following:

- the auditing agency continues to meet the criteria stated in regulation 3;
- the performance of the auditing agency during the previous validity period;
- the complaints, if any, received during the period of validity.
- the reference of the Screening Committee for evaluation.

6.2.8 Audit Agency Integrity Monitoring Program

The Monitoring Mechanism shall include

1. review of the audit reports and performance;
2. on site assessment of the auditors to ensure their competency of auditing the food safety management systems and the regulatory requirements;
3. assessment of auditing agency on the basis of report of the accreditation body and any other mechanism as specified by the Food Authority.

Verification systems are used to keep in check for compliance to set standards, systems and legislative requirements. This system will also enable the Food Authority to assess and monitor the performance of recognized food safety auditors.

Verification audits may be triggered by complaints, system reviews, trends, audit reports and requests by licensees.

Verification Inspections

The Food Authority may conduct verification inspections on a random selection of facilities audited by auditors of recognized agencies to verify the accuracy of the audit findings. Auditors will be notified, in writing, of the results of the verification inspections. Should significant breaches be identified, a warning letter may be issued or disciplinary action be taken.

Review of submitted audit reports

Incoming audit reports will be reviewed to ensure compliance with the Food Authority's audit management procedure. Areas that may be included in the review are:

- Audit durations followed
- Relevance of Conformities/ Observations issued
- Severity of conformities/ Observations issued
- Notification of critical food safety issues
- Notification of audit failure
- Timeliness of report submission
- Layout of detailed Audit Summary

Auditors will be notified of any findings of the review of audit reports in writing. Should significant breaches be identified, a warning letter may be issued or disciplinary action be taken.

6.2.9 Record Keeping

- The final conformance report and all other documents related to the audit conducted including the first audit report, actions taken and successive communications on rectification measures shall be preserved by the auditing agencies at least for a period of five years and full confidentiality of the documents shall be maintained.
- Food Business Operator shall maintain all records of audit findings and rectification for a period of five years.

6.2.10 Handling disputes

The details on handling disputes in case of conflicts are given in Section 14 of part IV of Food Safety and Standards, FSS (FSA) Regulations, 2018 as below:

The Central or the State Licensing Authorities shall be the contact point for Food Business Operator to engage in case of any dispute or disagreement with auditors. In case of any non-cooperation or resistance to the working of the auditing agencies or auditors by food business operator, the same shall be referred to the Central or the State Licensing authorities for resolution.

6.2.11 Complaints System

Complaints may be made via the website, email or by letter. The website of FSSAI has a link to address the complaints. This link will take all the complaints and queries and pass them on to the relevant divisions of FSSAI for investigations or response. The Food Authority's complaints system is accessible by licensees, auditors, other jurisdictions and the general public. The complainant may remain anonymous if they wish.

UNIT 6.3: Microbiological Hazards

Unit Objectives

At the end of this unit, you will be able to:

1. Identify microbiological hazards in production process, and its critical control point to minimize or prevent those hazards

6.3.1 Introduction

Food safety is gaining more and more importance throughout the world. Global food trade and the introduction of World Trade Organization (WTO) Agreement have prompted many countries to adopt modern quality assurance programs to make food safe for human consumption. In an effort to achieve food safety and prevent food-borne public health problems, almost all countries are enacting laws to enforce and implement procedures for ensuring safety and quality of all food items produced, processed and distributed for human consumption. In this context, a detailed idea, about the hazards which make food unsafe, as well as the quality problems or defects, which will indicate the adverse effect on wholesomeness of food, will be very much useful to the personnel in the food industry, regulatory authorities as well as the general public.

About Food Safety Hazard and associated microorganisms

A food safety hazard can be well-defined as a physical, chemical or biological parameter, the presence of which in the food can source the infection or injury or toxicity to the consumer. On the other hand, a quality defect is also a chemical or microbiological or physical parameter, which will only reduce consumer acceptability without causing infection or injury or toxicity to the consumer. For a food to be safe and acceptable, it should be free from hazards and quality defects.

The standards specify tolerance limits for each hazard and tolerance limits for quality defects. Periodic assessment of food samples at critical stages of production to meet the requirements of such standards will be effective in controlling food borne diseases and public health problems. The availability of safe and quality food will not only promote good public health but also considerably augment tourism and international trade in food commodities.

The biological parameters significant in food safety and quality are Total Plate Counts of bacteria such as Escherichia coli, E. coli 0157, Staphylococcus aureus, Vibrio cholerae, Salmonella, Listeria monocytogenes, Vibrio parahaemolyticus, Campylobacter spp., Clostridium spp. and Bacillus cereus. Out of these Total Plate Count (TPC), E. coli and Staphylococcus aureus counts are considered quality defects and classified as indicator organisms as their presence above the tolerance limit is indicative of either spoilage or contamination from unhygienic workers or unclean contact surfaces. Other listed organisms and the parasitic worms, Anisakis etc. are considered hazards and shall be absent in all food items.

- TPC: It will be interesting for you to know that Total Plate Count (also known as Total Bacterial Count, Total Viable Count, Heterotrophic Plate Count or Aerobic Plate Count) is a count of viable bacteria per gram of the Food Safety Hazards food based on counting of the colonies that develop on agar plate. This is commonly considered as an index of bacterial spoilage. The normal incubation period for determination of TPC is 48 hours at 30°C and the tolerance limit for TPC vary with the type of food and range from 10^3 to 10^7 cfu/g.

- E. coli: E. coli is a fecal indicator organism. You should understand that the presence of E. coli in food generally indicates direct or indirect contamination with fecal matter from human or animal origin. The tolerance limit for E. coli for different food items can vary from zero to <100 cfu/g for raw food and <10 cfu/g for cooked and ready-to-eat foods. The presence of E. coli above the tolerance limit is a sure indication of poor cleanliness of food contact surfaces and/or poor hygiene of food handlers. The presence of organisms like total coliforms, faecal coliforms, faecal streptococci, is also indicative of faecal contamination.
- Staphylococcus aureus: S. aureus is simultaneously an indicator organism as well as a food poisoning organism. S. aureus has its origin from oral secretions and skin of human beings and animals. Their presence in above tolerance limit suggests poor hygiene of workers, which lead to the occurrence of this toxigenic organism in food contact surfaces, as well as food materials. However, for toxin production and food poisoning, the S. aureus count shall be of the order of 10^5 or more organisms per g. of the food.
- Specific pathogens: The other species of bacteria indicated under biological hazards can be generally called as specific pathogens which are involved in food poisoning. They can cause public health problems either by production of toxin or by actual infection through the intestines of the consumers. The symptoms of food poisoning vary from nausea and vomiting (typical of staphylococcus aureus) and diarrhea and dehydration (Salmonella and Campylobacter) or a combination of vomiting and diarrhea (Vibrio cholerae) or paralysis, respiratory failure and death in extreme cases of botulism (Clostridium species). The infectious doses of the specific pathogens vary from a few organisms to 10^6 organisms/g. All these pathogens as far as possible shall be absent in raw as well as cooked products.

The ready-to-eat items can be raw (in certain cases), preserved or thermal processed. Depending on the type of processing, the tolerance for microbiological parameters, particularly TPC, E. coli and S. aureus, will be varying. These three parameters will give us a fairly good idea about the freshness of the food; extend of faecal contamination as well as the hygiene and sanitation of the food contact surfaces and food handlers involved in the processing and production of the food items.

Food borne sicknesses are resulting from the ingestion of ingredients containing toxic or infectious agents. In India, the sicknesses transmitted by means of food are commonly called food poisoning. Food poisoning, in different words, is the term used to refer to the damaging outcomes of eating food infected by means of microorganisms. Food borne disease outbreaks inside the network are of not unusual occurrence, both within the developed and developing countries. A meal borne disorder outbreak is defined as an incident in which two or greater persons revel in a similar illness, usually, gastrointestinal, after the ingestion of a common food which is recognized because the supply of food borne illness. More than 250 extraordinary food borne diseases had been described. Most of these sicknesses are infections, resulting from lots of microorganism, viruses and parasites that can be food borne. Other sicknesses are poisonings, due to harmful pollution or chemical substances that have contaminated the food, for instance, poisonous mushrooms. Certain molds also produce pollution, known as mycotoxins, within the food they attack. All these can lead to illness. Food borne sickness has been termed because the most full-size health problem within the present day international and a crucial motive of reduced financial prosperity.

6.3.2 Types of Food Borne Diseases

Food borne sicknesses or food poisoning is a condition as a result of consuming infected food. The ailment-inflicting culprits are the microorganisms or pathogens inclusive of fungi, microorganism, parasite or virus. On the opposite hand, a few pathogens produce toxins in food which whilst fed on can cause infection. Sometimes, pathogens may be found in food, which whilst fed on, may additionally produce a toxin within the gut or invade and ruin the healthful tissues. Accordingly, food borne diseases are categorized into 3 categories:

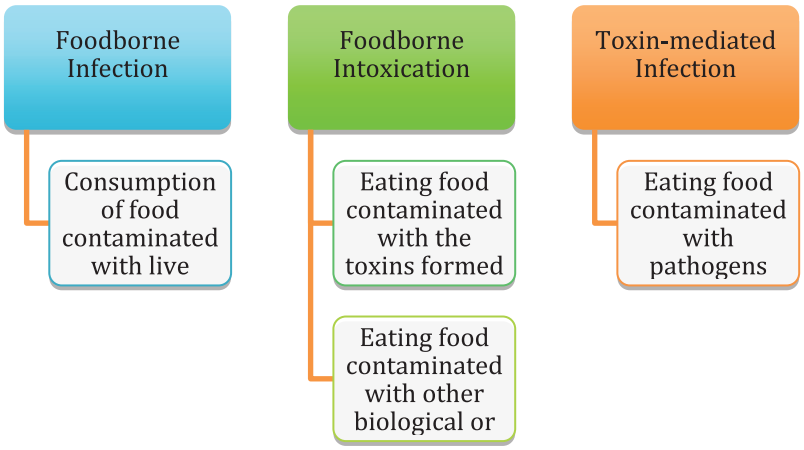

Fig. 6.3.1: Types of Foodborne Illness

Foodborne infection is caused by the ingestion of food containing live microorganism which grow and establish themselves inside the human intestinal tract. Salmonellosis, caused by the microorganism salmonella. Foodborne intoxication is as a result of eating food containing pollutants formed through bacteria which resulted from the bacterial growth in the food item. The stay microorganism does now not need to be fed on. Staphylococcus aureus food borne disease is an instance of contamination that consequences from the intake of toxins in food. Food borne poisonous infections are caused by the ingestion of a huge wide variety of enterotoxigenic strains of bacteria which, while multiplying in the gut produce and launch enterotoxins inside the intestines.

Preventing Food Poisoning and Food Infection

Food protection concerns every food managing facility. Each year, thousands of people go through the soreness and pain attributable to foodborne contamination. To save you such ailments, information the bacteria that purpose food poisoning is essential. The time period food poisoning is commonly used to describe infection because of all types of foodborne microorganisms. Food poisoning and food infection are unique, although the signs and symptoms are similar. True food poisoning or food intoxication is because of ingesting food that incorporates a toxin or poison because of bacterial growth in food. The bacteria which produced and excreted the poisonous waste products into the food can be killed, however the toxin they produced reasons the contamination or digestive disenchanted to occur. Staphylococcus aureus and Clostridium botulinum are two species of microorganism that reason food poisoning. Food contamination is the second kind of foodborne infection. It is because of consuming food that incorporates certain varieties of stay microorganism that are present within the food. Once the food is eating up, the bacterial cells themselves keep growing and infection can result. Salmonellosis is a superb instance of foodborne infection. Vibrio parahaemolyticus is another contamination organism and is discovered usually in shellfish from polluted waters. Clostridium perfringens grows in warm food like beef stews or gravies and produces toxins. It also causes a food infection via continuing to develop and producing toxins within the intestinal track. Each of those forms of food- borne illnesses may be discussed.

6.3.3 Food Poisoning Microorganisms

Staphylococcus aureus

Staphylococcus is a real food poisoning organism. The coccus, or round-shaped, organism appears in grape- like clusters when viewed below a microscope. It produces a heat solid toxin whilst allowed to grow for several hours in ingredients such as hen pot pie or cream filling. This bacterial growth may not motive any off color, odor, or textural or flavor change, but the toxin may be secreted into the food.

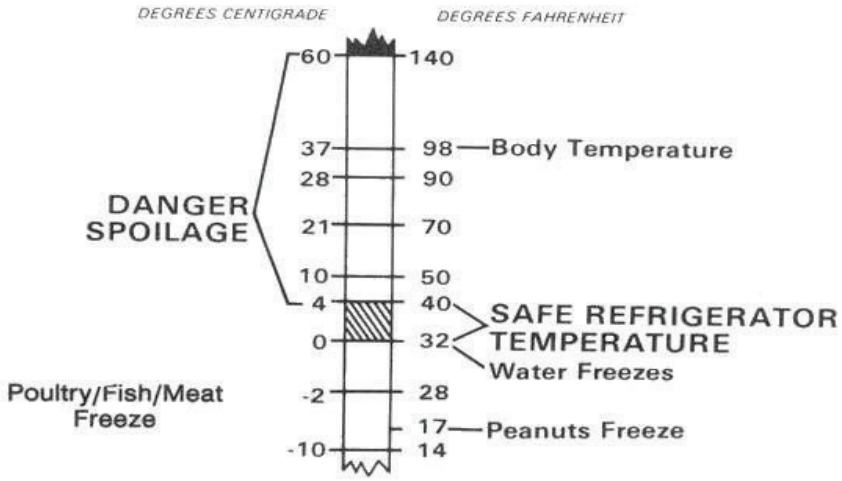

Fig. 6.3.2: The Temperature Line

Staphylococcus toxin isn't markedly suffering from heating or freezing as its heat stable. Even if the food is heated before eating, the poison within the food will cause illness despite the fact that the heat has killed the bacterial cells. The principal sources of staph infection are people and domestic animals. It is generally determined inside the nasal passages and on the pores and skin of most people. Staphylococcus microorganism may be located in cuts, scratches, boils and zits on the skin. These bacteria get into the food from cuts and sores on workers' arms or from sneezes at some point of food training. This organism grows great at frame temperature (98 degrees Fahrenheit), but it may grow over the much wider range of 50 degrees to one 115 degrees Fahrenheit. It prefers food with a pH above 4.5, so it's miles seldom discovered in acid foods consisting of tomatoes, pickles and citrus juices.

Symptoms of Staphylococcus Food Poisoning

The signs produced by way of the staph toxin occur very swiftly, four to six hours after eating. These consist of headache, nausea, vomiting, belly cramps, diarrhea and a standard washed out feeling. Many humans suffer from staph food poisoning and never file it or don't comprehend they have got it. Although a massive number of instances arise yearly, simplest a fraction of them is diagnosed as being resulting from staph bacteria.

Prevention

The best prevention of Staphylococcus food poisoning is to nicely shop food and reduce the temperature underneath 40 degrees Fahrenheit within four hours after preparation or serving. In order for staph to develop and convey toxin, it has to have enough time. Approximately to 4 hours, relying upon conditions, are required at a suitable growth temperature for toxin manufacturing. Therefore, it's far crucial to chill or heat foods via the threat area of 40 Degrees F to a 140-degree Fahrenheit as rapidly as possible. A second manner to save you infection by means of staph organisms is by using preserving cuts or sores included and avoiding hand contact with cooked food. Workers' palms are essential assets of infection.

Good personal hygiene and exact washing conduct are crucial in preventing contamination. Refer module 2 for more details.

Clostridium botulinum

The other sort of proper food poisoning is botulism. This organism has acquired a good deal exposure and rightly so. It does no longer just motive illness, it's far deadly in 60 percent of the instances. It is found in the soil, in water, in sewage and inside the intestines of people and animals. This organism cannot develop within the presence of oxygen and thus is called an anaerobe. Clostridium botulinum is a rod-formed organism that forms a warmness resistant spore.

You can kill the vegetative cells through heating or cooking, but the spores require 240 degrees Fahrenheit at sea level, or stress canning, to kill them. These spores are just like seed. When they're located in a dry region or underneath destructive situations, they'll not germinate. They can withstand long intervals of dry conditions a can resist boiling water for several hours. Once those spores are located in a food with the right temperature, moisture and coffee acid conditions and absence of oxygen, they'll germinate and grow. Once the bacterial cells are produced, they are able to then grow and feature the functionality of producing toxin. It is for this reason stress canning is the only safe technique for canning low acid foods.

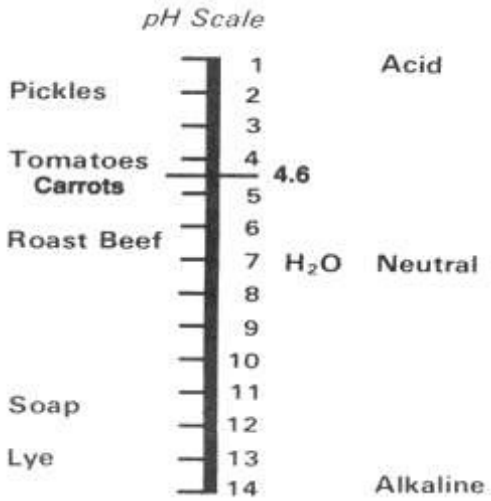

Fig. 6.3.3: pH scale

The key to the boom of Clostridium botulinum and manufacturing of its toxin is the pH of the canned food. All fruits, veggies and meats carry this microorganism, but because of their acid nature (pH of 4.6 or below), end result will now not permit its increase. Meats and maximum vegetables are not acid ingredients and will support its increase. They have a pH above 4.6. This microorganism does now not necessarily produce unfavorable affects within the food in the course of increase. For example, the toxin may be present and there can be no swelling, off-coloration or off-odor.

In order for toxin to develop, the temperature during canning need to be inadequate to kill the spores. This organism produces at least seven known toxins. Types A, B and E are most typically associated with human illness. Toxins are produced best at temperatures between 85 degrees Fahrenheit and 95 degrees Fahrenheit, but had been proven to be produced from 38 degrees Fahrenheit to 118 degrees Fahrenheit.

Symptoms of Botulism

In a number of the instances, death is the very last result of a botulism outbreak. Specific signs and symptoms may include fatigue, dizziness, headache, vomiting, diarrhea, nausea, acute indigestion observed with the aid of constipation, double imaginative and prescient and issue swallowing or speaking. Throat constriction and muscle paralysis come inside the final stages, accompanied by means of demise because of suffocation, except an antitoxin is run promptly.

Prevention

About 10 to 20 cases of botulism occur each year in the United States. The principal supply of the trouble is domestic canned foods which have no longer been properly processed. Remember, always test home stress canners to make sure the dial is accurate. Always use an approved processing time and temperature when home canning food. Extension publications are to be had with the most updated recommendations.

6.3.4 Food Infection Microorganisms

1. **Salmonellae**

   Over 1200 types of Salmonella exist. All are doubtlessly dangerous to people. Salmonella live in the intestinal tracts of humans and animals and are usually exceeded from individual to animal, animal to character, and person to man or woman in a continuous cycle. The top resources of Salmonella contaminants of our food deliver come from the intestines of animals. Vermin along with rodents, roaches and flies also convey Salmonella.

   Salmonellosis has passed off from the consumption of infected food together with cheese, milk, eggs, meat, poultry, pastries, desserts and candies. Salmonellosis is prompted when we consume foods which comprise the organism. This is a food contamination. These organisms keep growing and multiply within the small intestines. The end result is illness 8 to 24 hours after we consume the contaminated food.

   Salmonellosis is the maximum big of all foodborne illness. More than 20,000 instances are suggested to the Center for Disease Control annually. This is probably best a small percentage of the cases that arise every year.

   Symptoms of Salmonellosis

   Salmonellosis is characterized by means of an abrupt onset of diarrhea, nausea, stomach pain, prostration, chills, fever and vomiting. These symptoms vary in depth from slight to severe. The signs rarely reason death except to babies or the aged who can also dehydrate hastily.

   Prevention

   Salmonellosis can without problems be prevented. Cooking kills this organism. Sickness most usually occurs due to infection of the food after cooking. Salmonella can effortlessly be controlled through accurate sanitation practices to prevent cross contamination. Cooked food has to by no means be prepared on reducing boards or gadget that has been used to put together raw products.

   Since food infection type bacteria are killed with the aid of cooking, ingredients including meat, rooster and eggs ought to be accurately cooked to prevent feasible ingestion of the organism. Prompt refrigeration of cooked foods or leftovers is the primary line of defense towards this meal's infection organism. Never store food in boxes that will not permit fast cooling of the food product.

Use shallow pans no longer extra than 3 inches deep. If massive quantities must be chilled, use commercial heat exchangers to relax product or agitate the nutrition in an ice water bath till the product is chilled below the hazard quarter of speedy bacterial boom.

2. Clostridium perfringens

Clostridium perfringens food poisoning has often been tagged as a trouble of the food carrier industry since maximum outbreaks are related to mass feeding operations which includes cafeterias or at banquets. Each year, a huge variety of outbreaks of food poisoning from Clostridium perfringens arise in domestic kitchens and fast-food establishments, specifically those serving gravy, meat stews or broths. Clostridium perfringens, a soil and water organism, is like C. Botulinum in that it's miles a spore former, it isn't killed via boiling, and its miles an anaerobe. This approach that it grows first-class when there is no air or free oxygen present in its environment. This organism also has strict requirements for growth; thus, it is normally related to meats, gravies or meat dishes. This organism is somewhat extraordinary from other food poisoning bacteria as it produces a toxin and additionally causes a food infection by way of continuing to grow and bring toxin inside the digestive device after it's far consumed.

Symptoms

The signs and symptoms for this food poisoning are relatively moderate in maximum instances and can be known as a “belly virus” and cross unreported. If the outbreak takes place at a large gathering, however, including a ceremonial dinner or church function, it is also reported and documented.

Symptoms of the infection consist of belly cramps, diarrhea, occasional nausea, and once in a while fever or vomiting. The signs typically appear 4 to 22 hours after ingesting and might persist for one to 5 days.

Prevention

Many foods such as meat and hen can also deliver the organism, but the mere presence of C. Perfringens in food isn't enough to reason infection. Millions of growing cells are needed. The prevention of increase of this organism is excellent carried out via following the standard food service practices of rapidly chilling organized food in shallow boxes and retaining cold food cold and hot food hot. Remember, continually lessen the extent of contamination by way of preserving all paintings areas easy and sanitary.

3. Vibrio parahaemolyticus

Vibrio parahaemolyticus is a selected food contamination organism no longer familiar to many people; it nonetheless is a crucial problem. This organism is mostly associated with shellfish or different fish coming from contaminated or polluted marine waters. Vibrio parahaemolyticus is a comma-fashioned organism which grows at decrease temperatures, 50 degrees, as nicely as better temperatures. It is likewise a halophilic organism and is bale to grow properly in salt water.

Symptoms

Large numbers are required to motive contamination. Abdominal cramps, nausea and vomiting may additionally result.

Prevention

The important prevention of this foodborne illness stems from the banning of infected waters to fishermen. However, the quality assurance for a food service establishment to save you Vibrio food poisoning is to keep shell- fish nicely refrigerated to prevent increase. Always make certain the shellfish are thoroughly cooked. Since many fish, such as oysters, are eaten uncooked, the restaurant can buy from reputable resources coming from acknowledged waters.

4. Escherichia coli O157:H7

Escherichia coli O157:H7 and different verotoxin producing lines of E. Coli are pathogenic bacteria determined in uncooked meat, milk and different food merchandise which may have grown to be contaminated with this fecal organism. E. Coli O157:H7 has come to be a first-rate challenge because it's far resistant to common food acids consisting of vinegar and lactic acid. That permits E. Coli O157:H7 to live to tell the tale in acidic food like dry fermented sausage, apple cider, yogurt, and mayonnaise-based totally salad dressings. This organism can purpose infections at very low levels of infection, with best 2-5 microorganisms consistent with gram of food. Children and elderly men and women are most susceptible.

Symptoms

Severe stomach cramps are accompanied by way of watery, then grossly bloody diarrhea. Onset of the infection is three to three days, with a duration of two to nine days. Vomiting is not unusual, but fever is rare. Hemolytic uremic syndrome (HUS), characterized via kidney disorder and acute renal failure, is not unusual in children. Neurological disorders also are because of blood clots in the brain. The infection is sometimes fatal.

Prevention

Thorough cooking of ingredients, preventing cross contamination of cooked ingredients, and top production practices throughout slaughter and processing to save you initial contamination are the quality means to prevent E. Coli O157:H7 food poisoning. For acidic foods, several steps which build “microbial hurdles” and prevent contamination and increase are needed. Cook all ground red meat products to the nicely-done stage (165 degrees Fahrenheit).

5. Trichinella spiralis

No food poisoning and food contamination file would be entire unless we cowl the fundamentals for controlling the ancient Trichinella spiralis. Trichinosis is an extremely painful disorder and is among the maximum dreaded human illnesses. The microscopic parasite resides inside the muscle of infected pork or in other animals which consume flesh. Although it is not a bacterial food infection, it is an important foodborne illness.

Symptoms

Humans contract the illness by consuming improperly cooked infected meat. During the duration when the worms burrow into the intestinal walls and lay eggs, human signs and symptoms are nausea, vomiting and diarrhea. When the larvae encyst inside the muscle, the signs are excessive muscular pain, edema, enlarged lymph nodes and chronic fever.

The maximum critical segment of illness comes when the larvae grow and begin to coil. Edema, toxemia and dehydration arise. Death may additionally follow. The sickness lasts from to eight weeks after which the larvae cysts calcify and stay dormant in the muscle.

Prevention

Cooking the food breaks the cycle. Prevention is easy. Cook all red meat to a temperature of a 160 degrees Fahrenheit (medium) to 170 degrees Fahrenheit (properly finished). For micro-wave cooking of fresh red meat, touch your county extension agent for instructions. Because of possible bloodless spots that can arise during microwave cooking, instructions vary for each cut of meat.

Summary

To prevent foodborne contamination, observe these suggestions:

- Limit the creation of microorganisms into the food by way of washing and sanitizing your fingers before managing food; wash all uncooked food, easy and sanitize all food equipment, utensils and call surfaces.
- Destroy the microorganisms which have contaminated the food by properly cooking the ingredients, reheating the food rapidly above 140 degrees Fahrenheit and maintaining all hot foods above 140 degrees Fahrenheit
- Limit the boom of microorganisms by way of right away refrigerating leftovers, rapidly chilling hot food with the aid of using shallow containers, and checking your refrigeration to insure proper temperature control.
- When in doubt, throw it out.

UNIT 6.4: Environmental Monitoring in Food Processing Units

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the process of monitoring premises of the food processing unit, processing machineries, drainage system to ensure it meets food hygiene standards of the processing unit
2. Explain the process of monitoring storage area for raw materials, packaging materials, finished goods to ensure quality standards are met and food products are fit for human consumption

6.4.1 Introduction

Environmental monitoring (EM) is a planned categorization of samplings, observations, and measurements used to gauge the effectiveness of microbiological agents in food processing facilities. EM is a key prerequisite program (PRP) that regulates whether or not cleaning and sanitation procedures and frequencies are effective. The scope of EM covers all areas of a facility. As a PRP, EM supports the execution of food safety management systems such as HACCP, HARPC, and others.

Environmental monitoring is a technique used in facilities that produce ready-to-eat (RTE) foods that assesses how effectively the plant is being cleaned. This typically means swabbing various surfaces (e.g., cutting blades, tables, conveyers) for pathogens and transferring those samples out to a lab for analysis. The goal is to govern whether any pathogens (e.g., listeria, salmonella) are living in facility and to take appropriate actions if a positive result is found.

It's important to identify that a clean test result doesn't confirm that your food is safe, rather it verifies that your cleaning processes are effective. GFSI (Global Food Safety Initiative) aligned 3rd party audits typically need environmental monitoring programs to be in place for producers of ready-to-eat food that are exposed to the environment post-kill step.

Relevance

Microorganisms are generally familiarized into the food processing environment through raw materials, pests, water and air supply, cross-contamination with external sources, and workers. Pathogenic microorganisms, such as Escherichia coli O157:H7, Listeria monocytogenes, and Salmonella spp., are common contaminants found in food processing environments.

Despite advances in food safety, foodborne illness outbreaks remain common occurrences around the globe. Foodborne illnesses affect millions of people and cause thousands of fatalities every year. A substantial number of these occurrences result from poor environmental controls and/or hygiene practices.

Environmental Monitoring (EM) is a chief program for food plants, especially those that handle microbiologically sensitive foods. With the fresh regulatory focus on detecting and controlling food hazards, maximum food facilities are establishing and improving their environmental monitoring programs.

Easiest way to determine whether you need an environmental monitoring program is to answer the following questions (a "yes" would suggest that you may need one)

- Does your process have a kill-step (e.g., cooking)?
- Is your product exposed to the environment after the kill step and before packaging?

- Is your product a collection of ready-to-eat products combined to produce a ready-to-eat food that doesn't include a kill-step?
- If your product is refrigerated, is it one that is conducive to the growth of listeria monocytogenes (e.g., deli meat, raw cheese/milk, seafood, sprouts)

Because ready-to-eat foods are naturally not processed by the consumer before consumption, it's significant to know that there's not any chance they might be contaminated with pathogens in an unclean facility.

While testing the product itself can may inform you about the safety of that sample, testing the facility verifies that your cleaning activities are working and that each batch is being produced in a pathogen-free environment.

If you've already established that you should have an environmental monitoring program, consider the following queries before diving into a plan:

- Do you have an exhaustive sanitation program? Your environmental monitoring program is a test of your cleaning, so if you have doubts about the thoroughness of your sanitation practices, address those first.
- Do you have the resources to enact it loyally? Once you launch your program, it's important to follow it. If you doubt your ability to adhere to the program you've created or respond appropriately to a test result, then you should address those gaps prior to implementing the program.

6.4.2 Regulatory compliance

Preventive controls identified in the hazard evaluation phase need appropriate verification activities. This includes environmental monitoring to verify efficiency of those controls for pathogens or appropriate indicator organisms.

Under 21 code of federal regulations (CFR) Part 117 Subpart C Section 130 (2), the EM evaluation must consider the following issues, which affect food safety for the intended consumer:

- Food formulation
- Condition, function, and design of the facility and equipment
- Raw materials and other ingredients
- Transportation practices
- Manufacturing/processing procedures
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene
- Temporal (e.g., weather-related) factors that can affect the nature of some hazards (e.g., level of toxins)

6.4.3 Application and scope of EM

What should be tested?

There are three categories of organisms that can be included in EM:

Pathogens: It is important to test for the pathogens of relevance to your type of operation, e.g., Listeria monocytogenes, Salmonella, E. coli, Campylobacter, Staphylococcus aureus, Bacillus cereus, etc. The test for pathogens simply reveals whether they are present or absent; enumeration is not necessary.

Spoilage organisms: Yeast and mold are the most concerning spoilage organisms that food facilities must take care of environmental monitoring programs. The most common molds are Aspergillus, Fusarium, Penicillium, and Alternaria. Air and surface testing are equally important in recognizing the presence of these organisms.

Indicator organisms: These are a basic monitoring tool used to measure the potential presence of hard-to-detect pathogenic organisms, e.g., Coliforms, Enterobacteriaceae, and Aerobic Plate Count (APC).

Where should you test?

Zone 1 (Direct product-contact surfaces)	**Zone 2** (Nonfood-contact areas closely adjacent to Zone 1)	**Zone 3** (Non food-contact surfaces that are not close to Zone 1)	**Zone 4** (Areas remote from the product processing areas)
•Processing equipment (*e.g.*, mixers, ovens); utensils, work tables, conveyors, storage silos, and bulk containers	•Equipment framework, aprons, tables, maintenance tools, housings, ancillary equipment (*e.g.*, compressors, heat exchangers, pumps)	•Walls, ceilings, floors, drains, sinks, handling units (*e.g.*, forklifts)	•Office areas, locker rooms, warehousing, sanitation wash rooms, overhead doors, racks

- Little or no testing should be done in Zone 1. If pathogens are found in Zone 1, it is likely a recall condition and it is too late.
- Sampling should focus on high-risk areas, such as Zone 2, which has greater access to the product, and areas with wet and warm conditions that encourage bacterial growth.
- If Zone 4 areas are not maintained in good hygienic condition, this can lead to cross-contamination of other zones.

How can you accomplish this?

- It is valuable for food facilities to have a microbiologist on staff. Such a person may contribute a major science background and/or prior experience in environmental monitoring.
- Sampling swabs and sponges, air-sampling devices, and ATP bioluminescence assay kits are some options available that are vital for a correct site sampling.
- Mapping of all sampling locations should identify each area, and the specific zones within each area, that will be tested. This can be an effective way to identify hot spots that require appropriate corrective actions.
- Mapping locations of conforming (negative) results, increasing trends, and non-conforming (positive) samples/results on a facility design diagram can help define the scope of the problem.

6.4.4 Steps to build an Environmental Monitoring Program (EMP)

- Create the EMP team
- Apply the 4-Zone concept
- Define microbiological indicators
- Set sampling frequencies
- Set appropriate labeling and shipping procedures for swab samples for in-house analysis and external laboratory analysis
- Establish a result baseline/target
- Test surfaces
- Implement corrective action for nonconforming results
- Verify written EM procedures
- Keep records

You may test for these directly or indicator microorganisms that signify each pathogen. Additionally, you can conduct environmental monitoring for specific allergens to check that there is no allergen residue in your area. Environmental monitoring program stereotypically includes the following components:

- A risk assessment of the hazards you've identified: Looking at your elements and the nature of your operation, you should be able to recognize the specific pathogens that may exist in the environment. You may have started this in your hazard analysis.
- Your methodology
    - A map of your facility separated into hygienic zones (e.g., Zone 1 is the maximum risk part of the production process and Zone 4 is the office)
    - A process for exactly collecting your samples
    - A description of frequency of your environmental monitoring
    - A description of where you will swab. These should be the highest risk areas where bacteria may be hiding and could get into your product.
    - A description of test analysis process (most likely by an external party, but it also may be in an in-house lab). You must list the specific lab conducting the analysis and confirm they're accredited properly.
- Corrective Action procedures, i.e., response if you receive a positive result. The occurrence of environmental monitoring is determined by your process and the hazards you identified in your hazard analysis.

Raw Foods Example: Let's say your facility produces snack packages of raw carrots and ranch dressing. Since the product will be consumed raw, you'll want to have extremely high standards of hygiene in your space. After conducting preliminary, pre-operation environmental monitoring, you may choose to conduct monitoring activities weekly in high-risk zones (e.g., blades, conveyers, tables) and monthly in lower risk zones (walls, floors, drains). Ultimately, the decision of "how often" is up to you — you simply have to be able to justify that your frequency of sampling and testing is sufficient to determine that your sanitation efforts are effective. Still not sure? Consider exploring industry standards for environmental monitoring in plants producing products similar to yours. Start with that and then you can use historical data from your own site once your program is operative. You may only have to conduct environmental monitoring one time, such as when you move into a new facility and after you've completed a deep clean. This result would just be to confirm that you're starting with a clean, pathogen-free space.

If you get a positive result in your environmental monitoring you will endorse the corrective actions you've outlined in your plan. Depending on the type of result received, this may include re-cleaning, re-testing, holding product, and possibly a product recall

SOP for EM testing can be referred from module No. 5

Exercise

1. **What is TPC?**

_____

_____

_____

2. **Name one of the poisoning organisms?**

_____

_____

_____

3. **Name the three specific pathogens?**

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4. **Enlist the role and responsibility of food authority and audit agency.**

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5. **Explain the audit principles.**

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6. **What are the requirements of an audit team?**

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7. **What is the purpose of opening meeting?**

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8. **Define:**

(I) Food business

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(ii) Food safety audit

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_____

(iii) Risk assessment

_____

_____

(iv) Hazard Analysis and Critical Control Points or HACCP

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_____

(v) Microbiological Hazards

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_____

(vi) Foodborne Intoxication

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_____

(vii) Foodborne Infection

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9. **Describe environmental testing zones.**

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10. **Illustrate the steps to build an EM program.**

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7. Documentation and Record Keeping of Microbiological Analysis

FICSI
Food Industry Capacity and Skill Initiative

Unit 7.1 - Quality Assurance (QA) Programme for Food Microbiology Laboratory

Unit 7.2 - Documentation and Record Keeping Practcies in HACCP System

Unit 7.3 - Inventory Management

Unit 7.4 - Enterprise Resource Planning (ERP)

FIC/N7612

Key Learning Outcomes

At the end of this module, you will be able to:

1. Describe the entire documentation system followed in the organization.
2. Explain the need for documenting and maintaining records of purchase of: raw materials and packaging materials and machineries.
3. State the method of documenting and recording the details of materials to final purchase to inventory management

UNIT 7.1: Quality Assurance (QA) Programme for Food Microbiology Laboratory

Unit Objectives

At the end of this unit, you will be able to:

1. Describe the entire quality assurance procedure and documentation system followed in the food laboratory.

7.1.1 General Principles

The QA Programme for a laboratory covers all the policies and activities, which can affect the quality of its output[30].

Definition and Scope

A QA Programme maybe defined as a mechanism used to ensure that the data are fully reliable, suitable for the intended purpose, presented on time and at an acceptable cost. It is a formal, planned activity whose purpose is to provide assurance that the quality control Programme is actually affected and is designed to fit the needs of the laboratory.

The scope of the quality assurance system has to be developed in such a way that there is confidence that whenever data are reported.

- the identity and integrity has not been compromised;
- the analysis has been conducted by member of the staff who is competent for the task;
- the equipment and the methods are appropriate and are working properly;
- the laboratory can demonstrate its current capability to produce valid data.

The format adopted in meeting these requirements may vary from laboratory to laboratory.

Each laboratory (or group of laboratories) meets different requirements, operates within a different organizational environment, experiences different constraints and should have a QA Programme, which takes account of these factors.

There are certain factors, which are common

1. The use of validated methods;
2. The use of Standard Operating Procedure (SOP) in the laboratory;
3. Calibration and traceability of measurement (including use of certified reference material);
4. External assessment of performance.

[30] FSSAI Guidelines. "Good Food Laboratory Practices (GFLP's). (https://old.fssai.gov.in/Portals/0/Pdf/GFLP_Document_06_09_2016.pdf)

While facilities exist for accreditation of laboratories for particular types of work, it is usual to find requirements for these features within this scope of accreditation process along with the requirements for topics which may include organization and management, laboratory accommodation and environment, equipment maintenance, handling of test materials, test methods and quality control procedures (and method performance characteristics), staff training and performance, security, records and reports, sub-contracting of work , outside support services , handling of complaints , quality audit and system review.

Preparation

QA Programme is concerned with everything that goes on in the laboratory, which may affect "Quality". Each member of the staff involved in the QA Programme must be

- clear about what they are expected to do;
- know how to do it and
- be able to show that they had done it properly.

Documentation is a major feature of QA Programme. Formulation of a QA Programme should contain three essential components

- Prevention, which requires an orderly Programme of planning and positive actions before or during analysis to ensure that all analytical systems are performing appropriately, easy calibration and maintenance of instruments use of reference materials and training.
- Assessment, a form of control that includes periodic checks on the analyst performance e.g., analysis of check samples and validation of methodology.
- Correction, an action taken to determine cause (s) of quality defects and to re-establish proper functioning of analytical operations e.g., troubleshooting to correct malfunctioning equipment, re-evaluation of methodology and re-training.

To prepare a quality assurance Programme, one must consider the various elements of the Programme.

- Statement of objectives
- Policy statements
- Organization
- Quality planning
- Standard operating procedures
- Recordkeeping
- Chain of custody procedures
- Corrective action
- Quality training
- Document control
- Calibration of instruments
- Preventive maintenance
- Reagent and reference standards
- Procurement and control
- Sample identification and control
- Laboratory analysis and control
- Inter-laboratory and intra-laboratory testing Programme

- Handling, storage, and delivery of samples
- Statistical quality control
- Data validation
- System audits Element (e), above, is termed Standard Operating Procedure (SOP).

A Standard Operating Procedure may be considered a document describing any procedure which is not a method of analysis. It may describe an administrative routine, a non-analytical laboratory procedure such as starting up an instrument, or any other procedure used in the laboratory. An SOP will normally describe an activity in sufficient detail to enable it to be performed without supervision and in some cases without training. A method of analysis can be written in SOP format but is best regarded as a different type of document. Quality assurance covers all the working activities in the laboratory, not just analysis. All these activities are controlled and can only be controlled if there is a written record of them (or perhaps a computer record, but in that case a hard copy will normally be kept). That written record is the Standard Operating Procedure.

External Proficiency Testing:

Proficiency testing is the part of QA Programme, which looks at the accuracy (correctness') of the results actually being reported by the laboratory on real test materials. An independent external assessment of the correctness of the typical result provides an impartial test of analytical quality: this is done by proficiency testing scheme, i.e., methods of checking laboratory testing performance by means of inter laboratory tests. This includes comparison of a laboratory 's results at intervals with those of other laboratories. Procedures used when analyzing test materials for such a scheme are those normally used by the laboratory. The proficiency testing is likely to grow in importance because of regional and international developments which require laboratory data to be mutually acceptable between nations for many regulatory purposes.

A harmonized protocol for the proficiency testing of the chemical laboratories has been prepared by joint International Organization for standardization (ISO) / Association of Official Agricultural Chemists (AOAC) International/ International Union of Pure and Applied Chemistry (IUPAC) Working Group (November 1992, ISO /REMCO, N263). This identifies and explains the major features recommended for proficiency testing scheme.

Internal Quality Control Checks

- **Blank Analysis:** Blanks are to be included in analytical methods. A blank is characterized as a sample included in the analytical processes, which has all the properties of the actual sample except that it does not contain the substance of interests.
- **Duplicate Analysis:** Duplicate sample analysis is the analysis of the same sample twice in order to determine the precision of the analysis.
- **Spike Analysis:** A sample is split into two sub samples in the laboratory. One is analyzed according to the specified procedure. The other is treated by adding a known amount and concentration of the indicator being measured, running this specified procedure. This should increase the concentration in the spiked sample relative to the original sample, by a predictable amount. Usually, 10 percent of the sample are split and spiked. They are used to test the accuracy of the laboratory method.

External Performance Evaluation

In order to verify that a laboratory possesses the capability to provide accurate and reliable test data in its day-to-day operations and to maintain high standards of performance, a competent, disinterested third party is necessary to evaluate laboratories based on personnel, physical facility, instrumentation and quality assurance / quality control Programme, and the laboratory's performance. For this purpose, an organization should participate in inter laboratory comparisons of the proficiency testing programs.

QA Manual

Each laboratory with a QA Programme should have a manual that documents the operations of the laboratory. A typical manual might consist of the following:

- Title page with signatures of all approving officials and date of issue;
- Table of contents;
- Organizational structure and exactly where the laboratory fits into this structure;
- Objective of the quality assurance Programme;
- Essential elements of the QA Programme;
- Documentation forms g. Performance and frequency of Audit;
- Corrective and follow-up action.

A Statement of the QA Policy both general and specific is needed in the QA Manual; the objective of the laboratory should be clearly defined. The principal objective of the laboratory, for example, is to produce reliable results.

Implementation

Actual implementation of the QA Programme is a co-operative effort of the management, and member of QA unit, section leaders and analyst. Management decides the number of resources to be allocated to the QA Programme. This decision determines the nature and the size of the QA unit. In formulating the QA Programme, this unit receives technical input from the analyst. Once formulated by the QA Unit and approved by the management the QA Programme is ready for introduction.

Analysts are responsible for day-to-day maintenance of the Programme. The QA Unit periodically monitors this adherence and makes its report and recommendations to the management, which then decides on the action to be taken so as to achieve compliance with the Programme.

Revision of the QA Manual

The QA Manual must be designed so that the change is easily accommodated. It is essential that organizational pattern emerge, workload shifts and methodology develops. The QA Manual can react rapidly to these changes in the work of the laboratory.

Documentation Required or the QA Programme:

- Analyst Worksheet
- Laboratory Report
- Procedures for checking of results
- Procedures for authorization of report
- Period for retention of documents
- Procedures for archiving and disposal of documents

7.1.2 Laboratory Records

General Principles[31]:

All the information that has any particular relevance to the materials and the analysis performed on them must be documented in a systematic fashion at any point in its passage though the laboratory. Records must allow a test material to be traced back to its arrival and any information that arrive with it. Records should be such that if the need for reanalysis arises, it could be done under the same conditions and in the same way as before. Records must be retained and protected from misuse, loss or deterioration for an agreed time.

The Analyst's/ Microbiologist's Worksheets

The analyst worksheet provides a written account of the laboratory analytical results. Certain requirements apply to all worksheets.

1. All the basic information must be recorded directly on the worksheet before analysis has begun;
2. As soon as the worksheet is obtained it should be initiated;
3. All entries should be clearly legible and made in permanent ink;
4. No entries should be erased or over written if an incorrect entry is made. The analyst should draw a line through the incorrect entry; write above it the correct figure or word and then date and initial the corrected entry;
5. Data should not be discarded without explanation;
6. The exact analytical method should be referenced clearly and completely. If the method has not been published or is not covered by SOP it should be written in full on the worksheet or as an attachment to the worksheet;
7. If the analysis has been made in duplicate or triplicate etc. the result of each analysis as well as the summary of all result must be recorded;
8. If more than one analyst is involved in analysis the worksheet must indicate which analyst broke this seal and which analyst performed each segment of the analysis;
9. Any continuation sheets that accompany the analyst worksheets should be numbered in a consecutive series e.g., 1 of 8, 2 of 8, 8 of 8 pages;
10. Worksheets are check for accuracy, completeness and compatibility with other documents by the supervisor or the designated representative;
11. The date on which the analyst submitted the worksheet to the supervisor is indicated;
12. The exact method used is referenced. Any modification to the referenced method is stated and the reason for the modification is given;
13. All calculations are clearly shown with the proper number of significant figures used;
14. The use of controls and their results are specified.

[31] FSSAI Guidelines. "Good Food Laboratory Practices (GFLP's).
(https://old.fssai.gov.in/Portals/0/Pdf/GFLP_Document_06_09_2016.pdf)

Retention of Laboratory Record:

The sequence of records should form a continuity of documentation to produce a clear, accurate and in-disputable history of the test material with all aspects of documentation in agreement. All sample registers worksheets, reports and associated documents must be retained for a period, which is determined by the management in consultation with the customers and is documented. Storage of such material should follow the normal rules of archiving in terms of indexation, traceability, security, appropriate levels of protection against fraud and tampering, from fire, flood etc. Backup copies must be held of any records stored as electronic signal on magnetic media. This should be renewed at appropriate intervals. Dates and signature of individuals who withdraw and return documents in storage must be recorded.

The next unit will describe the documentation practices in HACCP system.

UNIT 7.2: Documentation and Record Keeping Practices in HACCP System

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the need for documenting and maintaining records of purchase of raw materials and packaging materials and machineries

7.2.1 Documentation and Record Keeping

A record displays the process history, the monitoring, the deviations, and the corrective actions (including disposition of product) that happened at the identified Critical Control Point (CCP). It may be in any form, e.g., processing chart, written and/or computerized record. The importance of records to the HACCP system cannot be overemphasized and is imperative that the producer maintain complete, current, properly filed, and accurate records. Four types of records should be kept as part of the HACCP program:

- Support documents for developing the HACCP plan.
- Records generated by the HACCP system.
- Documentation of methods and procedures used.
- Records of employee training programs.

Support Documents

The HACCP plan support documents consist of information and support data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. For example:

- Data used to establish the regulator measures to prevent microbiological growth.
- Data used to show the shelf life of the product (if age of the product can affect safety).
- Data used to establish the competence of critical limits in ensuring the safety of the product.

The HACCP plan support documents should also include a list of the HACCP team members and their responsibilities, as well as all the forms produced during the preparation of the HACCP plan, showing:

- Product description and intended use.
- Hazard analysis.
- Identification of CCPs.
- Identification of the critical limits for each CCP, as well as data from experimental studies or information collected to support the critical limits.
- Documented deviation and corrective action plans
- Planned verification activities and procedures.
- Identification of the preventive procedures for each hazard.

Records Generated by the HACCP System

HACCP system records demonstrate adherence of the HACCP system to the HACCP plan. These records are used to establish control at CCPs in the food process. The records created by the HACCP system include all activities and documentation required by the plan.

1. Monitoring Records for All CCPs

   All HACCP monitoring records should be reserved on forms that contain the following information:

   - Product identification (including product type, package size, processing line, and product code).
   - Critical limits.
   - Monitoring observation or measurement.
   - Operator's signature or initials.
   - Corrective action taken, where applicable.
   - Reviewer's signature or initials.

2. Deviation and Corrective Action Records
   - Identification of the deviant lot/product.
   - Number of affected products in the deviant lot.
   - Nature of the deviation.
   - Information on the disposition of the lot.
   - Description of the corrective action.

3. Verification/Validation Records
   - In-house on-site inspection.
   - Equipment testing and evaluation.
   - Accuracy and calibration of monitoring equipment.
   - Results of verification activities, including methods, date, individuals and/or organizations responsible, results or findings, and action taken.

Documentation of Methods and Procedures Used

The manufacturer should maintain records of the methods and measures used in the HACCP system.

- Description of the monitoring system for the critical limit of each CCP, including the methods and equipment used for monitoring, the frequency of monitoring, and the person performing the monitoring.
- Plans for remedial actions for critical limit violations or circumstances resulting in potential hazards.
- Description of record-keeping procedures, including copies of all record forms.
- Description of verification and authentication procedures.

Records of Employee Training Programs

Records should be kept of all employee trainings. This is of particular standing for employees involved in monitoring critical limits for CCPs and those involved with deviation review, corrective actions, and verification. These employees must be trained to fully understand the appropriate procedures/methods and actions to be taken regarding control of CCPs.

Special Notes

- The intent of the HACCP system is to focus control at CCPs. Redesign of the process should be considered if a hazard that must be controlled is identified but no CCPs are found.
- The HACCP application should be reviewed and necessary changes made if any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible when appropriate, given the context of the application, taking into account the nature and the size of the operation.
- Before application of HACCP to any sector of the food chain, that sector should be functioning conferring to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management declaration is essential for execution of an effective HACCP system.
- HACCP should be applied to each specific operation independently. CCPs known in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a unlike nature.
- During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, thought must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

UNIT 7.3: Inventory Management

Unit Objectives

At the end of this unit, you will be able to:

1. Apply the method of documenting and recording the details of materials to final purchase to inventory management

7.3.1 Introduction

Inventory Control System is the technique of managing stock so that you can meet customer call for at the bottom feasible value and with at the least investment. A correctly implemented stock manage software takes into account such things as buying goods commensurate with call for, seasonal variation, converting utilization patterns, and tracking for pilferage. A preliminary step within the system of stock manipulate is to determine the approximate costs of carrying stock. These charges consist of such fees as storage prices, stock risks, and the loss-of-opportunity prices related to tying up capital. Inventory management is an essential characteristic to help make certain the achievement of manufacturing and distribution companies. The effectiveness of stock management structures is without delay measurable through how successful an enterprise is in providing high ranges of purchaser service, low inventory funding, maximum throughput and low costs. The undertaking of productive inventory management is to help an upward trend in sales while keeping the investment at the bottom level consistent with ok patron service. Control of inventory, which normally represents 45% to 90% of all fees for enterprise, is needed to make sure that the business has the proper items accessible to avoid stock-outs, to prevent shrinkage (spoilage/theft), and to provide right accounting.

7.3.2 Basic Inventory Procedures

A key factor in effective kitchen management is inventory control. By understanding what elements are available at a given time, the manager will be able to plan food orders, calculate food charges since the previous stock, and make menu item adjustments if wanted. By maintaining an eye fixed on stock, it's miles feasible to observe potential issues with pilferage and waste.

Managing stock is like checking a financial institution account. Just as you are inquisitive about how much cash you have within the bank and whether that cash is paying you enough in interest, so the manager should be interested by the fee of the materials inside the storeroom and in the kitchen.

An inventory is everything this is located inside your establishment. Produce, dry stores, pots and pans, uniforms, liquor, linens, or whatever that fees cash to the commercial enterprise must depend as part of stock. Kitchen gadgets need to count one after the other from the front of residence and bar inventory and so forth.

Regardless of the dimensions of your operation, the ideas of inventory control are the same. In larger operations there may be more humans and sometimes even whole groups concerned with the diverse steps, and in a small operation all duty for dealing with the stock may also fall on one or key human beings.

Effective stock manipulate may be broken down into a few vital steps:

- Set up structures to music and document stock
- Develop specs and tactics for ordering and buying

- Develop standards and strategies to correctly acquire deliveries
- Determine the frequency and approaches for reconciling inventory
- Analyze inventory statistics and determine any regions for improvement

Setting Up Systems to Track and Record Inventory

One of the reasons you take inventory is to decide food costs and to work out cost percentages. There are several techniques that simplify finding the fee of goods in storage. These strategies are based totally on preserving good facts of how much materials value and when components have been purchased.

The temptation in small operations is to treat inventory control casually. Perhaps there are most effective one or human beings doing the purchasing and they're usually aware about the substances which are on hand. This doesn't get rid of the need to song purchases in opposition to income to see if you are managing your prices as well as you can.

Almost all stock control strategies are time consuming. Moreover, such information should be kept up to date and finished accurately. Trying to shop some hours by using slicing back on the time wanted to keep stock statistics may be cash poorly saved. The simplest method for tracking inventory is using a spreadsheet. A simple spreadsheet might list all of the products which are often purchased, with the current fees and the numbers on hand at the ultimate stock remember. The charges can be updated often as invoices are processed for payment, and a schedule may be set to count the product handy. In massive operations, the structures need to be more state-of-the-art as there are more humans concerned. Purchases might be made by way of a separate department, inventory records might be kept through a storeroom clerk, and the tracking and counting of stock is probably tied to a gadget using scanners and barcodes, which in turn can be linked with your income system so that there is continually a document of what ought to be in stock.

No count the depth of detail used, having a system to tune stock offers managers a good idea of substances handy and a tool to use to manage expenses.

Incoming Inventory

The number one motive for organizing a consistent approach for accepting ordered items is to ensure that the establishment gets precisely what has been ordered. Errors regularly occur, and unless the quantity and great of the gadgets delivered are carefully checked in opposition to what become ordered, full-size losses can take place. When receiving methods are cautiously performed, mistakes that might value the eating place time and money are avoided. In addition, a powerful receiving technique encourages honesty on a part of providers and delivery humans.

Invoices

The maximum crucial report in determining if the goods acquired are the goods ordered is the bill. An invoice is an itemized listing of the products or merchandise introduced to a meal's preparation premise. An invoice shows the quantity, great, charge according to kilogram or unit, and, in some cases, the entire extension of the value chargeable. Only by way of cautiously evaluating and checking can you be sure that the data at the bill tallies with the goods received. This comparison can also require that gadgets be weighed and/or counted.

Whenever possible, the receiver ought to take a look at the invoice against the purchase order or purchase request slips. This will make sure that the quantity and price of the products shipped suit those indexed on the order shape. If the invoice isn't checked against the acquisition order when the products arrive, there is the ability that you will be missing products you want or receive products that were no longer ordered or are in wrong quantities. In addition, the fine of the products must be

determined before they're accepted. For example, bins of fresh produce and frozen foods must be opened and inspected to make sure exceptional.

When you're happy that the shipping is in order, signal the bill. In maximum cases, the bill is in replica or triplicate: you keep the unique and the transport driver retains the opposite replica or copies. Once you've got signed, you have relieved the delivery enterprise of its obligations and the supplies now belong to your enterprise. You may additionally, therefore, become responsible for any discrepancies between what's at the invoice and what has been added. It is good exercise to carry any discrepancies or errors to the eye of the motive force and have her or him acknowledge the mistake by means of signing the invoice. If a credit score note is issued, that must additionally be marked on the bill through the motive force. Note: Do not signal the bill till you are sure that all discrepancies had been looked after and recorded at the bill. Take the signed bill and give it to whoever is answerable for collecting invoices for the organization.

The receiving of deliveries can be time eating for both the food status quo and the transport provider. Often the transport humans (in particular if they may be not the supplier) will not need to wait even as these tests are performed. In this case, it's far crucial that your company has an expertise with the provider that faults observed after the transport provider has left are the provider's problems, not yours.

Once the invoices had been signed, positioned the delivered merchandise in the proper locations. If you're required to song incoming inventory, achieve this at the equal time.

Outgoing Inventory

When a deliver leaves the storeroom or cooler, a document must be kept to song where it has gone. In most small operations, the materials go directly to the kitchen wherein they're used to produce the menu gadgets. In an ideal world, accurate information of incoming and outgoing supplies is saved, so knowing what is available is an easy be counted of subtraction. Unfortunately, structures aren't always that simple.

In a smaller operation, knowing what has arrived and what gets used each day can easily be reconciled via doing an ordinary rely of stock. In larger operations and hotels, the garage rooms and coolers can be on a different floor than the kitchen, and therefore a device is wanted that requires every department and the kitchens to requisition food from the storeroom or purchasing department, just like a small eating place could do directly from the dealer. In this model, the inn could buy all of the food and keep it in a central storage area, and character departments could then "order" their food from the storerooms.

Requisitions

To control inventory and to determine daily menu prices in a larger operation, it's far necessary to installation a requisition technique where whatever transferred from garage to the kitchen is done with the aid of a request in writing. The requisition shape should encompass the call and quantity of the objects wanted through the kitchen. These forms regularly have space for the storeroom clerk or whoever handles the storeroom stock to enter the unit charge and total cost of every asked item.

In an efficiently run operation, separate requisition forms need to be used by serving employees to update desk elements consisting of sugar, salt, and pepper. However, frequently personnel resist the use of requisition forms due to the fact they locate it much less difficult and faster to genuinely input the garage room and take hold of what is wanted, but this practice leaves no record and makes accurate record keeping impossible. To lessen the opportunity of this occurring, the storage area should be secure with just a few human beings having the right to go into the rooms, garage freezers, or garage refrigerators.

Not only does the requisition hold tabs on stock, it additionally can be used to decide the dollar fee of foods requested by each department and so be used to decide expenses. In a larger operation in which purchases can be crafted from exclusive providers at exceptional expenses, it could be vital to tag all staples with their prices and date of arrival. Expensive items consisting of meats are regularly tagged with a shape that contains information about weight, fee in step with unit (piece, pound or kilogram), date of purchase, and name of supplier.

Pricing all gadgets is time consuming, but that point will quickly be recovered when requisition bureaucracy is being crammed out or when the inventory has to take delivery of a financial price. In addition, having fees on goods may additionally assist to remind team of workers that waste is costly.

Inventory Record Keeping

There are two basic record keeping strategies to song inventory. The first is taking perpetual inventory. A perpetual inventory is sincerely a jogging stability of what is available. Perpetual inventory is exceptional executed by using preserving information for every product that is in storage.

Computerized Inventory Control

Most humans today use automatic structures to calculate, music, and increase stock. These structures enable the eating place to have a much tighter and greater accurate manage over the inventory on hand and the expenses of that inventory. Having get right of entry to facts including ordering history and the nice charge paid is just one of the benefits of these systems. They also can assist the customer predict demand levels during the year. These applications in many cases also are included with the point-of-sale (POS) gadget used to music sales, and might even cast off an object from a computerized stock listing whilst the waiter registers the sale of any menu object at the eating place terminal. That is, if a purchaser orders one chook dish from the menu, all the objects required to make one part of the chicken are discounted from stock. This provides management with a regular up to date perpetual stock of most inventory items.

Smaller operations will use a spreadsheet application to manage inventory, so that you have to also be familiar with a software like Microsoft Excel if you are chargeable for ordering and inventory. The statistics required for this system to do the calculations nicely is available from the invoices obtained along with your supplies. That is, the quantities and expenses of the products you maximum recently acquired must be entered into the pc program either by means of you or by the eating place's customer. These costs and quantities are robotically used to calculate the price of the goods handy. This automated process can prevent a widespread quantity of time and, if the statistics entered into the laptop is correct, can also save you money. In any inventory device, there is constantly an opportunity for error, but with automated assistance, this risk is minimized.

Costing Prepared or Processed Items

When you are constructing your stock forms, be sure to calculate the expenses of any processed objects. For instance, sauces and stocks which you make from raw ingredients need to be costed as it should be and recorded on the spreadsheet along with purchased merchandise so that whilst you are counting your inventory you are able to replicate the value of all supplies on the premises that have no longer been sold.

7.3.3 Inventory Management Techniques

Below is a listing of a number of the most popular and powerful stock control techniques you can use to improve your business.

1. **Economic Order Quantity**

   Economic order amount is the lowest quantity of stock you need to order to satisfy peak customer demand without going out of inventory and without producing obsolete inventory.

   Its purpose is to lessen inventory as tons as viable to maintain the price of stock as low as possible.

   Economic order quantity (EOQ) is the optimal order quantity that a business can purchase to reduce inventory costs such as cost keeping, cost shortage and cost of ordering.

   Economic order quantity uses three variables: demand, relevant ordering cost, and relevant carrying cost. Use them to set up an EOQ formula:

   $$Q = \sqrt{\frac{2DS}{H}}$$

   where:

   Q = EOQ units

   D = Demand in units (typically on an annual basis)

   S = Order cost (per purchase order)

   H = Holding costs (per unit, per year)

2. **Minimum Order Quantity**

   Minimum order amount (MOQ) is the lowest set quantity of inventory that a supplier is willing to promote. If you may not purchase the MOQ of a specific product, then the supplier won't sell it to you. The purpose of minimal order quantities is to allow providers to boom their profits whilst getting rid of greater inventory extra quick and removing the "bargain shoppers" simultaneously. A minimal order quantity is set based in your total value of stock and any other costs you need to pay earlier than reaping any profit which means MOQs help wholesalers live profitable and keep a healthful coin's flow.

3. **ABC Analysis**

   ABC analysis of inventory is a way of sorting your stock into 3 categories consistent with how nicely they promote and how much they cost to hold:

   - A-Items – Best-selling objects that don't take up all your warehouse area or value
   - B-Items – Mid-range objects that promote frequently but may cost a little more than A-objects to hold
   - C-Items – The relaxation of your stock that makes up the bulk of your inventory charges at the same time as contributing the least to your backside line

   ABC analysis of stock facilitates you keep working capital charges low as it identifies which objects you have to reorder extra often and which objects don't need to be stocked regularly lowering obsolete stock and optimizing the rate of stock turnover.

4. **Just-In-Time Inventory Management**

   Just-in-Time Inventory Management is surely making what is needed, whilst it's needed, in the amount needed. Many corporations perform on a "simply-in-case" basis – keeping a small quantity of inventory in case of a surprising height in call for. JIT attempts to establish a "0 stock" system by means of production goods to order; it operates on a "pull" machine whereby an order comes through and initiates a cascade response all through the entire deliver chain signaling to the personnel they want to order inventory or start generating the required item. Here are a number of the benefits of simply-in-time stock:

- Minimize expenses such as lease and coverage by way of lowering your inventory
- Less obsolete, outdated, and spoiled stock
- Reduce waste and boom efficiency through minimizing or eliminating warehousing and stockpiling, while maximizing stock turnover
- Maintain wholesome cashflow by way of ordering stock simplest while necessary
- Production errors can be recognized and stuck faster seeing that production occurs on a smaller, extra centered level, allowing simpler adjustments or upkeep on capital equipment

5. Safety Stock Inventory

Safety inventory is a small, surplus amount of inventory you maintain on hand to shield against variability in market call for and lead times. Safety inventory performs a necessary role inside the easy operations of your deliver chain in diverse ways. Here are a few ways:

- Protection in opposition to surprising spikes in demand
- Prevention of stockouts
- Compensation for inaccurate marketplace forecasts
- And a buffer for longer than predicted lead times

You possibly observed that the advantages of protection inventory are all tied to mitigating problems that could seriously harm your business.

That's because without safety inventory stock you could experience:

- Loss of revenue
- Lost customers
- And a loss in market share

A safety stock formula is relatively straightforward and requires only a few inputs for calculation.

Here's the formula we recommend using if you're just starting out:

(Max Daily Sales x Max Lead Time in Days) – (Average Daily Sales x Average Lead Time in Days) = Safety Stock Inventory

6. Reorder Point Formula

A reorder point formulation tells you about while you must order extra stock – that is, while you've reached the lowest amount of inventory you may sustain before you need more. Here's the reorder point formula you may use today: (Average Daily Unit Sales X Average Lead Time in Days) + Safety Stock = Reorder Point This equation can help you stop being a sufferer to marketplace spikes and slumps and instead, consistently order the right amount of stock each month.

7. Batch Tracking

Batch monitoring is sometimes known as lot monitoring, and it's a method for correctly tracing items along the distribution chain the use of batch numbers. From raw substances to completed items, batch monitoring permits you to see in which your goods got here from, where they went, how tons become shipped, and after they expire in the event that they have an expiration date.

What are the advantages of batch tracking?

- Easy and Fast Recall
- Streamlined Expiry Tracking
- Improved Relationships with Suppliers
- Fewer Accounting Errors from Manual Tracking

8. **Consignment Inventory**

Consignment Inventory is a commercial enterprise arrangement in which the consignor (a seller or wholesaler) agrees to offer their items to a consignee (commonly a retailer) without the consignee paying for the products up front – the consignor nonetheless owns the products, and the consignee can pay for the goods simplest once they actually sell.

This stock control technique creates a win-win partnership between providers and retailers as long as they're both willing to share the risks – and rewards.

Pros for Vendors:

- New Markets
- Low Inventory Carrying Costs
- Direct-to-Retailer Shipping

Pros for Retailers:

- Lower Cost of Ownership
- Minimal Risk
- Improved Cash Flow

9. **Perpetual Inventory Management**

A perpetual stock control machine is also known as a continuous stock machine. Perpetual stock systems music offered and stocked stock in real-time; they replace your accounting system whenever a sale is made, inventory is used, or new stock has arrived. All of this fact is dispatched to at least one crucial hub that any authorized worker can access. These are the advantages of perpetual stock:

- Proactive monitoring of inventory turnover
- Manage multiple locations with ease
- More informed forecasting

UNIT 7.4: Enterprise Resource Planning (ERP)

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the process of of documenting and recording the details of materials to final purchase to inventory management through ERP Software

7.4.1 Introduction

ERP is an industry shortening for Enterprise Resource Planning. Broadly speaking, ERP refers to mechanization and integration of a company's core business to help them focus on efficiency and simplified success. The IT industry is renowned for its adoption of acronyms, which are often widely used, but not fully understood. The term 'ERP' itself is not self-explanatory and denotes the business software that has been designed to record and manage your enterprise data.

An ERP system automates and integrates core business procedures such as taking customer orders, scheduling operations, and keeping inventory records and financial data. ERP systems have numerous benefits to help with overall business performance management for any organization providing intelligence, visibility, analytics, and efficiency across every single aspect of a business. Giving you one source of the truth and empowering the digitalization of your business.

7.4.2 Brief History of ERP

The term ERP was devised in 1990 by Gartner, but its roots date back to the 1960s. Back then, the notion applied to inventory management and control in the manufacturing sector. Software engineers created programs to monitor inventory, reconcile balances, and report on status. By the 1970s, this had evolved into Material Requirements Planning (MRP) systems for scheduling production procedures.

In the 1980s, MRP grew to incorporate more manufacturing processes, prompting many to call it MRP-or Manufacturing Resource Planning. By 1990, these systems had extended beyond inventory control and other operational procedures to other back-office functions like accounting and human resources, setting the stage for ERP as we've come to know it.

Benefits of Implementing an ERP System

Today's manufacturer and distributor face an innumerable of business challenges. These contain duplication of processes with disparate systems, the inability to support a mobile workforce, scrambling to keep track of resources, departments within the organization working in silos, and the list goes on. Executing an ERP system delivers key benefits to assist in overcoming these obstacles.

Reduce Costs & Saves Money

- Reduce administrative and operational costs through mechanized processes. This allows users to proactively be able to manage operations and prevent delays.
- A cut in operational costs is a cut in working capital outlay. An ERP System allows you to run your business at a lower cost.
- Reduce waste within their organizations, maximize inventory efficiency.

Streamlined Business Processes and Operations

- Data is accessible in a centralized location with complete visibility across all functionalities.
- An ERP System allows you to automate business processes.
- Decision makers can monitor processes and production in real-time.
- Automate tracking processes, and accurately determine and maintain inventory levels.

Improved Financial Consolidation

- Without ERP, many businesses are enforced to use different programs in different departments. An ERP system eliminates the data silos that arise from disparate systems
- ERP systems virtually remove tasks by doing the work for you.

Supply Chain Optimization

A robust ERP System allows for real-time visibility of your supply chain and other processes making it easier for decision makers to get a wider view of their supply chain, reduce planning cycles and be on top of your production scheduling.

Respond to Market Conditions Faster with Data Analysis

- ERP System provides real-time data analysis and reporting to assist the business to rapidly react to changing market requirements.
- The business can make informed decisions on time.
- Data analysis on ERP software enables access to accurate reports. This allows businesses to follow trends in real-time and determine realistic forecasts.

Traceability

- Allocation and detection of inventory and stock is critical in highly regulated industries.
- ERP benefits you in tracing stock, defects and hazards down to the level of individual parts and ingredients.
- You can recall and re-evaluate batches and improve scheduled and preventative maintenance, product configuration and change control.

Digitally Transform & Future-proof your Business with Mobility & Flexibility

- As your business grows, your ERP system will grow and adapt to cater for your changing needs.
- Gain better control over your business with choice in deployment; whether it is on premise, in the cloud (Cloud ERP), or on a Mobile App (Mobile ERP)

Improve Customer Satisfaction, Service & Relations

- Implementing an ERP solution enables you to produce the right product at the right time. This ensures accuracy in providing for customer needs.
- On-time delivery is critical in maintaining customer retention and service.

Increase Competitiveness with an Industry Built System

- An industry-built ERP solution allows for configuration to suit industry needs by adapting to individual business requirements.
- Gain competitive advantage with compliancy, agility and the ability to expand and adapt with little to no downtime.

Process Manufacturing

Process manufacturing is involved in many production tasks. An ERP system performs tasks such as production control, quality analysis and distribution scheduling. Automating your supply chain results in maximized workforce hours and ensured accuracy, which leads to cost savings. The production process is heavily involved in the profitability of your business. Here are some process manufacturing features and what they can do for you:

- **Quality management –** This functionality deals with the management of allergens (colors, gluten, etc.), quality testing, inspections and testing plans.
- **Shelf life –** Look for software that has an automated alert-mechanism to notifies managers when production materials are approaching or past their expiration date.
- **Sales and inventory management –** Your software system should have the ability to manage stock efficiently, preventing both spoilage and shortage. That data is then linked to sales order data to provide managers with critical information about stock level, stock location and replenishing stock back to optimum levels.
- **Recipe control –** This is a complex task which handles information like formula, quantity, costing and historical information. Handling conversions is considered a cardinal feature

7.4.3 The Types of ERP

Enterprise Resource Planning Software can help improve inventory management, bills payable, manufacturing, human resources, and pleasant manipulate for your organization. There are different sorts of ERP systems ranging from industry-particular ERP solutions which include the ones offered by way of Infor ERP; to web-primarily based, or cloud ERP; to small enterprise ERP.

The kind of ERP gadget with a purpose to work pleasant for your business relies upon on the size of your company and the features of the ERP solution that can satisfactorily aid your enterprise requirements.

- **Industry Specific ERP**

  Infor ERP offers an answer for the producing and distribution industries and has been assisting the necessities of corporations for many years and utilized by extra than 70,000 organizations in over 200 countries. Industry precise ERP are commonly for huge businesses and are custom designed to the enterprise's exact wishes.

- **Web-Based, or "Cloud" ERP**

  Instead of running superior ERP software on your organization's computers, some groups go with a web-based answer, referred to as Software as a Service (SaaS). Cloud ERP lets groups pay a subscription for having access to the software program and storing facts over the internet. The ERP machine runs on a far-off server, giving your agency anywhere, anytime get entry to from any device with an internet connection at the same time as presenting a cheap solution to your ERP wishes. It's ideal for businesses of any size, however nice applicable to small agencies with smaller budgets.

- **ERP for Small Businesses**

  If you need a solution for sales and order control, or human resources, but don't need a complete warehouse management or production component – ERP for small corporations is an option. As a small commercial enterprise, you may now not have a want to automate accounting solutions or consumer relations management. A scaled-down ERP answer is right for small corporations whilst providing simply the capability you want at a price you could afford.

7.4.4 Selecting an ERP System

So, you're thinking about purchasing an ERP system for your food and beverage organization? Follow these simple steps to get started.

- **Gather Requirements-** The first step to choosing a system is gathering your requirements. We have an interactive requirements template available for ERP which will help you identify which features your organization will use.
- **Compare Software-** Once you have your requirements in order, the next step is to compare different software vendors. Our comparison report for ERP allows you to compare top vendors based on their performance in different requirements.
- **Reference Pricing Guide-** The last step is to reference our pricing guide which will help you understand what vendors typically charge for their services. After you've done that, you should have a couple top vendors in mind.

Exercise

1. **Disclose the responsibilities of a Hygiene Team Leader.**

   _____

   _____

   _____

2. **Elucidate the important steps of effective inventory control**

   _____

   _____

   _____

3. **Define:**

   (i) Minimum Order Quantity

   _____

   _____

   (ii) ABC Analysis

   _____

   _____

(ii) FIFO

_____

_____

(iv) Drop shipping

_____

_____

(v) Enterprise Resource Planning (ERP)

_____

_____

4. What are the benefits of an ERP system?

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_____

_____

_____

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सत्यमेव जयते
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N·S·D·C
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Transforming the skill landscape

FICSI
Food Industry Capacity and Skill Initiative

8. Food Safety, Hygiene and Sanitation

Unit 8.1 - Food Safety, Hygiene and Sanitation in Food Industry

Unit 8.2 - Application of Hazard Analysis and Critical Control Point (HACCP) in Achieveing Food Safety

Unit 8.3 - Occupational Health and Safety (OSH) at Workplace

FIC/N9001

Key Learning Outcomes

At the end of this module, you will be able to:

1. State the importance of safety, hygiene and sanitation in the food industry.
2. List the industry standards to maintain a safe and hygiene workplace.
3. Apply HACCP principles to eliminate food safety hazards in the process and products.
4. Apply safety practices in the work area.

UNIT 8.1: Food Safety, Hygiene and Sanitation in Food Industry

Unit Objectives

At the end of this unit, you will be able to:

1. State the importance of safety, hygiene and sanitation in the food industry.
2. List the industry standards to maintain a safe and hygiene workplace.

8.1.1 Importance of safety, hygiene and sanitation in the food industry

What is Food safety?

Food Safety means assurance that food is acceptable for human consumption according to its intended use. It is a scientific practice which involves supervision, preparation, and storage of food with the aim to avoid food borne illness. It comprises of different pattern that must be followed to stay away from rigorous health hazards.

Goal of food safety

Main aim is to lessen the food borne illnesses by modifying or implementing food safety interrelated behavior's and system. Illnesses derived from food are trouble for communal health and it supplement to the health care cost. Some proportion of illness is the outcome of well-known food borne epidemic, which mostly take place when some cases of related illnesses occur due to consuming same food. The root cause of food borne epidemic should be find out including data analysis on the root cause or germs that is responsible for sickness and our usual behavior which will add to food contamination. All this will contribute in identifying region of improvements in the nation's food safety system.

The safety system will cover whole food chain, from cultivating the food, processing, packing, supplying, shipping, and storage to fork.

Why Is Food Safety Important?

Food borne outbreaks are communal health issues which are avoidable and improperly reported. They are surcharge on communal wellbeing and add to the expenditure of health care. They pose a key threat to definite groups of people. It can affect everyone but some groups are at higher risk.

- Following are the objectives of Food Safety:
- Food must be safe, hygienic and fit for human consumption;
- Unbiased trade exercises must be ensured in food trade;
- Food chain must be followed;
- Accounting the broad variety of Food safety standards;
- Laying a rigid groundwork to ensure food sanitation and hygiene along with every specific code of hygiene observe to all segments.

Understanding Food Safety

The concept of food safety can be understood by laying out the two major determinants of food safety. These are Physical, social and behaviour determinants. The following are discussed below:

1. **Physical Determinants of Food Safety**

   Hazards are classified as physical, biological and chemical. These hazards can come into the food chain at any time ranging from field to fork. Mostly hazards could not be investigated in food at the time of purchasing or consuming. Also, food may result in rigorous reactions in individuals who are affected by it. In some countries like United States the cases of food allergies are of major issues in children below 18 and few adults.

2. **Social and Behavioral Determinants of Food Safety**

   It is essential for every individual to recognize how their interaction and actions lead to safe food and how one can reduce the threat of food borne diseases. Human beings' actions play major function in food safety and it ranges from processing on the field to activities in the kitchen. One can undergo a lot of challenges to keep their food safe.

8.1.2 Industry standards to maintain a safe and hygienic workplace

Some of the pre-requisites for maintain safe work environment are discussed below:

Machinery and production line design

The layout of the production line should permit easy maintenance and cleaning of machinery and surrounds and prevent contamination of the food products and ingredients through the production process.

The design of machinery used for food processing also has to be taken into account to fulfill food safety regulations. Poor design can lead to build-up of food material in concealed places that are difficult to clean. There are standards for machinery design, such as the NSF equipment design standard, to confirm all food handling and processing is performed to a high standard of hygiene.

The 10 principles of sanitary design are:

- Cleanable to a microbiological level;
- Made of compatible materials;
- Accessible for inspection, maintenance, cleaning and sanitation;
- No product or liquid collection;
- Hollow areas hermetically sealed;
- No niches;
- Sanitary operational performance;
- Hygienic design of maintenance enclosures;
- Hygienic compatibility with other plant systems;
- Validate cleaning and sanitizing protocols.

Pest control

Pest manipulate performs an important part in food protection. Troublesome bugs which include cockroaches and flies can spread food-borne diseases by using contaminating food at any level of production. Rodents additionally unfold diseases as well as causing harm to homes, fixtures and machinery. Stored product insects can damage and contaminate food for the duration of shipping and storage.

Food businesses need to ensure the ideal structures are in vicinity to save you or minimize danger of pest infestation from rodents, bugs and birds. This includes:

- An operative pest control Programme managed by someone competent;
- Keeping external areas free of waste, debris and food sources;
- Keeping an entirely clear perimeter area around buildings of about 0.5m;
- Keeping all doors and windows closed and making sure there are no gaps that allow pest access;
- Ensuring there is a suitable cleaning and waste disposal regime;
- Monitoring of target pest species with appropriate equipment such as bait stations, electronic fly killers, traps, etc. and sited appropriately to reduce risk of contamination by pests of raw materials, ingredients, finished products, surfaces or during monitoring;
- Making and maintaining a map of all pest control stations;
- Pest control activities in food premises should be done by a licensed pest control specialist or by staff who have been trained and properly licensed;
- All monitoring activities should be planned, carried out and recorded.

Waste management

The standards should be such that it has provision of appropriate packing containers and appropriate waste storage areas, having adequate processes/SOP for the storage and removal of waste. This prevents build-up of waste and pests and reduces risk of infection of ingredients, system and products. Waste disposal should be managed according with legal necessities thus, preventing accumulation, chance of contamination and the appeal of pests.

Cleaning

The standards should be such that it has provision of establishing cleaning and disinfection programmes to ensure the proper hygiene standards are met and decrease the threat of a foodborne infection outbreak. This consists of well cleansing and disinfecting food preparation regions in addition to equipment and utensils used inside the food processing cycle to do away with the microorganisms that reason food poisoning. These standards are essential because adhering to an appropriate cleaning SOP will also lessen the hazard of pests inclusive of rodents, flies and cockroaches in food coaching and processing areas with the aid of removing capacity food assets and insect breeding sites.

Maintenance

The standards should be such that it has provision of establishing proactive protection measures for premises and food processing machinery to make sure they run smoothly and nicely, and ensures the production of safe food. An article from the Food Safety Magazine states that some of food-borne infection outbreaks may be related to the failure to ensure system is well maintained under the suitable sanitary conditions

Personal hygiene & Training

Personal Hygiene

Installing the correct centers for personnel to ensure right private hygiene has to be met which will contributes toward essential food safety necessities. Following strict guidelines needs to be ensured in the industry premises.

- Hand Washing —correct and effective hand washing techniques is recommended;
- Minimize hand touch— try to minimize direct hand contact with raw materials and by using appropriate utensils and safe use of disposable gloves;
- Personal cleanliness — some basics such as are required to be followed viz. cover hair; do now not sneeze or cough over food; cowl cuts and sores; and do not wear jewelry
- Wear protective covering's — put on suitable smooth protective covers and deal with appropriately to prevent cross contamination
- Exclude ill workers from work— staff must report every illness; exclude team of workers with vomiting or diarrhea etc.

For details refer module number 2

Environmental hygiene

Food processing facilities rely on the usage of doubtlessly dangerous chemicals for sanitation and pest manipulate. Because of this interest has to be implemented to lessen the hazard of unintentional environmental infection at some stage in the food processing cycle. Food safety practices want to be carried out to ensure the chemical compounds stored and used on food processing premises do now not contaminate the food products at any degree in production.

Correct handling, storage & transport

On pinnacle of food production and education, protection also has to be applied all through handling, storage and transportation, for each incoming deliveries and merchandise going out to customers.

A range of things has to be taken into consideration at some point of these levels to make certain food products from preventing them contaminated.

Temperature and humidity, hygiene of vehicles, packing containers and packaging, or even cyber security are all elements which need to be taken into consideration throughout these levels of the food deliver chain.

UNIT 8.2: Application of Hazard Analysis and Critical Control Point (HACCP) in Achieveing Food Safety

Unit Objectives

At the end of this unit, you will be able to:

1. List the HACCP principles to eliminate food safety hazards in the process and products.
2. State the history of HACCP (Hazard Analysis and Critical Control Points).
3. Apply the use of HACCP.
4. Define the terms used in HACCP system.
5. Communicate the seven principles of HACCP system.
6. Enumerate benefits of HACCP and barriers to the successful implementation of HACCP system.
7. Analyze the implementational and operational costs of HACCP.

8.2.1 Necessity of HACCP

HACCP is a systematic preventative method to food protection that addresses bodily, chemical and biological hazards as a method of prevention in place of completed product inspection. HACCP is used in the food enterprise to identify capability food protection risks, so that key actions, referred to as Critical Control Points (CCP's) can be taken to lessen or do away with the danger of the risks being realized. The machine is used in any respect tiers of food manufacturing and preparation processes.

Food safety has been of problem to humankind for the reason that sunrise of history, and lots of the troubles encountered in our food deliver go returned to the earliest recorded years. Many guidelines and suggestions endorsed in religious or historical texts are evidence of the priority to protect humans against foodborne illnesses and food adulteration. However, in recent many years this subject has grown. There are many motives for this as follows:

- Foodborne diseases remain one in every of the maximum vast public fitness issues within the current world, and a vital cause of reduced financial productivity, in spite of development in food technology and technologies. The World Declaration on Nutrition, adopted via the Food and Agricultural Organization (FAO)/World Health Organization (WHO) International Conference on Nutrition (Rome, December 1992), emphasizes that loads of tens of millions of human beings suffer from communicable and noncommunicable sicknesses resulting from contaminated food and water;
- The growing prevalence of many foodborne sicknesses, e.g., Salmonellosis and campylobacteriosis, in many regions of the world;
- Increased understanding and recognition of the extreme and chronic fitness results of foodborne pathogens;
- The possibility of detecting minute quantities of contaminants in food, due to advances in medical and analytical methods;
- Emerging foodborne pathogens, e.g., Listeria monocytogenes, verocytotoxin producing E. Coli, Campylobacter sp., foodborne nematodes, etc.;
- An increase within the wide variety of vulnerable people, which include the elderly, immune compromised people, the undernourished, and individuals with other underlying fitness troubles;
- Increased cognizance of the economic outcomes of foodborne sicknesses;
- Industrialization and improved mass production, main to improved risks of food infection;

- The considerably large numbers of people affected in foodborne ailment outbreaks as a result;
- Urbanization, leading to a more complicated food chain, and thus greater possibilities for food infection;
- New food technologies and processing methods, causing concern either approximately the protection of the products themselves or the eventual effects due to inappropriate handling all through guidance in families or food service/catering establishments;
- Changing lifestyles, depicted by using increasingly people ingesting outdoor the home, in food service or catering establishments, at road food stalls, or in fast-food restaurants;
- Responsibility for food education shared between circle of relative's members who are not always aware about food safety policies;
- Increased global tourism and international trade in foodstuffs, main to a greater publicity to food borne risks from different areas;
- Increased contamination of the environment;
- Increased customer awareness of food protection;
- Lack of or decreasing assets for food protection.

In the light of the above motives, there is a growing issue about food safety, the dearth of sufficient sources, and the recognition of the restrictions of traditional procedures to food protection warranty that have accentuated the need for a cost-powerful food protection warranty method. The HACCP device has confirmed to be such a machine.

8.2.2 Guidelines for Application of HACCP Principles

Introduction

HACCP is a management machine in which food protection is addressed through the evaluation and control of biological, chemical, and bodily dangers from uncooked material production, procurement and managing, to manufacturing, distribution and consumption of the completed product. For a hit implementation of a HACCP plan, control must be strongly committed to the HACCP concept. A corporation commitment to HACCP by pinnacle control provides business enterprise employees with a feel of the importance of producing secure food.

HACCP is designed to be used in all segments of the food enterprise from growing, harvesting, processing, manufacturing, distributing, and merchandising to making ready food for intake. Prerequisite packages which include modern Good Manufacturing Practices (cGMP's) are a crucial basis for the development and implementation of successful HACCP plans. Food protection systems based totally at the HACCP ideas have been effectively carried out in food processing plants, retail food stores, and food carrier operations. The seven ideas of HACCP were universally standard by authorities' agencies, change institutions and the food industry around the world.

The following guidelines will facilitate the improvement and implementation of effective HACCP plans. While the particular software of HACCP to manufacturing centers is emphasized here, these recommendations have to be implemented as suitable to every section of the food industry under consideration.

Prerequisite Programs

The production of secure food products calls for that the HACCP device be built upon a stable foundation of prerequisite programs. Examples of commonplace prerequisite applications are indexed in Appendix A. Each segment of the meal's enterprise must offer the conditions necessary to defend food while it is beneath their manage. This has traditionally been accomplished via the utility of cGMP's. These

situations and practices are now taken into consideration to be prerequisite to the improvement and implementation of powerful HACCP plans. Prerequisite applications provide the simple environmental and operating situations which can be necessary for the manufacturing of secure, wholesome food. Many of the situations and practices are laid out in federal, country and local policies and recommendations (e.g., cGMP's and Food Code). The Codex Alimentarius General Principles of Food Hygiene describe the primary conditions and practices anticipated for food meant for international alternate. In addition to the requirements laid out in guidelines, enterprise regularly adopts regulations and techniques which are unique to their operations. Many of these are proprietary. While prerequisite packages may additionally impact upon the protection of a food, they also are worried with making sure that ingredients are wholesome and suitable for consumption (Appendix A). HACCP plans are narrower in scope, being confined to making sure food is safe to consume. Examples of Common Prerequisite Programs:

Appendix A

The production of secure food merchandise requires that the HACCP machine be built upon a stable foundation of prerequisite programs. Each phase of the food industry must offer the conditions important to defend food while it is below their manipulate. This has historically been accomplished through the utility of cGMP's. These conditions and practices are now considered to be prerequisite to the improvement and implementation of effective HACCP plans. Prerequisite applications provide the primary environmental and operating conditions which are important for the manufacturing of safe, healthy food. Common prerequisite packages may additionally include, but are not limited to:

- Facilities: The establishment must be located, constructed and maintained in step with sanitary design ideas. There have to be linear product waft and visitors manage to reduce cross-infection from uncooked to cooked materials.
- Supplier Control: Each facility ought to assure that its suppliers have in location effective GMP and food protection applications. These may be the difficulty of continuing dealer assure and dealer HACCP gadget verification.
- Specifications: There must be written specs for all ingredients, products, and packaging materials.
- Production Equipment: All device needs to be constructed and installed in line with sanitary layout concepts. Preventive upkeep and calibration schedules need to be established and documented.
- Cleaning and Sanitation: All approaches for cleansing and sanitation of the equipment and the facility should be written and followed. A grasp sanitation schedule ought to be in place.
- Personal Hygiene: All personnel and other men and women who enter the producing plant ought to follow the requirements for private hygiene.
- Training: All employees have to obtain documented education in private hygiene, GMP, cleaning and sanitation methods, non-public safety, and their role inside the HACCP program.
- Chemical Control: Documented procedures ought to be in area to guarantee the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.
- Receiving, Storage and Shipping: All uncooked materials and products need to be stored below sanitary conditions and the proper environmental situations along with temperature and humidity to assure their safety and wholesomeness
- Traceability and Recall: All uncooked substances and products have to be lot-coded and a recall device in vicinity so that fast and whole lines and recalls can be achieved whilst a product retrieval is vital.
- Pest Control: Effective pest manipulate packages have to be in area.
- Other examples of prerequisite applications might include first-rate guarantee processes; popular operating methods for sanitation, processes, product formulations and recipes; glass manage;

techniques for receiving, garage and shipping; labeling; and employee food and ingredient handling practices.

- The existence and effectiveness of prerequisite programs ought to be assessed during the design and implementation of every HACCP plan. All prerequisite packages have to be documented and often audited. Prerequisite programs are installed and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be included right into a HACCP plan. For example, many establishments have preventive renovation approaches for processing device to keep away from unexpected gadget failure and loss of manufacturing. During the development of a HACCP plan, the HACCP team may additionally determine that the routine preservation and calibration of an oven have to be included inside the plan as a pastime of verification. This could further make sure that all the food in the oven is cooked to the minimum inner temperature that is important for food safety.

Education and Training

The achievement of a HACCP gadget relies upon on teaching and training control and employees in the importance of their function in producing safe foods. This should also encompass facts the manager of foodborne dangers related to all levels of the food chain. It is important to apprehend that personnel must first apprehend what HACCP is and then research the capabilities essential to make it function properly. Specific education activities have to consist of working commands and procedures that outline the duties of personnel monitoring each CCP.

Management need to provide good enough time for thorough training and education. Personnel should accept the substances and equipment important to carry out these obligations. Effective education is an important prerequisite to a success implementation of a HACCP plan.

8.2.3 Developing a HACCP Plan

The format of HACCP plans will vary. In many instances the plans may be product and technique particular. However, a few plans may additionally use a unit operations approach. Generic HACCP plans can serve as useful courses inside the improvement of technique and product HACCP plans; however, it's far critical that the unique conditions within every facility be considered during the improvement of all components of the HACCP plan.

In the development of a HACCP plan, 5 preliminary tasks want to be accomplished before the application of the HACCP concepts to a particular product and technique. The 5 initial obligations are given in Figure.

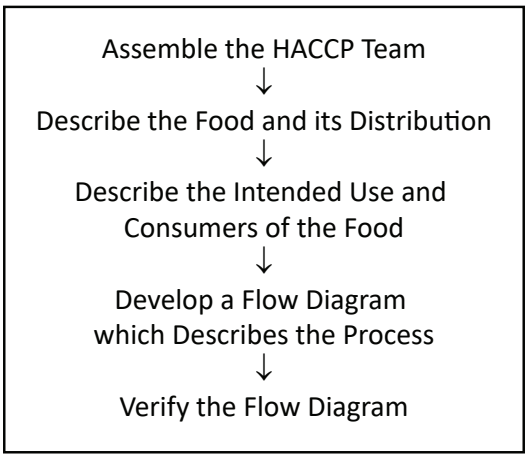


Fig. 8.2.1: Preliminary Tasks in the Development of the HACCP Plan

Preliminary Tasks in the Development of the HACCP Plan

Assemble the HACCP Team

The first task in growing a HACCP plan is to bring together a HACCP crew consisting of people who have specific understanding and expertise appropriate to the product and method. It is the crew's responsibility to expand the HACCP plan. The crew ought to be multi-disciplinary and consist of people from areas which include engineering, production, sanitation, exceptional assurance, and food microbiology. The team have to also consist of local personnel who're involved within the operation as they are more acquainted with the range and limitations of the operation. In addition, this fosters an experience of possession among those who have to put into effect the plan. The HACCP crew may also need help from out of doors professionals who're knowledgeable within the capacity biological, chemical and/or physical dangers related to the product and the system. However, a plan which is developed definitely by outdoor sources may be erroneous, incomplete, and missing in guide at the nearby level.

Due to the technical nature of the records required for hazard evaluation, its miles endorsed that professionals who are knowledgeable within the meal's technique must either take part in or affirm the completeness of the threat evaluation and the HACCP plan. Such people should have the understanding and experience to correctly: (a) conduct a threat analysis; (b) discover capacity risks; (c) identify hazards which ought to be controlled; (d) advise controls, crucial limits, and techniques for tracking and verification; (e) suggest suitable corrective actions whilst a deviation occurs; (f) propose research associated with the HACCP plan if crucial records isn't known; and (g) validate the HACCP plan.

Describe the food and its distribution

The HACCP team first describes the food. This consists of a preferred description of the food, ingredients, and processing methods. The method of distribution should be defined along with statistics on whether or not the food is to be disbursed frozen, refrigerated, or at ambient temperature.

Describe the intended use and consumers of the food

Describe the normal anticipated use of the food. The supposed consumers can be the overall public or a particular phase of the population (e.g., infants, immunocompromised people, the elderly, etc.).

Develop a flow diagram which describes the process

The motive of a flow diagram is to offer a clear, easy outline of the stairs involved within the procedure. The scope of the float diagram ought to cover all of the steps within the technique which can be directly beneath the manager of the establishment. In addition, the float diagram can include steps in the food chain which are earlier than and after the processing that occurs in the establishment. The float diagram need not be as complex as engineering drawings. A block kind go with the flow diagram is satisfactorily descriptive (see Appendix B). Also, a simple schematic of the power is often useful in understanding and comparing product and method go with the flow.

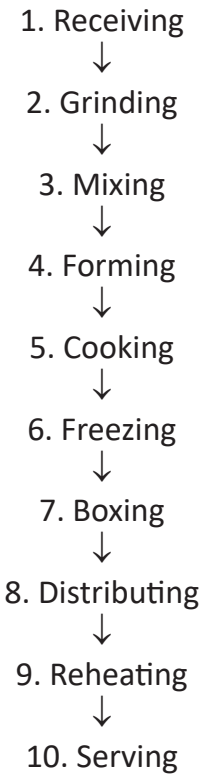


Fig. 8.2.2: Example of a flow diagram for the preparation of frozen cooked meat patties

Verify the flow diagram

The HACCP group need to perform an on site assessment of the operation to confirm the accuracy and completeness of the go with the flow diagram. Modifications ought to be made to the glide diagram as important and documented. After these five preliminary obligations have been completed, the seven standards of HACCP are applied.

Principle 1: Conduct a hazard analysis

After addressing the initial obligations mentioned above, the HACCP group conducts a risk evaluation and identifies suitable manage measures. The motive of the danger evaluation is to increase a listing of risks which are of such importance that they may be reasonably in all likelihood to reason damage or infection if not correctly controlled. Hazards that are not reasonably probably to occur would not require in addition consideration inside a HACCP plan. It is essential to recall within the risk analysis the elements and raw materials, every step inside the procedure, product storage and distribution, and final preparation and use by means of the consumer. When carrying out a threat evaluation, safety concerns must be differentiated from great concerns. A danger is described as an organic, chemical or bodily agent that is reasonably probably to cause contamination or damage inside the absence of it manipulate. Thus, the word danger as used on this record is confined to protection.

A thorough hazard analysis is the key to preparing a powerful HACCP plan. If the threat analysis isn't always done effectively and the dangers warranting control within the HACCP system aren't recognized, the plan will now not be powerful no matter how well it's far followed.

The hazard evaluation and identification of associated manage measures accomplish 3 objectives: Those hazards and associated control measures are identified. The analysis may additionally become aware of needed adjustments to a method or product so that product protection is in addition assured or improved. The evaluation affords a foundation for figuring out CCPs in Principle 2.

The system of conducting a chance analysis involves stages. The first, chance identity, may be regarded as a brain storming session. During this stage, the HACCP crew evaluations the elements used within the product, the activities performed at each step within the method and the gadget used, the final product and is approach of garage and distribution, and the supposed use and purchasers of the product. Based in this assessment, the crew develops a list of capacity organic, chemical or bodily risks which may be introduced, increased, or controlled at every step inside the production system. Appendix C lists examples of questions that can be useful to take into account while identifying capacity hazards. Hazard identification focuses on developing a listing of capability hazards related to every technique step below direct manipulate of the meal's operation. An information of any damaging health-related activities historically associated with the product could be of fee on this exercise.

After the list of potential hazards is assembled, stage two, the danger evaluation, is carried out. In stage of the danger evaluation, the HACCP team decides which ability hazards ought to be addressed inside the HACCP plan. During this stage, each ability threat is evaluated based on the severity of the ability threat and it's probably occurrence. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., effect of sequelae, and value and duration of infection or harm) may be beneficial in expertise the public health impact of the risk. Consideration of the in all likelihood occurrence is typically based totally upon a combination of experience, epidemiological data, and facts inside the technical literature. When undertaking the chance assessment, it is helpful to take into account the likelihood of exposure and severity of the capability effects if the chance isn't properly managed. In addition, consideration have to be given to the results of brief term as well as long term exposure to the capacity chance. Such considerations do no longer include not unusual dietary alternatives which lie outside of HACCP. During the assessment of every ability hazard, the food, its approach of preparation, transportation, storage and persons possibly to consume the product must be taken into consideration to determine how each of these elements may also influence the in all likelihood prevalence and severity of the chance being managed. The team ought to bear in mind the effect of in all likelihood processes for food instruction and storage and whether or not the supposed clients are liable to a capability danger. However, there can be variations of opinion, even amongst specialists, as to the probable prevalence and severity of a danger. The HACCP group may additionally have to rely on the opinion of professionals who assist in the development of the HACCP plan.

Hazards diagnosed in a single operation or facility won't be significant in some other operation producing the same or a similar product. For example, due to variations in device and/or a powerful upkeep program, the possibility of metallic contamination may be good sized in one facility however not in another. A precis of the HACCP group deliberations and the rationale developed all through the hazard evaluation have to be stored for future reference. This information might be beneficial all through destiny evaluations and updates of the chance evaluation and the HACCP plan.

Principle 2: Determine critical control points (CCPs)

A crucial manipulate factor is defined as a step at which control may be implemented and is important to prevent or eliminate a food safety threat or lessen it to a suitable stage. The ability dangers that are reasonably in all likelihood to reason infection or injury inside the absence of their manage need to be addressed in figuring out CCPs.

Complete and accurate identification of CCPs is essential to controlling food safety risks. The records evolved at some point of the chance analysis is important for the HACCP team in figuring out which steps inside the method are CCPs. One approach to facilitate the identity of each CCP is the use of a CCP choice tree (Examples of selection timber are given in Appendices E and F). Although application of the CCP selection tree may be beneficial in figuring out if a particular step is a CCP for a previously recognized danger, it is simply a device and not a mandatory element of HACCP. A CCP choice tree is not a substitute for professional knowledge.

Critical control points are located at any step-in which risks may be either prevented, eliminated, or reduced to desirable levels. Examples of CCPs can also include: thermal processing, chilling, trying out ingredients for chemical residues, product formulation control, and testing product for metallic contaminants. CCPs need to be cautiously advanced and documented. In addition, they need to be used handiest for purposes of product protection. For example, a specified warmth technique, at a given time and temperature designed to destroy a particular microbiological pathogen, might be a CCP. Likewise, refrigeration of a precooked food to save you risky microorganisms from multiplying, or the adjustment of a food to a pH important to prevent toxin formation could also be CCPs. Different facilities preparing similar food items can differ in the risks identified and the steps which can be CCPs. This may be due to differences in each facility's layout, equipment, choice of elements, techniques employed, etc.

Principle 3: Establish critical limits

A critical restriction is a maximum and/or minimum cost to which an organic, chemical or bodily parameter have to be managed at a CCP to prevent, take away or lessen to a suitable stage the incidence of a food protection danger. A vital limit is used to differentiate between secure and hazardous operating situations at a CCP. Critical limits need to not be careworn with operational limits which are established for reasons aside from food protection.

Each CCP could have one or greater control measures to guarantee that the diagnosed dangers are prevented, eliminated or decreased to proper levels. Each manage degree has one or extra associated crucial limits. Critical limits can be based upon elements consisting of: temperature, time, bodily dimensions, humidity, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory statistics which includes aroma and visual appearance. Critical limits have to be scientifically based. For each CCP, there is at least one criterion for food safety this is to be met. An instance of a criterion is a selected lethality of a cooking manner such as a 5D discount in Salmonella. The vital limits and standards for food safety can be derived from resources such as regulatory requirements and guidelines, literature surveys, experimental results, and experts.

An instance is the cooking of red meat patties (Appendix B). The method has to be designed to make sure the production of a safe product. The chance analysis for cooked meat patties diagnosed enteric pathogens (e.g., verotoxigenic E. Coli which includes E. Coli O157:H7, and salmonellae) as good-sized biological hazards. Furthermore, cooking is the step inside the process at which manage may be implemented to reduce the enteric pathogens to an acceptable stage. To make sure that an appropriate stage is continually achieved, accurate facts is needed on the possibly range of the pathogens within the raw patties, their warmness resistance, the factors that have an effect on the heating of the patties, and the location of the patty which heats the slowest. Collectively, this records paperwork the scientific basis for the important limits which are hooked up. Some of the elements that may have an effect on the thermal destruction of enteric pathogens are listed within the following table. In this instance, the HACCP team concluded that a thermal system equal to 155° F for sixteen seconds might be vital to assure the protection of this product. To ensure that this time and temperature are attained, the HACCP crew for one facility decided that it might be necessary to establish crucial limits for the oven temperature and humidity, belt speed (time in oven), patty thickness and composition (e.g., all red meat, beef and other substances). Control of these factors enables the facility to produce a wide variety of cooked patties, all of on the way to be processed to a minimum inner temperature of 155° F for 16 seconds. In every other facility, the HACCP crew may finish that the high-quality approach is to use the internal patty temperature of 155° F and keep for 16 seconds as vital limits. In this 2nd facility the inner temperature and maintain time of the patties are monitored at a frequency to ensure that the vital limits are constantly met as they go out the oven.

Monitoring is a deliberate series of observations or measurements to evaluate whether a CCP is under manage and to supply an accurate document for future use in verification. Monitoring serves three main purposes. First, monitoring is critical to food safety control in that it allows tracking of the operation. If tracking indicates that there is a trend closer to loss of control, then action may be taken to convey the system again into manipulate before a deviation from an essential limit occurs. Second, monitoring is used to decide when there's loss of manipulate and a deviation takes place at a CCP, i.e., exceeding or now not assembly a critical limit. When a deviation takes place, the perfect corrective action ought to be taken. Third, it presents written documentation for use in verification.

A hazardous food can also end result if a process isn't always well managed and a deviation happens. Because of the potentially serious effects of an essential restrict deviation, tracking approaches need to be powerful. Ideally, tracking need to be continuous, which is feasible with many types of bodily and chemical methods. For example, the temperature and time for the scheduled thermal technique of low-acid canned ingredients is recorded constantly on temperature recording charts. If the temperature falls under the scheduled temperature or the time is insufficient, as recorded at the chart, the product from the retort is retained and the disposition decided as in Principle 5. Likewise, pH measurement can be performed continually in fluids or with the aid of testing every batch earlier than processing. There are many methods to reveal critical limits on a non-stop or batch basis and report the statistics on charts. Continuous monitoring is continually desired when feasible. Monitoring equipment ought to be cautiously calibrated for accuracy.

Assignment of the duty for tracking is a crucial attention for each CCP. Specific assignments will depend on the quantity of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line employees and preservation personnel) and, as required, satisfactory control personnel. Those individuals have to be taught within the monitoring method for which they are responsible, fully apprehend the motive and significance of monitoring, be independent in monitoring and reporting, and accurately record the effects of tracking. In addition, employees should study in procedures to observe whilst there's a trend toward loss of control in order that adjustments can be made in a timely way to guarantee that the method remains underneath manage. The person liable for monitoring have to additionally immediately record a manner or product that does not meet vital limits.

All records and documents related to CCP tracking must be dated and signed or initialed by using the individual doing the tracking.

When it isn't always possible to display a CCP on a continuous foundation, it's far important to establish a tracking frequency and method to be able to be reliable sufficient to indicate that the CCP is beneath control. Statistically designed information series or sampling systems lend themselves to this reason.

Most tracking approaches need to be rapid due to the fact they relate to on-line, "real-time" techniques and there will no longer be time for prolonged analytical checking out. Examples of monitoring activities include: visual observations and size of temperature, time, pH, and moisture level.

Microbiological exams are seldom powerful for tracking due to their time-ingesting nature and issues with assuring detection of contaminants. Physical and chemical measurements are regularly favored due to the fact they may be speedy and typically more effective for assuring control of microbiological risks. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating instead of checking out the heated milk to assure the absence of surviving pathogens.

With sure food, procedures, ingredients, or imports, there can be no opportunity to microbiological testing. However, it is critical to apprehend that a sampling protocol that is good enough to reliably hit upon low ranges of pathogens is seldom possible due to the large quantity of samples needed. This sampling drawback could bring about a false experience of security with the aid of folks who use an inadequate sampling protocol. In addition, there are technical limitations in lots of laboratory processes for detecting and quantitating pathogens and/or their toxins.

Principle 5: Establish corrective actions

The HACCP gadget for food protection control is designed to identify fitness hazards and to establish techniques to save you, eliminate, or reduce their occurrence. However, ideal occasions do no longer usually be triumphant and deviations from established procedures may occur. A critical purpose of corrective moves is to save you foods which can be risky from achieving consumers. Where there's a deviation from established crucial limits, corrective actions are vital. Therefore, corrective movements have to encompass the subsequent elements: (a) determine and correct the cause of non-compliance; (b) decide the disposition of non-compliant product and (c) report the corrective moves that have been taken. Specific corrective movements should be advanced earlier for each CCP and included within the HACCP plan. As a minimum, the HACCP plan has to specify what is executed whilst a deviation happens, who is chargeable for imposing the corrective moves, and that a document might be evolved and maintained of the movements taken. Individuals who have a thorough know-how of the method, product and HACCP plan ought to be assigned the duty for oversight of corrective actions. As appropriate, experts can be consulted to study the facts available and to help in figuring out disposition of non-compliant product.

Principle 6: Establish verification procedures

Verification is defined as the one's activities, other than tracking, that decide the validity of the HACCP plan and that the machine is operating in step with the plan. The NAS (1985) (2) pointed out that the predominant infusion of technological know-how in a HACCP device centers on right identity of the hazards, important manage points, essential limits, and instituting right verification approaches. These processes should take place during the improvement and implementation of the HACCP plans and preservation of the HACCP system.

One factor of verification is evaluating whether the facility's HACCP system is functioning in step with the HACCP plan. A powerful HACCP system calls for little end-product testing, since enough tested safeguards are built in early in the procedure. Therefore, alternatively than counting on end-product testing, companies ought to depend on frequent opinions in their HACCP plan, verification that the HACCP plan is being effectively followed, and evaluation of CCP monitoring and corrective action information.

Another crucial thing of verification is the preliminary validation of the HACCP plan to decide that the plan is scientifically and technically sound, that everyone hazards have been diagnosed and that if the HACCP plan is well applied these dangers will be efficiently controlled. Information needed to validate the HACCP plan regularly consist of (1) expert recommendation and scientific studies and (2) in-plant observations, measurements, and evaluations. For instance, validation of the cooking manner for pork patties must include the medical justification of the heating times and temperatures needed to obtain the correct destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to affirm that the situations of cooking will deliver the required time and temperature to each beef patty.

Subsequent validations are completed and documented by a HACCP crew or an impartial expert as needed. For example, validations are carried out when there is an unexplained gadget failure; a considerable product, process or packaging change occurs; or new dangers are recognized.

In addition, a periodic comprehensive verification of the HACCP device ought to be conducted by means of an unbiased, independent authority. Such authorities can be inner or outside to the meal's operation. This should consist of a technical assessment of the danger evaluation and each detail of the HACCP plan in addition to on-web site evaluation of all go with the flow diagrams and appropriate statistics from operation of the plan. A comprehensive verification is impartial of different verification techniques and ought to be completed to ensure that the HACCP plan is resulting in the control of the dangers. If the outcomes of the comprehensive verification identify deficiencies, the HACCP crew modifies the HACCP plan as necessary.

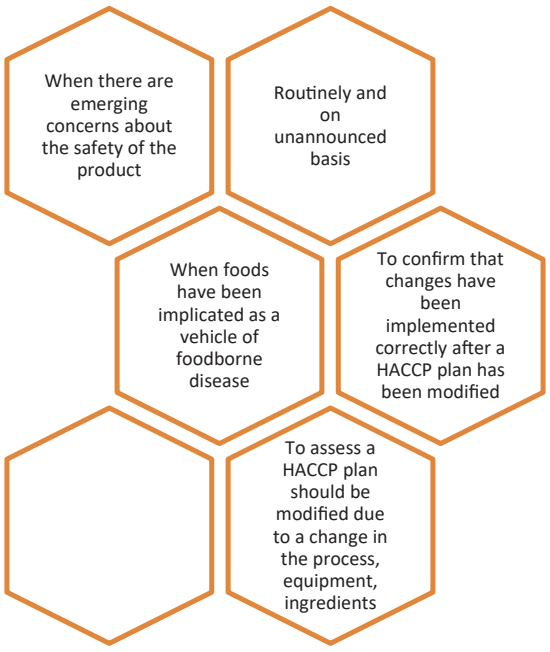
Verification sports are carried out by individuals within a company, third birthday party experts, and regulatory agencies. It is vital that individuals doing verification have suitable technical expertise to perform this function.

Examples of Verification Activities

1. Verification procedures may include:

- Establishment of verification schedule
- Review HACCP plan for completeness
- Confirm accuracy of flow diagram
- Review of the HACCP system to determine facility compliance
- Review of CCP monitoring records
- Review of records for deviations and corrective actions
- Validation of critical limits to confirm adequacy to control hazards
- Validation of HACCP plan, including on-site review
- Review of modifications of the HACCP plan
- Sampling and testing to verify CCPs

2. Verification should be conducted:



3. Verification reports may include information on the presence and adequacy of:

- HACCP plan and the person(s) responsible for administering and updating the HACCP plan
- Records associated with CCP monitoring
- Direct recording of monitoring data of the CCP while in operation
- Certification that monitoring equipment
- Corrective actions for deviations
- Controll of sampling and testing methods used to verify that CCPs
- Modifications to the HACCP plan
- Training and knowledge of individuals responsible for monitoring CCPs
- Validation activities

Activity	Frequency	Responsibilities	Reviewer
Verification activity scheduling	Yearly or upon HACCP system change	HACCP coordinator	Plant manager
Initial validation of HACCP plan	Prior to and during initial implementation of a plan	Independent experts[(a)]	HACCP team
Subsequent validation of HACCP plan	When critical limits changed, significant changes in process, equipment changed, after system failure, etc.	Independent experts[(a)]	HACCP team
Verification of CCP monitoring as described in the plan (e.g., monitoring of patty cooking temperature	According to HACCP plan (e.g., once per shift)	According to HACCP plan (e.g., line supervisor)	According to HACCP plan (e.g., quality control)
Review of monitoring, corrective action records to show compliance with the plan	Monthly	Quality assurance	HACCP team
Comprehensive HACCP system verification	Yearly	Independent experts	Plant manager

[(a)] Done by others that the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies.

Fig. 8.2.3: Example of a Company Established HACCP Verification Schedule

Principle 7: Establish record-keeping and documentation procedures

Generally, the records maintained for the HACCP System should include the following:

- A summary of the hazard analysis, including the rationale for determining hazards and control measures.
- The HACCP Plan

A brief summary of position responsible for performing the activity and the procedures and frequency should be provided

The following is an example of a HACCP plan summary table:

- Support documentation such as validation records.
- Records that are generated during the operation of the plan.

Examples of HACCP Records

1. Ingredients for which critical limits have been established.
    - Supplier certification records documenting compliance of an ingredient with a critical limit.
    - Processor audit records verifying supplier compliance.
    - Storage records (e.g., time, temperature) for when ingredient storage is a CCP.
2. Processing, storage and distribution records
    - Information that establishes the efficacy of a CCP to maintain product safety.
    - Data establishing the safe shelf life of the product; if age of product can affect safety.
    - Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for food safety.
    - Monitoring records.
    - Verification records.
3. Deviation and corrective action records.
4. Employee training records that are pertinent to CCPs and the HACCP plan.
5. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.

UNIT 8.3: Occupational Health and Safety (OSH) at Workplace

Unit Objectives

At the end of this unit, you will be able to:

1. Apply safety practices in the work area

8.3.1 Scope and Application

Fig. 8.3.1: Microbiological Workplace Safety and Health

Work in the biomedical sciences industry includes basic and clinical research, product and process development and diagnostic procedures that need handling of biological agents. Biological agents include microorganisms, cell cultures and human pathogens, which may well cause infection, allergy or toxic effects.

Other hazards to be expected present include chemical, mechanical and radiation hazards. It is important to bear in mind that any chemical, fire, electrical or radiation accident can result in collapse of containment of infectious biological agents. Hence, for these hazards, high standards of safety must also be maintained.

The guidelines have current international and national containment requirements and operational practices for the control of biohazards. Also included are key features of the safety management system, which reflects occupational health and safety management philosophy, objectives and practices.

These guidelines apply to work in laboratories and production facilities in the biomedical sciences industry.

As exposure to biological agents is the most significant hazard encountered in this industry, the primary objective of the document is to give guidance on minimizing such risks. For the control of chemical, fire, electrical and radiation hazards, the guidelines provide the key principles and make reference to relevant guidelines and legislation.

The work nature, size and safety and health risks in distinct workplaces vary. The elements of the safety management system described in these guidelines should be applied as appropriate and integrated into any existing health, safety and environment management system. The guidelines should be customized for the specific workplace.

8.3.2 OSH Organization and Systems

Employer's Responsibilities

The employer has overall accountability for assessing risks and determining the level of biosafety requirements relating to work practices, safety equipment and the facilities requirements for work involving biological agents.

The employer must guarantee the effective implementation of the elements of the safety management system which are pertinent to the set-up of the laboratory or facility. Standards on these elements should be established and can be integrated into prevailing safety framework in the workplace.

The employer should appoint relevant safety personnel to assist him in the implementation of the safety management system.

Safety Management System

The safety management system would normally cover the following elements:

1. **Safety Policy and Organization**

   An integral aspect of a safety management system is the top management's commitment and its overall safety philosophy.

   The successful implementation of a safety management system is facilitated if everyone understands his or her organizational role. The management should therefore issue a written safety policy comprising:

   - General statement pertaining to its overall safety philosophy for safety commitment; and
   - A description of a logical delegation of responsibility for safety and health from the top management to the workers.

2. **In-house Safety Rules and Regulations**

   Written safety rules and regulations that are relevant to the organization, and in compliance with legal requirements. This involves inculcating in employees, their roles and responsibilities in safety whilst performing their work in the laboratory.

3. **Safety Inspection**

   An effective Programme to carry out sporadic inspection to spot-check, and correct unsafe work practices and conditions.

4. **Hazard Analysis**

   Systematic procedures for identification, evaluation and control of hazards in the laboratory.

5. **Safe Work Practices**

   Set of procedures to ensure that all work is carried out safely and the risks of injury to employees and property/equipment damage are eliminated or minimized.

6. **Control and Use of Hazardous Substances**

   System for the identification and management of all hazardous agents and substances through the establishment of well-defined procedures for their receipt, issuance, storage, handling, use and disposal.

7. **Safety Training**

   Provision of employee training relating to the operations, processes and work as well as maintenance of facilities and equipment to enable them to carry out their jobs safely and efficiently.

8. **Safety Meetings**

   Adequate facilities and effective means for communicating the safety and health message, information and knowledge to all employees, including contractors. Employees at all levels should be encouraged to participate in regular discussion on safety and health issues arising from the workplace.

9. **Testing and Maintenance Programme**

   Effective and practical maintenance regime for equipment and facilities to prevent occurrence of accidents.

10. **Evaluation, Selection and Control of Contractors**

    System or procedures to evaluate, select and control contractors before any work is being awarded so as to ensure that they are aware of and meet their safety obligations.

11. **Accident and Incident Investigation and Analysis**

    Procedures for ensuring that all incidents (accidents and near misses) are investigated promptly and effective and practical remedial measures are taken to prevent recurrence.

12. **Safety Promotion**

    Programmes and activities to create awareness of safety and health among all personnel, instill a positive attitude and behavior, and help create a caring safety culture.

13. **Emergency Preparedness and Plans**

    Written rejoinder to mitigate consequences arising from potential emergency situations and to familiarize employees with the response procedures in the event of an emergency.

14. **Document Control and Review**

    Effective system to document and record the establishment and maintenance of all the elements in the safety management system. This is to facilitate informal and effective retrieval of relevant documents and also enhance the effectiveness of the system reviewing process

15. **Safety Personnel**

    Safety personnel should be appointed to advise management on all occupational health and safety matters including biosafety issues.

16. **Safety Coordinator (Biosafety)**

    Production facilities and laboratories operating at BSL-2 and above should have at least a Safety Coordinator (Biosafety). The safety coordinator should have microbiology / biotechnology or equivalent biomedical education background with relevant working knowledge. He / she should have attended a recognized course in biosafety. The safety coordinator may be a senior staff in the laboratory who performs these duties on a defined part-time basis.

The safety coordinator can serve as technical advisor and liaison officer for existent site safety committee. He/she should help implement the relevant elements of the safety management system.

Safety Officer

Production facilities are required to appoint a registered safety officer in accordance with criteria relating to number of employed persons, as specified in the Factories (Safety Officers) Order. The safety officer shall with assistance from the Safety Coordinator (Biosafety) or members of the safety committee:

- Implement safety training programs such as staff orientation, general safety and biosafety, usage of biological safety cabinet (BSC), animal biosafety, and containment suite training.
- Review safety aspects of all plans, protocols and operative procedures for work involving biological agents.
- Perform risk assessments and develop recommendations for biosafety improvements.
- Discuss infringements of safety code with appropriate persons and investigate accident and take preventive measures.
- Supervise the decontamination, disinfection, and disposal procedures for infectious waste in the facility or laboratory.
- Keep records of safe storage system for all infectious material entering the facility.
- Coordinate emergency response activities.
- Audit the effectiveness of the safety program at suitable regular intervals.

Safety Committee

Facilities handling biological agents employing 50 or more employees should form a safety committee. The committee should consist of the safety officer or coordinator (who will function as the committee secretary), members of the scientific and technical staff and representatives of the senior management. It may also include in its membership other departmental safety personnel or specialist and may at times require advice from independent experts in various associated fields, the local authorities and national regulatory agencies.

Smaller institutions or laboratories may group together to form the safety committee.

The functions of the committee include promotion of occupational safety and health, regular inspection of the workplace and investigation of incidents. The Committee should also oversee the overall facility's biological safety program by developing specific biosafety policies and programs to be used in all the laboratories in the facility.

Engineering and Other Supporting Services

Engineering, maintenance and cleaning personnel entering work area that handle biological agents should adopt the personal protection procedures in accordance with the biosafety level requirement. Preferably, these personnel should be staff of the laboratory who are familiar with the work operations and the safety requirements. However, when external personnel (e.g., contract cleaners, supplier service engineers) are engaged for the work, they should be made aware of the hazards and trained in the safe work procedures. External personnel entering and working in Biosafety Level (BSL) 3 and 4 laboratories should work under the supervision of the safety coordinator or other competent laboratory personnel.

Safety Training

A continuous on-the-job safety training Programme is essential among the laboratory and support staff. All employees should be equipped with the required skills, knowledge and safety information related to the operations, work processes and maintenance of facilities and equipment to enable them to carry out their jobs safely and efficiently.

The management with the assistance of the safety coordinator should analyses the occupational safety and health training needs for all employees.

A comprehensive safety-training Programme should be established in the organization. This Programme should include:

- New employee orientation
- Refresher training
- Safety awareness training
- Contractor briefing and training

8.3.3 Training Requirements

Safety Coordinator (Biosafety)

Having attended and passed a recognized short course in biosafety. For safety coordinators operating at BSL-3, additional approved training is required.

Safety Officer

Having attended and passed Safety Officer Training Certificate course

Laboratory Employees

Having attended a minimum of 8 hours of training annually. Additional approved training is required for personnel responsible for managing operations in BSL-3 facilities.

Engineering and Other Supporting Personnel

Having attended and passed a recognized short course in biosafety. For personnel responsible for supervising equipment and facility maintenance for BSL-3 facilities, additional approved training is required.

Health Surveillance and Immuno-prophylaxis

Medical Monitoring

The objectives of the health and medical surveillance are to provide:

- a means of preventing occupationally acquired disease in healthy people by the exclusion of highly susceptible individuals as well as by regular review of those accepted for employment;
- active or passive immunization where indicated;
- a means for the early detection of occupational disease including laboratory-acquired infections and
- to assess the efficacy of protective equipment and procedures.

To achieve the above objectives, a medical surveillance program should be established. The Programme should include:

- identification of exposed workers
- arrangement for medical examinations in accordance with the kind of hazards they are exposed to.
- Evaluation of the results of medical examinations
- Maintenance of medical records.

All employees who are exposed to biological hazards should undergo appropriate pre-employment/ pre-placement interview and immune status check for previous infection. Baseline serum sample may be obtained for employees exposed to microorganisms in Risk Group 2 and above with their consent. Employees who are immunocompromised should not be employed in a Biosafety Level 3 containment laboratory.

Women of childbearing age should be made aware of the risk to the unborn child of occupational exposure to certain microorganisms e.g., rubella virus. The measures taken to protect the fetus will vary depending on the microorganisms to which the women may be exposed.

Health surveillance medical record should be kept for at least 10 years following the end of exposure for employees handling microorganisms in Risk Group 3 and above.

Under the Factories (Medical Examinations) Regulations employees who are involved in activities where they are exposed to certain hazards listed in First Schedule would require to undergo compulsory medical examination. For those exposed to radiation medical examinations should be carried out in accordance with that which is stipulated in the Radiation Protection Act.

Immunoprophylaxis

When indicated, effective vaccines should be made available for those employees who are not already immune to the biological agent to which they are exposed or are likely to be exposed. Vaccination should be given prior to exposure and at specified intervals.

Recommendations for giving less efficacious vaccines and those associated with high rates of local or systemic complications should be carefully considered and not be required for employment.

A written organizational policy is essential. This should define at-risk personnel, specify risks as well as benefits of specific vaccines, and distinguish between required and recommended vaccines. Guidelines given in Ministry of Health's National Immunization Programme and WHO may be adopted.

A complete record of vaccines received on the basis of occupational requirements or recommendations should be maintained in each employee's permanent medical file.

Disease Notification

An employee who is found to be suffering from an infectious disease or is a carrier of the infectious disease should be notified to the relevant authority.

Employee's Responsibilities

Safety and health are also the responsibility of all laboratory and facility employees (including support staff). Employees should not willfully interfere with or misuse any instruments or equipment, which are provided for the health and safety of those in the workplace. Safety devices and personal protective equipment should be used when they are provided. Safe work practices should be adopted so as not to endanger oneself and others. Unsafe acts or conditions should be reported to their superiors or safety personnel.

8.3.4 Control of Biohazards

Classification of Biological Agents

Biological agents are classified into four risk groups that are dependent upon a number of factors. Some of the most important ones are:

- the virulence, pathogenicity, biological stability, mode of transmission, and communicability of the agent;
- the endemicity of the agent;
- the availability of effective vaccines or therapeutic measures.
- the nature or function of the laboratory, the procedures and manipulations involving the agent;

Risk Group 1 (low individual and community risk)

A biological agent that is not known to consistently cause disease in healthy persons or animals.

Risk Group 2 (moderate individual risk, limited community risk)

A pathogen that can cause human or animal disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment. Laboratory exposures seldom cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 3 (high individual risk, low community risk)

A pathogen that typically causes serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another. The disease can be treated by antimicrobial and anti-parasitic agents.

Risk Group 4 (high individual risk, high community risk)

A pathogen that typically produces very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission.

Risk Assessment

Detailed risk assessments shall be carried out for work involving biological agents classified under Risk Group 2 or higher, so as to determine the appropriate biosafety levels required. The risk assessment should take into account the inherent risk factor of the organism and the laboratory operations, which include the following:

- pathogenicity of the agent and infectious dose
- outcome of exposure
- route of infection
- stability of the agent in the environment
- concentration of the agent and volume of concentrated material to be manipulated
- information available from animal studies and reports of laboratory-acquired infections or clinical reports
- laboratory activity planned (concentration, sonication, aerosolization, centrifugation, etc.)
- any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens

Risk assessment should be conducted for all new biological agents to be used in the laboratory and should be reviewed periodically or whenever there is a change in the procedure or protocol that would result in significant deviation from the identified risk and the containment level assigned.

There are various methods of conducting risk assessment in workplaces. A useful reference is the risk assessment guidelines published by Centers for Diseases Control and Prevention (CDC) United States of America.

Specimens for which there is limited information

In situations when the information is insufficient to perform an appropriate risk assessment, a conservative approach to specimen manipulation should be taken. Universal precautions should always be followed, and barrier protection applied (gloves, gowns, eye protection), regardless of the origin of the samples.

Biosafety Level 2 should be the minimum requirement for the handling of such specimens.

The biosafety levels assigned are based on the assumption of typical activities handled by immunocompetent persons. Additional personnel precautions and increased levels of physical containment may be indicated where increased concentrations of biological agents are used or when they are handled by immuno-compromised persons. Special considerations should also be taken where experimental animals are used.

8.3.5 Biosafety Levels

Persons handling infectious agents can be exposed to these agents via numerous ways, such as ingestion, inhalation, contact with non-intact skin or transfer of microorganism to the eyes by contaminated hands. Thus, it is of high priority that these infectious agents must be effectively contained to prevent exposure during handling and transfer.

An important element in the containment of infectious agents or potentially infected materials is strict adherence to safe work practices and techniques. Persons working with these agents must be aware of the potential hazards and is trained and proficient in these practices and techniques required for safe handling. Each laboratory should develop or adopt a relevant biosafety manual that identifies the hazards that employees are exposed to or likely to be exposed to, and specifies practices and procedures to minimize or eliminate the exposure.

All work involving biological agents is classified into four biosafety levels. These biosafety levels describe the general work practices, safety equipment and the facility design required for the safe handling of biological agents.

Laboratories handling biological agents in volume less than 10 liter, should apply the appropriate work practices and requirements as given in this section (BSL). Production facilities and laboratories handling biological agents greater than 10 liters should also apply the requirements given under the Biosafety Level (Large Scale) (BSL).

However, the volume of 10 liter is used only as a general guide to differentiate between laboratory-scale and large-scale production. Where these work practices and requirements are not sufficient to control the hazards associated with any particular biological agent or procedures, additional measures should be adopted as necessary.

Biosafety Level 1

The following procedures and requirements are for the manipulation of biological agents which are not known to result in or consistently cause disease in healthy persons or animals.

Safe Work Practices

- The laboratory should be kept neat, orderly and clean, and storage of materials not pertinent to the work should be minimized.

- Eating, drinking, handling of contact lenses, applying cosmetics, and storing of food for human consumption are not permitted in the work areas.
- Hands should be washed after handling of viable materials, removal of gloves and before leaving the laboratory.
- Mouth pipetting of any substance is prohibited.
- All procedures should be performed in a manner that minimizes the creation of aerosols.
- Disinfectants effective against the agents in use must be available at all times within the laboratory area where biohazardous material is handled.
- Work surfaces must be cleaned and decontaminated with suitable disinfectant when work is completed, at end of the day and after any spill of viable material
- All cultures, stocks, and other regulated wastes must be decontaminated (e.g., by autoclaving) before disposal. Materials to be decontaminated at site away from laboratory should be placed in a durable, leak-proof secondary container or be double bagged
- Used gloves should be removed aseptically and autoclaved with another laboratory wastes before disposal
- An effective insect and rodent control Programme must be implemented.
- Animals not involved in the work of the laboratory should not be permitted in or near the laboratory

Safety Equipment

- Protective laboratory clothing must be properly worn by all personnel entering or working in the laboratory and should not be worn in non-laboratory areas. Closed footwear should be worn.
- Eye and face protection devices must be worn when there is a risk of splashing hazardous materials, flying particles and harmful UV light or other rays.
- Gloves must be worn for all procedures that may involve direct skin contact with toxins, blood or infectious materials. Reusable gloves may be used only when necessary and must be appropriately decontaminated after each use.
- Special containment devices or equipment are generally not required for work with agents assigned to Biosafety Level 1.

Laboratory Facilities

- Laboratory should have impervious open bench top with sink.
- Hand washing facilities should be provided, with at least one preferably located near the exit door.

Biosafety Level 2

Biosafety Level 2 requirements are for the manipulation of biological agents, which may result in human or animal disease, but under normal circumstances, is unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment. Furthermore, laboratory exposure rarely cause infection leading to serious disease. Effective treatment and precautionary measures are available and the risk of spread is limited.

The procedures and requirements of Biosafety Level 1 shall apply to Biosafety Level 2. In addition, the following requirements should be included:

Safe Work Practices

- Access to the laboratory is limited to laboratory personnel and authorized persons only. Laboratory doors shall normally be shut when work is in progress.
- Biohazard signs should be posted on or near to the access door to the work area. Appropriate information supplementary to the warning sign should include the biosafety level required, the contact information supervisor or responsible person, the personal protective equipment and other essential information.
- Needles, syringes and other sharp instruments should be restricted for use only when there is no other alternative. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when fitting.
- Used disposable needles must be carefully placed in conveniently located puncture resistant containers used for sharps disposal. Non disposable sharps must be placed in a hard-walled container for storage and transportation.
- Plasticware should be substituted for glassware whenever possible. Broken glassware should only be handled by mechanical means such as brush and dustpan, tongs or forceps and not directly by hand
- Culture shall be clearly labelled and dated and appropriately stored. They should not be stored for long periods on the bench and should be transferred to a dedicated storage area.

BSL	Agents	Practices	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	• Safe Work Practices	• PPEs: laboratory coats; gloves; face protection as needed	• Impervious open bench top with sink • Handwashing facilities
2	Unlikely to be a serious hazard to laboratory employees, the community, livestock, or the environment They have potential for bloodborne transmission.	BSL-1 practice plus. • Limited access • Biohazard warning signs • "Sharps" precautions • proper storage of cultures	• Class I or II BSCs or other physical containment • devices used for all manipulations of agents that cause splashes or • aerosols of infectious materials; • Autoclave available	BSL-1 plus: • Laboratory design for easy cleaning • Bench top resistance to disinfecting chemicals • Eyewash available and in good condition

BSL	Agents	Practices	Safety Equipment	Facilities
3	May result in serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another	BSL-2 practice plus: • Controlled access. • Entry and Exit protocol • Decontamination of all waste • Infectious agents to be securely sorted inside laboratory	• Class II or III BCSs or other physical containment • devices used for • manipulations of agents; • PPEs: Respiratory protection to be worn when aerosol cannot be safely containing within BSC • Decontamination of lab clothing before laundering	BSL-2 plus: • Physical separation from access • corridors • Self-closing, double-door access • Exhausted air not recirculated to other parts of the building • Directional airflow into laboratory. Supply and exhaust system designed to interlock • Drain traps filled with disinfectants • Structural designed and built to withstand pressure load
4	May result in very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • Only materials required are permitted • All material decontaminated on entry and exit from facility • Viable agents to be stored and transport on non-breakable containers	• All procedures conducted in Class III BSCs or II BSCs in combination • with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Access doors self-locking and lockable • Hand washing sink and eyewash should be automatically operated • Liquid effluents to be decontaminated before discharge • Dedicated non recirculated ventilation system • Exhaust from general room facility to be treated before discharge

Table 8.3.1 Summary of Recommended Biosafety Levels for Infectious Agents

Safety Equipment

- Biological Safety Cabinets Class I or II (BSC) should be used for procedures with a potential for creating significant quantity of aerosols or splashes, high concentration or large volume of infectious agents
- Autoclave should be located within or near to the laboratory to provide convenient access and minimize the need for the transportation of materials

Laboratory Facilities

- Laboratory should be designed to facilitate easy cleaning. Furniture used in the laboratory should be made of material that can be easily decontaminated
- Bench tops should be impervious to water, resistant to acids, alkalis, organic solvents, moderate heat and the chemicals used for decontaminating their surfaces
- Eyewash should be readily available and in good operating condition.

Biosafety Level 3

Biosafety Level 3 requirements are for the manipulation of biological agents, which may result in serious human or animal disease. It has potential for aerosol transmission but does not ordinarily spread by casual contact from one individual to another. The disease can be treated by antimicrobial or antiparasitic agents.

There should be a specific biosafety manual that outlines specific operative procedures. Laboratory personnel should be specifically trained in handling the agents and are supervised by competent persons who are experienced in working with these agents. The procedures and requirements of Biosafety Level 2 shall apply to Biosafety Level 3. In addition, the following requirements apply:

Safe Work Practices

- Access to the laboratory should be controlled and restricted to authorized personnel only. Laboratory doors should be kept closed when work is in progress and locked when the room is unoccupied.
- Entry and exit protocol for persons, animals, equipment, samples, wastes, etc. must be established and followed.
- Personal clothing and items should not be taken into the laboratory.
- Contaminated equipment, wastes, containers and other items should be decontaminated before removal from the laboratory
- All infectious agents should be stored inside the laboratory, unless the same level of biosecurity and biosafety is maintained at the alternative storage location.

Safety Equipment

- Biological Safety Cabinets Class II or III must be used for all manipulation of infectious materials whenever possible
- For work performed outside Biological Safety Cabinet, appropriate personal protective equipment should be used in combination with other physical containment devices (e.g., centrifuge safety cup).
- Efficient respiratory protection e.g., cartridge respirator with High Efficiency Particulate Air (HEPA) filters, Self-Contained Breathing Apparatus, powered air-purifying respirators should be worn when aerosols cannot be safely contained within the Biological Safety Cabinet.

- Equipment specified for Biosafety Level 3 requirements should be used for the process it is meant for in designated areas.
- Laboratory protective clothing must be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes. Front-buttoned standard laboratory coats are unsuitable.
- Laboratory protective clothing must not be worn outside the laboratory, and it must be decontaminated before it is laundered.

Facilities Requirements

- The laboratory should be separated from areas that are accessed by the general public. Access to the laboratory should be through a series of double self-closing doors.
- The interior surfaces of walls, floors and ceilings should be constructed to facilitate easy cleaning and decontamination. Walls, ceiling and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants used. Any penetrations and openings should be sealed or sealable to facilitate decontamination.
- Drain traps should be filled with approved disinfectant
- A ventilation system that establishes a negative pressure in the laboratory should be provided so that there is a directional airflow into the laboratory working area. The exhaust air should not be re-circulated to any other area of the building, and is discharged to the outside with proper filtration (HEPA)
- For laboratories having supply air systems, it should be designed such that the supply air and exhaust systems are interlocked to maintain inward airflow at all times. The proper directional air flow into the laboratory should be verified by regular airflow tests
- The exhaust air from Biological Safety Cabinets (BSC) should be discharged directly to the outside with proper filtration (HEPA). When the exhaust air is to be discharged through the building exhaust system, the air should be properly filtered and connected in such manner that avoid any interference with the air balance of the cabinets or building exhaust system (e.g., thimble unit connection).
- The exhaust air from biological safety cabinets may be re-circulated within the laboratory only if the work procedures do not include the usage of volatile or toxic chemicals and radionuclides. The discharged air must be adequately filtered. The cabinet should be operational and properly maintained.
- The structural design of all surfaces of the laboratory including windows should allow for all air pressure loads imposed by the ventilation fans during normal and restricted inlet operation
- The construction and finish of all of the room surfaces should be selected to ensure substantially airtight construction. Benches, cupboards and engineering services should be either sealed to the room surfaces or mounted on stand-off, thus permitting wipe down access for decontamination. Windows in the laboratory should be closed and sealed

Biosafety Level 4

Biosafety Level 4 requirements are for the manipulation of biological agents, which may result in very serious human or animal disease, often untreatable. It may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact; or has unknown risk of transmission. For such facilities, there should be a site-specific biosafety manual that outlines specific operative procedures. The procedures and requirements of Biosafety Level 3 shall apply to Biosafety Level 4. In addition, the following requirements apply:

Safe Work Practices

- Laboratory must adopt security practices to prevent unauthorized entry into work and storage areas, and the unauthorized removal of materials. Authorized persons must comply with all instructions and procedures for entry and exit
- Persons entering into containment laboratory must remove street clothing and change into dedicated laboratory clothing (including undergarments) and shoes. A decontamination shower is required on exit from the containment laboratory
- Materials not required for the experiment are not permitted in the laboratory
- Supplies and materials should be brought into and out of the laboratory via a pass containment barrier containing suitable decontamination facilities (e.g., double door autoclave, fumigation chamber, air lock or dunk tank)
- Materials that cannot be autoclaved (e.g., heat sensitive equipment) must be sterilized by other proven technologies for sterilization (e.g., chemical or gas sterilization)
- Biological materials in a viable or intact state are to be transferred to a non- breakable sealed primary container enclosed in a non-breakable sealed secondary container for storage and transportation

Safety Equipment

- Biological Safety Cabinet Class III should be used for all manipulation of infectious materials; or if Biological Safety Cabinet Class II is used, it should be used in conjunction with one-piece positive pressure suits

Facilities Requirements

- The laboratory shall either be a separate building or a clearly demarcated and isolated zone within a building. Entry into the laboratory should be via a minimum of double doors incorporating outer and inner change rooms, which should be separated by shower for personnel entering and leaving the laboratory.
- Double door autoclave should be located and sealed on to the outer wall of the containment facility. The autoclave is equipped with interlocking doors to prevent both doors opening at the same time.
- Access doors to the laboratory should be self-closing and lockable.
- Windows should be break resistant.
- Hand washing sink and eyewash should be hands-free or automatically operated
- Internal facility such as light fixtures, air ducts, utility pipes, are to be arranged in such a way that they will minimize dust settling on their surfaces.
- Liquid effluents from laboratory sinks, Biological Safety Cabinets, floor drains and autoclave chambers are to be decontaminated by effective sterilization system (e.g., heat treatment) prior to discharge into the sanitary sewer.
- There should be a dedicated non-recirculated ventilation system. The system is balanced such that the directional airflow is from one with least potential hazard to one with greatest potential hazard. The differential pressure and directional airflow are continuously monitored with alarm to indicate malfunction of the system.
- The exhaust from the general room facility is to be treated by passing it through a HEPA filter prior to discharge to the environment. The discharge direction should be away from occupied spaces and air intakes. The HEPA filters should be located as near as practicable to the source so as to minimize the length of potential contamination to ductwork. The HEPA filter housing shall be designed such that the filters can be decontaminated prior to removal or removable in a sealed gas-tight container for subsequent decontamination or destruction by incineration. The design of the filter housing should facilitate validation of the filter installation

Emergency Response Plan

The laboratory should establish emergency response plan to mitigate consequences arising from potential emergency situations. The plan should cover biological, chemical, mechanical as well as radiation risk, if applicable. The plan should be documented and effectively communicated to all levels of the organization and a copy prominently located near the exits of each laboratory. Laboratory should establish procedures to:

- Identify emergency situations, such as accidents, spillages, failure of critical equipment and natural disasters (e.g., flood), and their impacts. This also includes biological, chemical, mechanical and radiation risks.
- Implement emergency response plans for each level of the organization, with clear scope, roles and responsibilities.
- Identify emergency equipment requirements, including the provision for adequate first-aid facilities and trained first-aid personnel.
- Implement a Programme of drills and exercises to familiarize the staff with the emergency procedures and assess the preparedness of the laboratory for prompt and effective response to emergency.
- Maintain an up-to-date emergency response plan. The emergency response plan should include the following:
- Establishment of Emergency Teams and their duties and responsibilities
- Fire and other services should be involved and told in advance locations containing potentially infectious materials.
- Appointment of Safety Coordinator and/or Safety Officer to coordinate the emergency procedures in accordance with the requirements of the emergency response plan.
- Procedure for notification and raising of alarms. After a flood or other natural disasters, local or national emergency services should be warned of the potential hazards within and/or near laboratory buildings
- Procedure for initial response to emergency situations such as preliminary fire-fighting, first-aid and containment response.
- Procedure for evacuation, rescue and decontamination of personnel.
- Procedure for medical surveillance, clinical management and medical treatment of exposed and injured persons.
- Procedure for epidemiological investigation.
- Capability of in-house resources, such as rescue and medical facilities.
- Capability of nearest Government response agency, their roles and response time to emergency situations.

In addition, contact information of critical personnel (e.g., safety coordinator, safety officer, medical doctor), facilities and relevant authorities should also be prominently displayed at suitable locations such as the exit and near telephones.

Vandalism

Vandalism is usually selective (e.g., aimed at animal houses). Suitable defenses are strong, heavy doors, good locks and restricted entry. Screened windows and intruder alarms are desirable. Action after vandalism is the same as that for other emergencies.

8.3.6 Documentation and Record Keeping

Record keeping is an integral component of the Safety Management System. Proper records would help in the evaluation of the effectiveness of the various components of the Safety Management System. The following is a summary of the types of records to be kept.

Items	Components to be included
Register of Employees who are handling: • Biological agents that can cause undiagnosable disease or have unknown effects • Biologic agents with long duration of incubation • Biological agents which cause sequelae in the long term.	• Type of duties done • Organic agent which is exposed to • Nature and length of the treatment • Accidents and accidents, where applicable • Training and Development • To be held 10 years after exposure ends
Medical Records	Medical examination prior to employment Being immune to exposed agents Records on vaccination

Table 8.3.4 Type of Records to be Kept

Exercise

1. **Underline the necessity of HACCP.**

_____

_____

_____

2. **Write down the principles of HACCP.**

_____

_____

_____

3. **Elucidate the safe work practices.**

_____

_____

_____

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सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation
Transforming the skill landscape

FICSI
Food Industry Capacity and Skill Initiative

9. Manage and Lead a Team

Unit 9.1 - All about Work Ethics and Attitude
Unit 9.2 - Leadership and Team Management
Unit 9.3 - Gender and Disability Sensibility
Unit 9.4 - Practical

FIC/N9004

Key Learning Outcomes

At the end of this module, you will be able to:

1. Discuss about work ethics and attitudes.
2. Describe leadership and team management ability.
3. Explain about gender and disability diversity at the workplace.

UNIT 9.1: All about Work Ethics and Attitude

Unit Objectives

At the end of this unit, you will be able to:

1. Define ethics and workplace ethics.
2. Describe the importance and elements of workplace ethics.
3. Illustrate the ways of fostering good workplace ethics.
4. Understand and cultivate positive attitude.

9.1.1 Meaning of the Term, 'Ethics'

- Ethics is broadly defined as the moral rules or principles of behavior that help us to decide what is right or wrong.
- Ethics are moral codes or principles that guide behavior. Being ethical is not the same as being religious, doing what society feels is acceptable, or following the law.
- Standards of behavior can vary between societies and differ from what is ethical.
- Ethical behavior is not necessarily the same as following the law, but there is a relationship between ethics and the law. The relationship between ethics and the law is like the relationship between the bricks and mortar in a wall.
- In its simplest definition, a system of moral principles is called ethics. They affect how people lead their lives, for life is an unbroken stream of decision-making, and ethics are concerned with what is the right moral choice, for individuals and society.

9.1.2 Workplace Ethics

- Workplace ethics are nothing but the rules and procedures that should be carried out in an office by the employer and the employees to maintain a professional company culture and to build a better relationship with their customers by providing better services.
- Traditionally, work ethic has been understood as a value based on hard work and diligence. Capitalists, for example, suggest 'working hard' is necessary and it results an ability of enhancing one's character. Socialists says that the concept of "hard work" makes the working class into being loyal workers of the elite; and working hard, in itself, is not necessarily an honorable idea, but simply a way to create greater wealth for those at the summit of the economic pyramid.
- An alternative perception suggests that the work ethic is now subverted in a broader, and readily marketed-to society. This perspective has given us the phrase 'work smart.'
- In recent times, many say that a work ethic is now obsolete and that it is no true any longer that working more means producing more, or even that more production leads to a better life this is, of course, not to be confused with quality productivity.

9.1.3 Importance of Workplace Ethics

- Workplace ethics ensures positive ambiance at the workplace, which leads to happy and satisfied employees who enjoy coming to work rather than treating it as a mere source of burden.

- Workplace ethics ensures management guides and mentors their employees well. This is important as it enables management to treat all employees as equal and think from their perspective as well.
- Workplace ethics also go a long way in strengthening the bond among employees and most importantly their superiors. It has been observed that organizations which are impartial to employees, lend a sympathetic ear to their grievances and are employee friendly seldom face the problems of unsatisfied employees and high attrition rate.

9.1.4 Elements of Strong Workplace Ethics

The elements of strong workplace ethics are described in table 9.1.1

Elements	Explanation
Professionalism	This involves everything from how you present yourself in a corporate setting to the manner in which you treat others in the workplace.
Respectfulness	This means remaining poised and diplomatic regardless of how stressful or volatile a situation is.
Dependability	This means always keeping your word, whether it's arriving on time for a meeting or delivering work on time.
Dedication	This means refusing to quit until the designated work is done, and completing the work at the highest possible level of excellence.
Determination	This means embracing obstacles as challenges rather than letting them stop you, and pushing ahead with purpose and resilience to get the desired results
Accountability	This means taking responsibility for your actions and the consequences of your actions, and not making excuses for your mistakes.
Humility	This means acknowledging everyone's efforts and hard work, and sharing the credit for accomplishments.

Table 9.1.1 Elements of Workplace Ethics

9.1.5 Ways to Foster a Good Workplace Ethics

As a food microbiologist, it is important that you clearly define the kind of behaviour that you expect from every team member in the workplace. You should make it clear that you expect employees to display positive work ethics like:

- **Honesty:** All work assigned to a person should be done with complete honesty, without any deceit or lies.
- **Good attitude:** All team members should be optimistic, energetic, and positive.
- **Reliability:** Employees should show up where they are supposed to be when they are supposed to be there.
- **Good work habits:** Employees should always be well-groomed, never use inappropriate language, conduct themselves professionally at all times, etc.
- **Initiative:** Doing the bare minimum is not enough. Every team member needs to be proactive and show initiative.

- **Trustworthiness:** Trust is non-negotiable. If an employee cannot be trusted, it's time to let that employee go.
- **Respect:** Employees need to respect the company, the law, their work, their colleagues and themselves.
- **Integrity:** Each and every team member should be completely ethical and must display above board behavior at all times.
- **Efficiency:** Efficient employees help a company grow while inefficient employees result in a waste of time and resources.

Note

1. Don't get angry when someone tells you the truth and you don't like what you hear.
2. Always be willing to accept responsibility for your mistakes.

9.1.6 Understanding Attitude

- Attitude is a psychological tendency that is expressed by evaluating a particular entity with some degree of favor or disfavor"
- Attitude can be described as your tendency (positive or negative), to think and feel about someone or something. Attitude is the foundation for success in every aspect of life.
- Our attitude can be our best friend or our worst enemy. When you start a business, you are sure to encounter a wide variety of emotions, from difficult times and failures to good times and successes. Your attitude is what will see you through the tough times and guide you towards success.
- Attitude is infectious. It affects everyone around you, from your customers to your employees to your investors.
- A positive attitude helps build confidence in the workplace while a negative attitude is likely to result in the demotivation of your people.

9.1.7 How to Cultivate a Positive Attitude

Attitude is a choice. Hence, it is possible to improve, control, and change our attitude, if we decide we want to! The following tips help foster a positive mindset:

- Remember that you control your attitude, not the other way around.
- Devote at least 15 minutes a day towards reading, watching or listening to something positive.
- Avoid negative people who only complain and stop complaining about yourself.
- Expand your vocabulary with positive words and delete negative phrases from your mind.
- Be appreciative and focus on what's good in yourself, in your life, and in others.
- Stop thinking of yourself as a victim and start being proactive.
- Imagine yourself succeeding and achieving your goals.

9.1.8 Structure of Attitude

Components	Description
Affective Components	Involves a person's feelings / emotions about the attitude object. For example: "I am scared of spiders".
Behavioral (or conative) components	The way the attitude we have influences how we act or behave. For example: "I will avoid spiders and scream if I see one".
Cognitive Components	Involves a person's belief / knowledge about an attitude object. For example: "I believe spiders are dangerous".

Table 9.1.2 Structure of Attitude

9.1.9 How to Conduct Yourself at Workplace

You just can't behave the same way at the office as you behave at home. Your Boss can be your best friend outside the office but at work, you have to respect him and also treat him like your superior. Employee ethics is essential for maintaining discipline at the workplace.

- **Make It a Priority to Be on Time:** Pay attention to the clock. Set alarms if you have to. Show up at least a few minutes before you are supposed to start work and return from your breaks on time.
- **Don't Be a Grump:** Leave your bad mood at the door when you come to work. We all have days when we aren't feeling our best. Remember not to take it out on your boss, your co-workers, and especially your clients. If work is the thing that is causing your bad mood, it may be time to think about quitting your job.
- **Dress Appropriately:** Your appearance should always be neat and clean. Choose the type of clothing your employer requires. If there isn't a dress code, pick attire that is the norm for your place of employment.
- **Watch Your Mouth:** Swearing, cursing, or cussing—whatever you call it—has no place in most workplaces.
- **Offer Assistance to Your Colleagues:** A true professional is willing to help their co-workers when they are overburdened or facing a challenge at work. They aren't afraid to share knowledge, opinions, or simply an extra pair of hands.
- **Try to Stay Positive:** If you see something that should be fixed, give your boss feedback along with a plan for how to make improvements. If you are just complaining for no reason, stop.
- **Learn from Your Mistakes:** In life, no one is immune from mistakes. It's inevitable that workplace mistakes will occur, but acknowledging your errors, making your best effort to correct them, and learning along the way can help you recover and avoid future falters.
- **Give Up on Gossip:** No one expects you to like all of your co-workers, but sharing your negative opinions and personal gossip interferes with productivity.
- **Listen Up:** Just as you should be willing to share your knowledge and talents with your co-workers, you should be equally receptive to the contributions of others.
- **R.E.S.P.E.C.T.:** Independent of level or title, every person in your workplace deserves to be treated with respect. The more respected team members feel, the better you'll be able to communicate and collaborate for optimal results.

UNIT 9.2: Leadership and Team Management

Unit Objectives

At the end of this unit, you will be able to:

1. Define Leadership and understand effective leadership skills.
2. Discuss the benefits of effective leadership.
3. Identify the importance of teamwork.

9.2.1 What is Leadership?

- Some view leadership as a series of specific traits or characteristics. Others see it as comprised of certain skills and knowledge. And some others think, leadership is a process. This view of leadership, as a process, places an emphasis on social interaction and relationship. This is the idea that leadership is a type of relationship, one that typically includes influencing others in a certain direction.
- "Leadership is a process of giving purpose (meaningful direction) to collective effort, and causing willing effort to be expended to achieve purpose."
- "Leadership is about articulating visions, embodying values, and creating the environment within which things can be accomplished."
- Leadership is about figuring out what to do in order to win as a team, and as a company. Leaders believe in doing the right things. They also believe in helping others to do the right things. An effective leader is someone who:
    - Creates an inspiring vision of the future.
    - Motivates and inspires his team to pursue that vision.

9.2.2 Some Critical Leadership Skills

- **Pragmatism:** This means having the ability to highlight all obstacles and challenges, in order to resolve issues and reduce risks.
- **Humility:** This means admitting the mistakes often and early, and being quick to take responsibility for your actions. Mistakes should be viewed as challenges to overcome, not opportunities to point blame.
- **Flexibility:** It is critical for a good leader to be very flexible and quickly adapt to change. It is equally critical to know when to adapt and when not to.
- **Authenticity:** This means showing both, your strengths and your weaknesses. It means being human and showing others that you are human.
- **Reinvention:** This means refreshing or changing your leadership style when necessary. To do this, it's important to learn where your leadership gaps lie and find out what resources are required to close them.
- **Awareness:** This means taking the time to recognize how others view you. It means understanding how your presence affects those around you.

Benefits of Effective Leadership

Effective leadership results in numerous benefits. Great leadership leads to the leader successfully:

- Gaining the loyalty and commitment of the team members.
- Motivating the team to work towards achieving the company's goals and objectives
- Building morale and instilling confidence in the team members
- Fostering mutual understanding and team-spirit among team members
- Convincing team members about the need to change when a situation requires adaptability.

9.2.3 What is Called a Problem and How to Solve a Problem?

What is a Problem

- As per The Concise Oxford Dictionary (1995), a problem is, "a doubtful or difficult matter requiring a solution."
- All problems contain two elements: 1. Goals 2. Obstacles
- The aim of problem solving is to recognize the obstacles and remove them in order to achieve the goals.

How to Solve a Problem?

Solving a problem requires a level of rational thinking. Here are some logical steps to follow when faced with an issue:

Step 1: Identify the problem.

Step 2: Study the problem in detail.

Step 3: List all possible solutions.

Step 4: Select the best solution.

Step 5: Implement the chosen solution.

Step 6: Check that the problem has really been solved.

Important Traits for Problem Solving

Highly developed problem-solving skills are critical for both, business owners and their employees. The following personality traits play a big role in how effectively problems are solved:

- Being open minded.
- Asking the right questions
- Being proactive.
- Not panicking.
- Having a positive attitude.
- Focusing on the right problem.

How to Assess Problem Solving Skills

As a Supervisor, it would be a good idea to assess the level of problem-solving skills of potential candidates before hiring them. Some ways to assess this skill are through:

- **Application forms:** Ask for proof of the candidate's problem-solving skills in the application form.
- **Psychometric tests:** Give potential candidates logical reasoning and critical thinking tests and see how they fare.
- **Interviews:** Create hypothetical problematic situations or raise ethical questions and see how the candidates respond.
- **Technical questions:** Give candidates examples of real-life problems and evaluate their thought process.

9.2.4 Team Management

Teamwork occurs when the people in a workplace combine their individual skills to pursue common goal. Effective teams are made up of individuals who work together to achieve this common goal. A great team is one who holds themselves accountable for the end result.

Importance of Teamwork in Supervisory Success

For an entrepreneurial leader, building an effective team is critical to the success of a venture, an entrepreneur must ensure that the team he builds possesses certain crucial qualities, traits, and characteristics. An effective team is one which has:

1. **Unity of purpose:** All the team members should clearly understand and be equally committed to the purpose, vision and goals of the team.
2. **Great communication skills:** Team members should have the ability to express their concerns, ask questions and use diagrams, and charts to convey complex information.
3. **The ability to collaborate:** Every member should feel entitled to provide regular feedback on new ideas.
4. **Initiative:** The team should consist of proactive individuals. The members should have the enthusiasm to come up with new ideas, improve existing ideas, and conduct their own research.
5. **Visionary members:** The team should have the ability to anticipate problems and act on these potential problems before they turn into real problems.
6. **Great adaptability skills:** The team must believe that change is a positive force. Change should be seen as the chance to improve and try new things.
7. **Excellent organizational skills:** The team should have the ability to develop standard work processes, balance responsibilities, properly plan projects, and set-in place methods to measure progress and ROI.

NOTE:

- Don't get too attached to your original idea. Allow it to evolve and change.
- Be aware of your weaknesses and build a team that will complement your shortfalls.
- Hiring the right people is not enough. You need to promote or incentivize your most talented people to keep them motivated.
- Earn your team's respect.

The Supervision Framework

- The supervisor's overall role is to communicate organizational needs, oversee employees' performance, provide guidance, support, identify development needs, and manage the reciprocal relationship between staff and the organization so that each is successful.

The Supervisors/microbiologist's are responsible for:

- Aligning individual performance expectations with organizational goals.
- Developing performance goals collaboratively with their direct reports.
- Ensuring that performance goals are communicated and current.
- Providing fair, constructive, and timely feedback towards performance expectations and goals
- Aiding, guidance, and coaching support as needed.
- Ensuring that staff has professional development plans in place.
- Conducting performance evaluations according to established systems and policies.

Manage the Team

There are several factors which play an important role in managing teams effectively.

- **Communicating expectations:** For employees to understand what is expected of them, you should communicate expectations in terms of behaviors by explaining what it "looks like or sounds like" when an employee is, for example, behaving "professionally," treating co-workers with "respect," or being "accountable" for his or her work.
- **Effective Delegation:** Successful delegation starts with matching people and tasks, so you first need to explain what your team's role and goals are. think about the skills, experience and competencies within your team, and start matching people to tasks. BALM is a four-stage process that you can use to allocate tasks to the team members who are best placed to complete them successfully. The acronym stands for:
  - Break down broad team goals into specific, individual tasks.
  - Analyze the competencies required to perform each task.
  - List the competencies of each of your team members.
  - Match individuals to task competencies.
- **Create SMART goals for the team:** SMART goals clarify what and when not how or why. They clarify roles and responsibilities so everyone who reads the goals can fully understand the scope and accountability. They identify accountability for task completion. Every SMART goal should have the following five characteristics:

Table 9.2.1 Supervision Framework

S	**Specific**: A single key result to be accomplished; clarifies what and when
M	**Measureable**: The metric and expected performance level/result (e.g. percent increase, completion of project)
A	**Attainable / Achievable**: The goal is attainable; can you actually accomplish the goal?
R	**Relevant**: Employee has control and the ability to effect; aligned with organizational strategic goals
T	**Time-bound**: Expected completion date or when the goal will be achieved

Motivating the team

Different people have different needs when it comes to motivation. Some individuals are highly self-motivated, while others will under-perform without the supervisor's input. A supervisor needs to take care that every individual is motivated enough to produce desired results.

Developing the team

Teams are made up of individuals who have different outlooks and abilities, some may find that the tasks allocated to them are challenging, and they may need support. Others may be "old hands" at what they're doing and maybe looking for opportunities to stretch their skills. Either way, it's the supervisor's responsibility to develop all the team. The most effective way of developing a team is to ensure regular feedback to members.

Managing discipline

When supervisors face a potential discipline issue, one must take time to gather information about the situation, decide what they are going to do, and act. Discipline issues rarely go away of their own accord, and they usually get worse, often causing considerable resentment amongst other team members. Discipline may be subtly different from basic feedback because it doesn't always relate specifically to the employee's work.

Training and development of the team

- **Training New Hires:** When a new employee joins the team, their supervisor should help them understand their role and support them during their transition. This might include providing workplace orientation and explaining company policies or job duties. The supervisor may manage all onboarding activities, or they may work with the human resources department to make sure the new hire receives the guidance and information they need.
- **Training on New Skill:** A supervisor needs to consider the diverse learning abilities of his team and accordingly plan the training instruction.

Development of Team

- Most learning and development don't come from training. Rather, sustainable development comes from on-the-job learning—doing the work while learning how to do the work. Learning from training, unless applied immediately, is lost shortly after the class is over.
- **Professional development through feedback:** Feedback plays an important role in the professional development of the team. Supportive feedback reinforces behavior that is effective and desirable. Supervisors are for often assume that good performance is to be expected and only bad performance should be followed with feedback. The supervisor should discuss what the employee is doing well, thus highlighting characteristics of strong and desired performance.
    - Acknowledge people as soon as possible after you observe the desired performance. Timing is critical to reinforce behavior and encourage more of the same.
    - Be authentic. Provide positive feedback when you can genuinely appreciate the behavior otherwise, you run the risk of appearing patronizing.
    - Be specific; avoid generalities. "Thank you" and "great work" alone is insufficient. What exactly do you appreciate and why? Provide examples and details of how their actions contributed to the desired performance.

- Give feedback in person when able. Email or phone messages can be used only when too much time will lapse between in-person opportunities.
- Be supportive. Do not follow positive feedback with a “but” comment.

- A successful Supervisor:
  - Always supports the team.
  - Assists employees with career advancement.
  - Takes responsibility for your team.
  - Creates a positive team culture.

UNIT 9.3: Gender and Disability Sensibility

Unit Objectives

At the end of this unit, you will be able to:

1. Identify how to promote gender equality at workplace
2. Identify how to communicate with the persons with disability.

9.3.1 Attitude towards Disable People

- Negative attitudes towards PW's continue to challenge their full and equal participation in society. Disrespectful or patronizing language and/or behavior may cause offense and may indirectly or directly impact the inclusion of people with disabilities. Hence, one should always practice basic etiquettes towards the PW's.
- some general instructions for conducting yourself while communicating with a person with disability:
  - Pay attention to what they can do. Do not talk them down by mistaking them to be stupid.
  - Remain considerate but treat all as equals.
  - Maintain dialogue at an adult-to-adult level.
  - Be considerate but never patronize them.
  - Interact with them directly and not with those accompanying them.
  - Discuss and ascertain the required modifications to your workplace by working with people with disabilities.
  - Apologizing for expressions used in everyday language like 'I got to run' or 'see you later' may cause offense. Hence, conversation should be as normal as possible such that you need not remind them of their disability.
  - Always ask before offering help. Never assume that people with disabilities always require help.

9.3.2 Promote gender equality at workplace

- Gender inequality in the workplace has plagued the global economy for many decades; if it is not addressed by integrating women as an integral part of the workforce in general, it loses out on the skills, ideas, improved decision-making, and perspectives that are essential to address the global issues and to harness new scopes and opportunities.
- Gender equality is more than a goal in itself; it is a pre-condition for meeting the challenge of reducing poverty, building good governance, and promoting sustainable development."
- So how to promote gender equality at workplace?
  - Altering Hiring Practices to increase diversity
  - Considering Leadership Roles for both Men and Women.
  - Equal Pay.
  - Prioritizing Work-life Balance.
  - Strict and Effective Policies against Harassment and Workplace Offence
  - Creating an Open-minded atmosphere

UNIT 9.4: Practical

Unit Objectives

At the end of this unit, you will be able to:

1. Plan and schedule activities or task assigned in an organised way
2. Identify potential problems to make sound and timely decisions

9.4.1 Techniques to Plan and Organize Yourself at Workplace

Knowledge and Understanding

- Planning and scheduling activities and organize yourself at the workplace

Method

- Organising and planning are process of completing a given task efficiently and successfully.
- Organising and planning include:

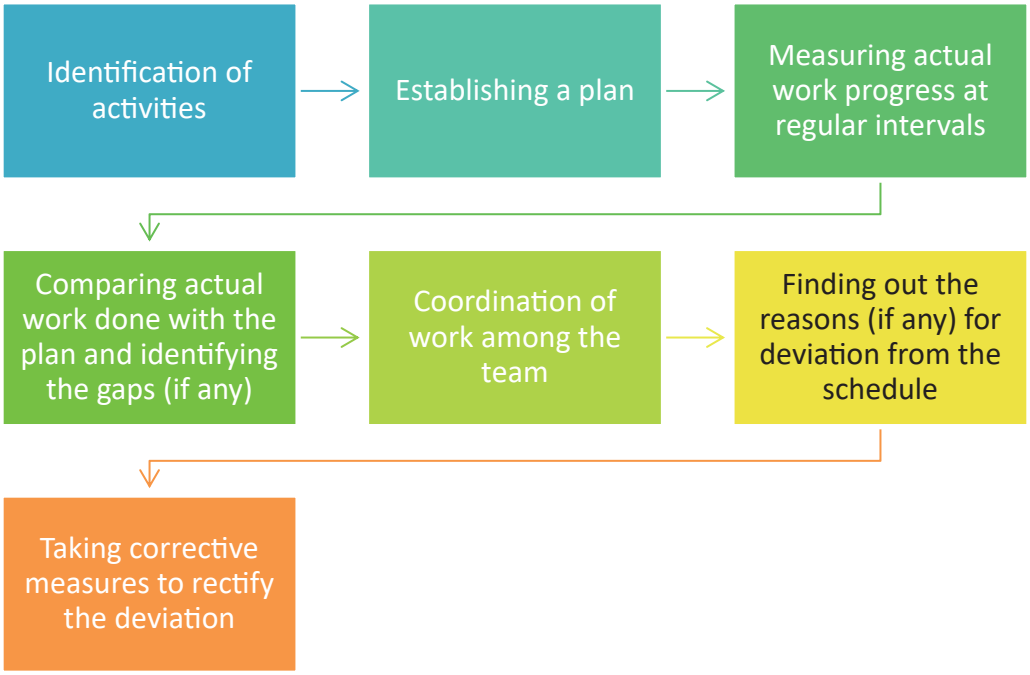

Fig. 9.4.1: Ways to plan and organize yourself

Benefits of Organizing and Planning

1. **Write the benefits of planning.**

_____

_____

_____

2. **Write the benefits of organizing.**

_____

_____

_____

9.4.2 Problem Solving

Knowledge and Understanding

- Analyse problem at the workplace

Method

- A problem is a situation faced by an individual or a group that requires resolution. The apparent path for the solution may or may not be visible to people initially. Problem is what is different between 'what is' and 'what can' or 'should be'.

Writing the problem

1. **Write your problem statement (for e.g.: The output or product is not as per the desired quality and specifications).**

_____

_____

_____

Template to solve the problem

Sl. No	Steps to solve the problem	Notes for the solution
1	**Identify the problem**	
	Identify what is wrong.	
	Speak about it to your peers.	
2	**Analyse the problem**	
	What is the issue?	
	Why did it happen?	
	When did it get noticed?	
	Who is going to get affected by it?	
3	**Set the goals**	
	What do I want?	
	What is the current state and what is the desired state?	
	What are the steps that I should take to resolve the issue?	

Sl. No	Steps to solve the problem	Notes for the solution
	Am I following the steps and finishing on time?	
	What is getting in my way of reaching the desired outcome?	
4	**Evaluate potential solutions**	
	What are the different options that will solve the problem?	
	What are the positive and negative side of each option	
5	**Select the best solution and apply it**	
	Which one do you think is the best solution?	
	How will you apply the best solution?	
6	**Evaluate the applied solution**	
	Was my solution the best one?	
	Did I have a better way of solving the issue?	
	Did I judge the problem correctly?	
	Could I stop the loss?	
	Can I apply this solution next time for a similar problem?	

Exercise

Answer the following Questions

1. Explain the elements of workplace ethics.
2. How to conduct yourself at workplace.
3. Explain the factors of managing the team effectively.
4. How to promote gender equality at workplace?

Quick Recall Quiz

1. Which of the following is true?
   b. Leading is traditionally one of the four management function.
   c. Most important form is leading others.
   d. Most important form is leading oneself.

2. Leading is different than managing.
   True False

3. Gender equality is more than a _____ itself.

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10. Professional and Core Skills

Unit 10.1 - Communications Skills
Unit 10.2 - Decision Making Skills
Unit 10.3 - Listening Skills
Unit 10.4 - Time Management
Unit 10.5 - Self-Assessment
Unit 10.6 - Practical

Key Learning Outcomes

At the end of this module, you will be able to:

1. State communication and feedback skills
2. Understand decision making
3. Demonstrate listening skills
4. Demonstrate time management
5. Understand individual strengths and development needs

UNIT 10.1: Communications Skills

Unit Objectives

At the end of this unit, you will be able to:

1. Understand the process necessary for effective communication.
2. Identify barriers and situations that can inhibit effective communication.
3. Define effective communication process and identify the skills of effective communication.
4. Identify the significance and barriers of effective communication.
5. State the guidelines for giving and receiving instructions.
6. Apply feedback and problem-solving skills.

10.1.1 What do you mean by Communication?

- Communication is the act of being understood. Communication is a process, which involves sharing of information between people through a continuous activity of speaking listening, and understanding.
- Communication is the connection between people but as long as one person is sending a message and another person is understanding it, communication is happening.

10.1.2 What is Effective Communication?

- Effective communication is a process of exchanging ideas, thoughts, knowledge and information such that the purpose or intention is fulfilled in the best possible manner.
- In other words, it is the presentation of views by the sender in a way best understood by the receiver.
- An effective communication generally involves;

  Sender: The person who initiates the process of communication by sending a message;

  Receiver: The one to whom the message is to be delivered.
- It goes through five stages: (1) Interpretation, (2) Encryption, (3) Delivery, (4) Acceptance, and (5) Feedback.
- To achieve the objective of effective communication, the principles of effective communication are also required. To have a smooth communication, it is necessary to use the principle of effective communication. Principles include Respect, Empathy, Audible, Clarity, and Humble.

10.1.3 Characteristics of Effective Communication

Effective communication is more than just delivering a message, it should meet the purpose of the sender. The characteristics or elements of effective communication are:

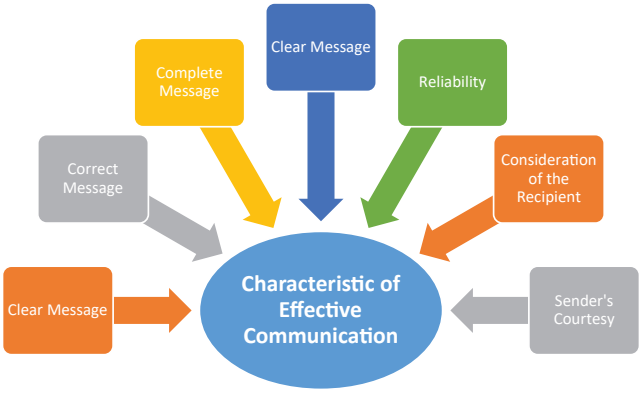

Fig. 10.1.1: Elements of effective communication

10.1.4 Process of Effective Communication

Effective communication, basically, is an activity that is connected with a series of steps that are deliberately undertaken to reach a goal. A communication process comprises the following steps:

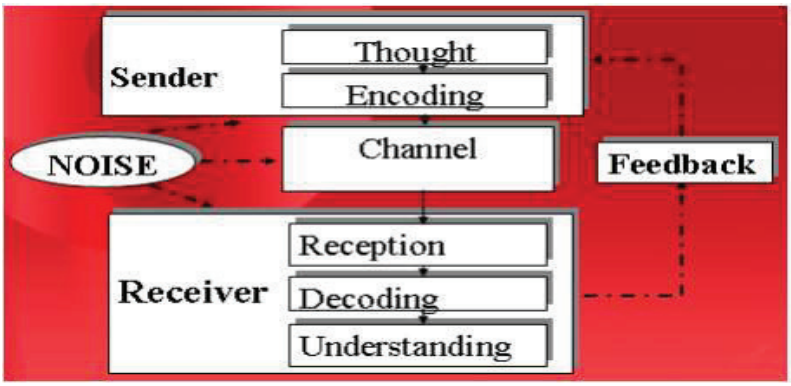

Fig. 10.1.2: Process of Effective communication

10.1.5 Significance of Effective Communication at Workplace

Many writers have identified the following advantages of effective communication at workplace:

- Leads to personal effectiveness.
- Helps to network with people.
- Influences motivation for enhanced performance.
- Builds better understanding between boss and subordinates.
- Creates better interpersonal relations.
- Increases listening ability.

10.1.6 Barriers Effective Communication at Workplace

In the process of communication, caution needs to be exercised as barriers to communication are either consciously or unconsciously created by the sender or the receiver. Some of the barriers to are:

- Over-communication
- Conflicting Information
- Language Differences
- Prejudice
- Differing status
- Interest and attitude
- Prejudgment

10.1.7 Pre-determined skills of Effective Communication

Conveying a message effectively is an art as well as a skill developed after continuous practice and experience. The predetermined set of skills required for an influential communication process are as follows:

Skills	Description
Observance	A person must possess sharp observing skills to gain more and more knowledge and information.
Clarity and Brevity	The message must be drafted in simple words, and it should be clear and precise to create the desired impact over the receiver.
Listening and Understanding	The most crucial skill in a person is he must be a good, alert and patient listener. He must be able to understand and interpret the message well.
Emotional Intelligence	A person must be emotionally aware and the ability to influence others from within.
Self-Efficacy	He/she must have faith in himself and his capabilities to achieve the objectives of communication.
Self-Confidence	Being one of the essential communication skills, confidence enhances the worthiness of the message being delivered.
Respectfulness	Delivering a message with courtesy and respecting the values, believes, opinions and ideas of the receiver is the essence of effective communication.
Non-Verbal Communication	To connect with the receiver in a better way, the sender must involve the non-verbal means communication too. These include gestures, facial expressions, eye contact, postures, etc.
Selection of the Right Medium	Choice of the correct medium for communication is also a skill. It is necessary to select an appropriate medium according to the situation, priority of the message, the receiver's point of view, etc.
Providing Feedback	Effective communication is always a two-way process. A person must take as well as give feedback to bring forward the other person's perspective too.

Table 10.1.1 Effective Communication Skills

10.1.8 Guidelines for Giving and Receiving Instructions at the Workplace

Giving Instructions	Receiving and Following Instructions
• Determine what needs to be accomplished the intended outcome. • Give the reasons for doing the job. • Use concrete action words rather than abstract words. • Have the other person paraphrase the instructions back to you. • Demonstrate the skills in the task if your instructions involve machinery or equipment. • Encourage questions. • Ensure your timing is appropriate. • Follow up as the person does the task on the job. Offer timely and specific feedback.	• Listen carefully. • Focus on the person giving the instructions. • Avoid jumping to conclusions. • Ask questions about the standards to be reached. • Paraphrase to check on your understanding. • Double-check any safety issues. • Ask for help if you feel you do not understand or are unable to follow the instructions.

Table 10.1.2 Guidelines for effective communication at the workplace

10.1.9 Providing Feedback at Workplace

- Feedback is an essential part of successful interpersonal communication. It indicates how well the sender's message is being understood or has been understood by the recipient.
- The importance of feedback cannot be overemphasized.
- Feedback makes communication a two-way process, it indicates effective understanding or misunderstanding of the message, it stimulates further communication and discussion.
- Feedback can be classified in different ways. Such as:
  - Verbal and Non-verbal
  - Positive and Negative
  - Action
  - A combination of any of these

10.1.10 Characteristics of Both Effective and Ineffective Feedback at Workplace

- **Intention:** Effective feedback is directed toward improving job performance and making the employee a more valuable asset it is not a personal attack and should not compromise the individual's feeling of self-worth or image. Rather effective feedback is directed towards aspects of the job.
- **Specificity:** Effective feedback is designed to provide recipients with specific information so that they know what must be done to correct the situation. Ineffective feedback is general and leaves questions in the recipient's minds. For example, telling an employee that he or she is a poor worker.

- **Description:** Effective feedback is descriptive rather than evaluative. It tells the employee what he or she has done in objective terms, rather than presenting value judgement.
- **Usefulness:** Effective feedback is information that an employee can use to improve performance. If it is something that an employee cannot correct, it is not worth mentioning.
- **Timeliness:** Time feedback properly. The more immediate the feedback the better.
- **Readiness:** in order for feedback to be effective, employee must be ready to receive it. When feedback is imposed or forced on employees it is much less effective.
- **Clarity:** Effective feedback must be clearly understood by the recipient.
- **Validity:** Effective feedback must be reliable and valid. When the information employee will feel that the supervisor is unnecessarily biased or the employee may take corrective action that is inappropriate and only compounds the problem.

UNIT 10.2: Decision Making Skills

Unit Objectives

At the end of this unit, you will be able to:

1. Understand the decision-making skills.
2. Outline common techniques of decision making.
3. Identify the importance of teamwork.

10.2.1 What is Decision Making?

A decision is a choice made from various available alternatives.

What are some common techniques do you use for making decisions?

- **Marginal analysis:** This technique is used in decision-making to figure out how much extra output will result if one more variable (e.g., raw material, machine, and worker) is added.
- **Linear programming:** This is a quantitative technique used in decision-making. It involves making an optimum allocation of scarce or limited resources of an organization to achieve a particular objective.
- **Financial analysis:** This decision-making tool is used to estimate the profitability of an investment, to calculate the payback period (the period taken for the cash benefits to account for the original cost of an investment), and to analyze cash inflows and cash outflow.

What is the Importance of Decision Making?

- Efficient utilization of resources
- Problem solving
- Enables business growth
- Effective management of company
- Motivates employees

What are the Steps Followed in Decision Making?

- Awareness of the problem
- Diagnose and state the problem
- Develop the alternative
- Evaluate the alternatives
- Select the best alternative
- Implement the decision
- Verify and incorporate feedback in the decision steps and repeat

UNIT 10.3: Listening Skills

Unit Objectives

At the end of this unit, you will be able to:

1. Define listening.
2. State listening skills improvement.

10.3.1 What is listening?

Listening is the ability to accurately receive and interpret messages in the communication process.

How can you improve your listening skills?

- Face the speaker and maintain eye contact
- Be attentive and relaxed
- Keep an open mind
- Listen to the ideas and feelings behind the words
- Don't interrupt
- Don't provide solutions
- Ask clarifying questions
- Watch for non-verbal cues
- Provide listening cues during the conversation and summarize at the end

UNIT 10.4: Time Management

Unit Objectives

At the end of this unit, you will be able to:

1. Define time management.
2. Discuss the benefits of time management.
3. Identify the tools to improve time management

10.4.1 What is Time Management?

"Time management" is the process of organizing and planning how to divide your time between specific activities.

10.4.2 What are the Benefits of Time Management?

- Good time management enables you get more done in less time.
- Failing to manage your time leads to ineffectiveness and stress.

10.4.3 What are the tools to Improve Time Management?

Make a To-Do list

- Write down all the tasks you need to complete. Break down large tasks into smaller actionable steps.
- Allocate priorities to each task
- Focus on high priority items first and work your way through the list.

UNIT 10.5: Self-Assessment

Unit Objectives

At the end of this unit, you will be able to:

1. Define self-assessment.
2. Discuss how to find your strength and development need.

10.5.1 What is Self-Assessment?

Self-assessment helps individuals monitor their own work or abilities, find out what their weaknesses and strengths are, and self-diagnose relevant solutions.

10.5.2 How can you find your strengths and development needs?

1. Ask yourself questions about what, how, and why you have a problem at doing something or how and why you succeeded in something.
2. Write down the targets for the most important aspects or goals of your work and assess your performance in comparison to each of them.
3. Take an assessment test. There are paid and free tools available online for self- assessment. One popular tool is DISC. A free version of this tool is available on the following site.

UNIT 10.6: Practical

Unit Objectives

At the end of this unit, you will be able to:

1. Choose between two or more courses of action to solve problems quickly and effectively
2. Manage time effectively to complete the tasks assigned

10.6.1 Decision Making

Knowledge and Understanding

- Understanding of decision-making techniques.

Method

- Decision making is an act of choosing between two or more courses of action. There may not always be a 'correct' decision among the available choices. There may have been a better choice that had not been considered, or the right information may not have been available at the time.

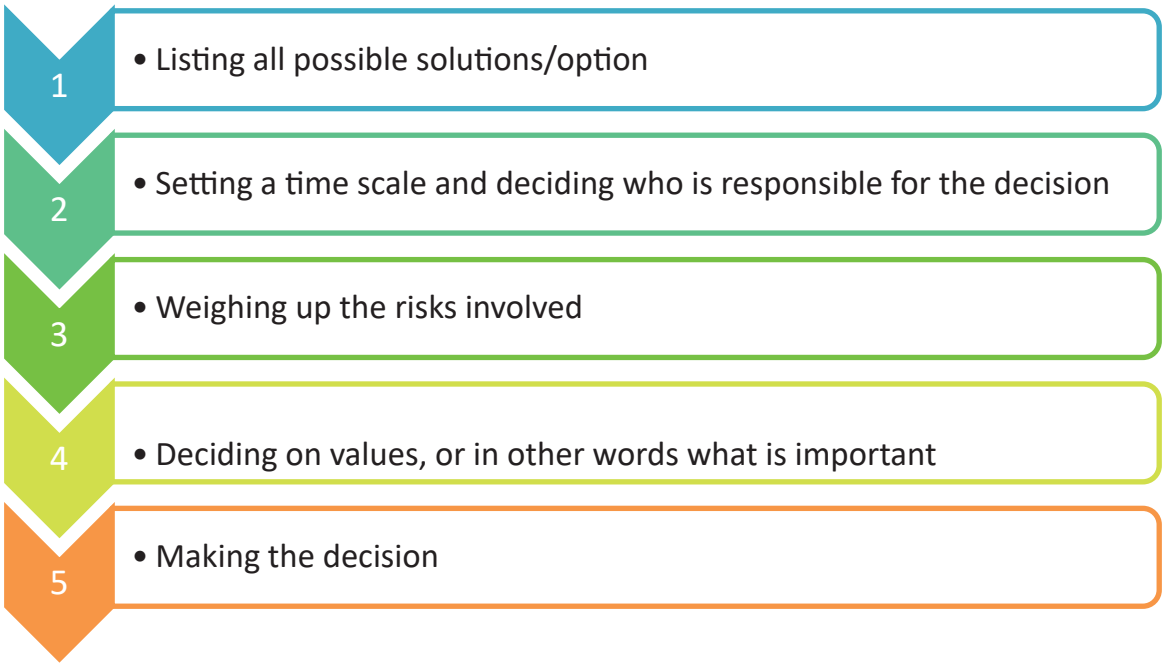

Fig. 10.6.1: Steps of Decision Making

Developing Decision Making Skills

- Answer each of the following questions as honestly as possible.
- Circle your answer for each question.
- Refer to the result table given below and evaluate the result of your answers.

Mark Where you Stand (Tick your answer)						
Sl. No	Decision Making Skills	Strongly Disagree (5)	Agree (4)	Somewhat agree (3)	Somewhat Agree (2)	Strongly Agree (1)
1.	Desire to actively participate in the process of solving/ improving a situation.					
2	Too much analysis of situation results in delaying decision.					
3.	Respect other people's suggestion and recommendations					
4.	Analyse and calculate the risk and problems which may occur after taking a decision.					
5.	Follow workplace rules and guidelines in situations involving high level of risk at work.					
6.	Use your job specification to take appropriate decision.					
7.	Do not hesitate to consult your supervisors and subordinates before arriving to a decision point.					
8.	Do not make workplace decision based on emotions.					

Table 10.6.1 Develop Decision Making Skills

- Evaluate your answers after you complete the above table.
- Check the result for each question if your answer is:

Score	Evaluation	Result
1-3	You need to work hard to develop this quality.	Work hard
4	You possess this quality but need to enhance it for better success.	Keep evolving
5	You possess this quality and this is your strength use it to make timely and effective decision.	Use this strength

10.6.2 Time Management

Knowledge and Understanding

- Planning and scheduling activities and managing your time.

Methods

- It is easy to manage our time effectively, especially if we follow a few simple steps.

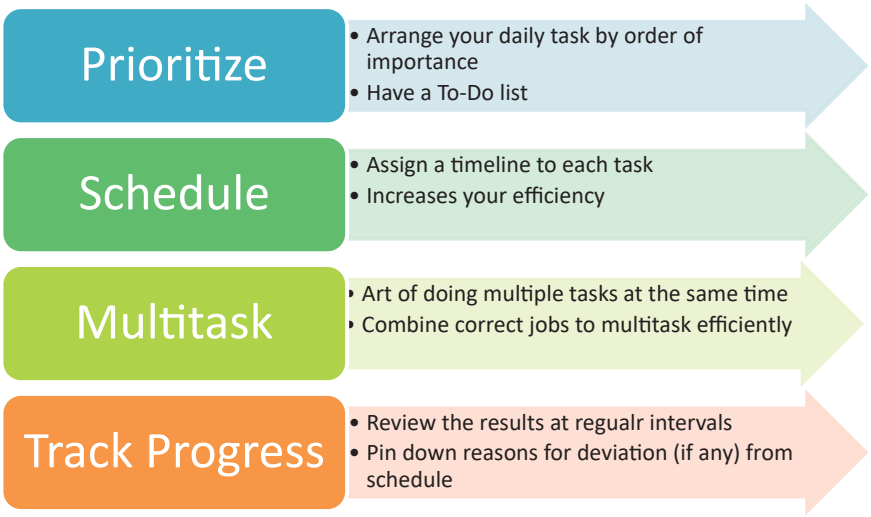

Fig. 10.6.1: Steps to manage your time

- Ask yourself how important and how urgent is the work and then plan accordingly.

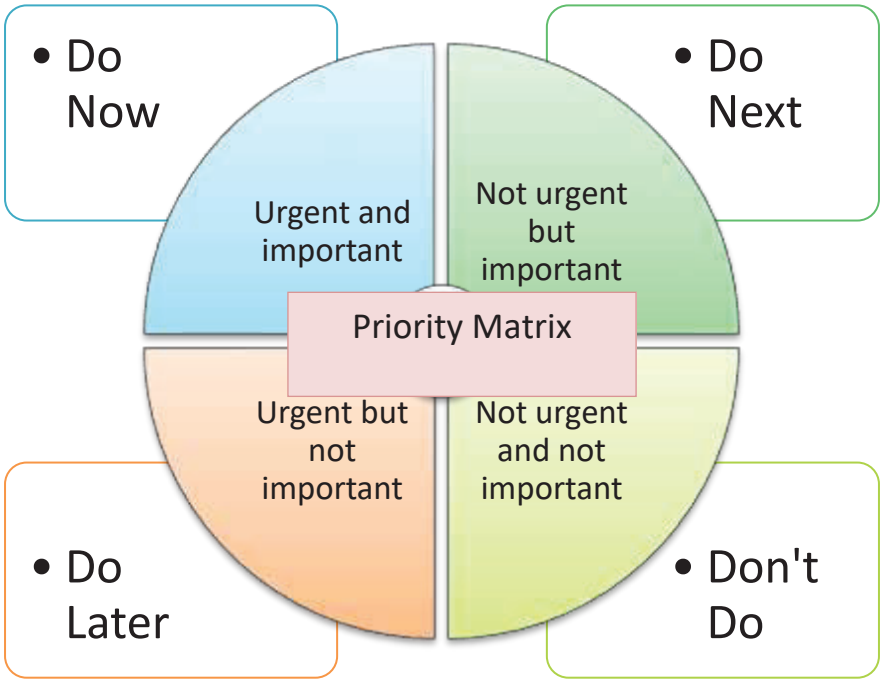

Fig. 10.6.2: Priority Matrix: Ways to Manage Your Time

To-Do List

Create a To-Do list to keep track of the job received identifying the priority.

Sl. No	Date	Job code/ number	Task/ activities	Target completion	priorities

Exercise

Answer the following Questions

1. Describe the effective communication process.
2. Explain the following:
3. Attitude, Effective communication, Leadership skills, workplace ethics.
4. Briefly discuss the assessment process of problem-solving skills.
5. State the three common techniques of making any decisions.

Quick Recall Quiz

1. Effective communication is an activity, that is connected with the?

   _____

   _____

2. Which of the following is not included in elements of communications?

   a. Clear message

   b. Precise message

   c. Incorrect message

3. Attitude is infectious.

   True False

4. Decision making is a choice made from?

   _____

   _____

5. Self-assessment helps to monitor

   a. Others work

   b. Own work

   c. Both

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सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation
Transforming the skill landscape

FICSI
Food Industry Capacity and Skill Initiative

11. IT Skills

Unit 11.1 - Computer and It's Parts

Unit 11.2 - Basics of MS Office

Unit 11.3 - Typing Tutor

Key Learning Outcomes

At the end of this module, you will be able to:

1. Identify the important parts of a computer.
2. Explain the usage of MS Office.
3. Identify the keys on a keyboard to enable faster typing.

UNIT 11.1: Computer and It's Parts

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss about types of computers.
2. Understand the standard parts of a computer.

11.1.1 Introduction

A computer is an electronic machine. It takes instructions from the user in the form of input. It works on the instructions, or in other words, processes the instructions and provides the required results in the form of output. So, we can say that every computer works on this basic principle of Input - Process - Output. At the end of this Unit, you will be able to identify the computer and its parts.

11.1.2 Types of Computer

- Desktop computers (Personal Computers or PCs) are designed for use at a desk or table.
- Laptop computers combine the CPU, screen, and keyboard in a single case. The screen folds down onto the keyboard when not in use. They are light in weight, can run on battery and are easy to carry.

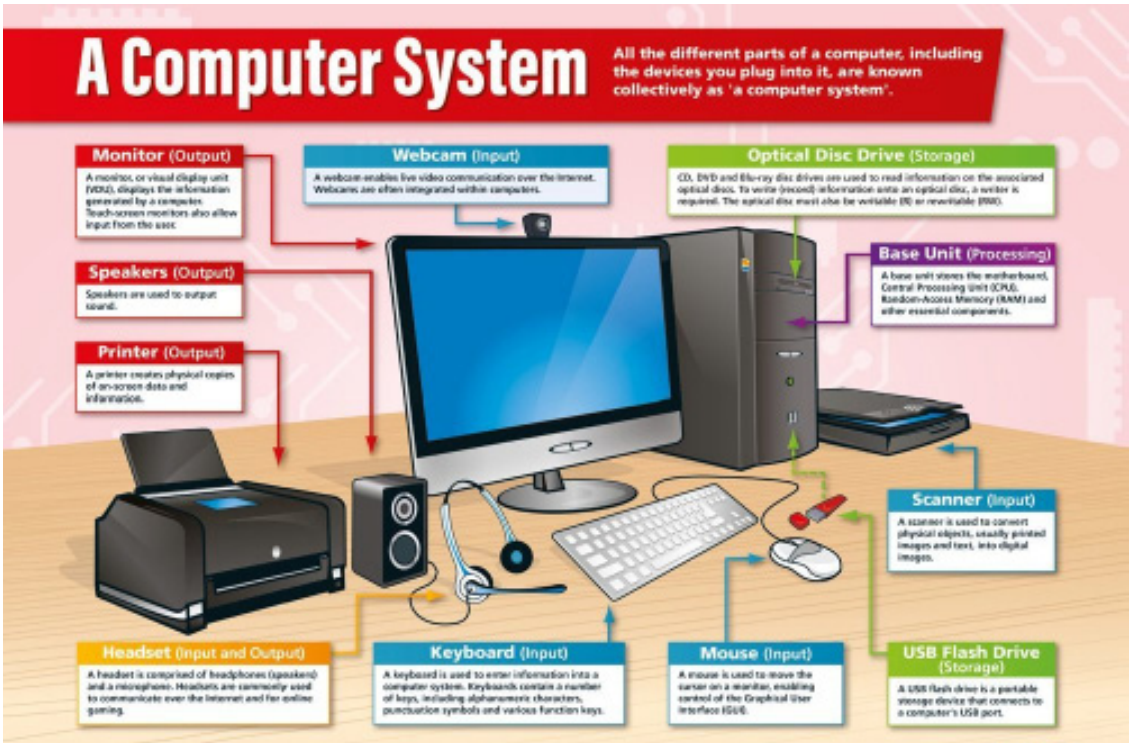

Fig. 11.1.1: A Desktop and Its Peripherals

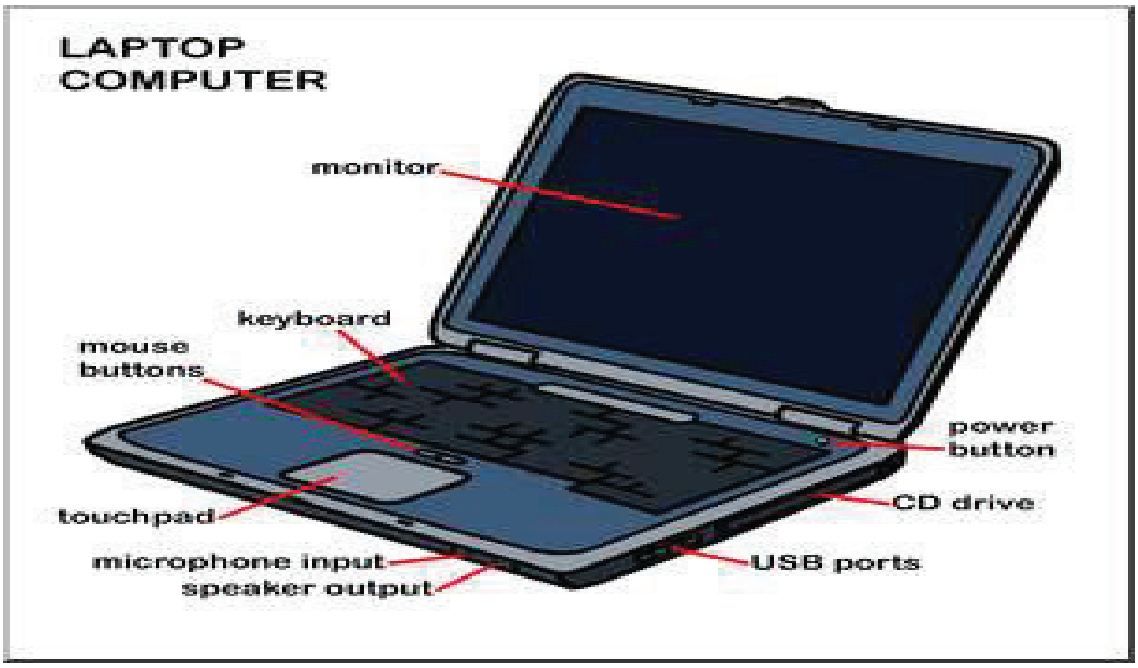

Fig. 11.1.2: A Laptop and Its Parts

- Handheld computers are battery-powered computers and can be carried anywhere. Instead of keyboards, the handhelds have touch screens that you can use with your fingers or a stylus. Figure PCs are mobile PCs, and like laptops, they are powerful and have a built-in screen. You may write notes or draw pictures on the screen with a tablet pen.

Fig. 11.1.3: A Desktop and Its Peripherals

11.1.3 Functions of a Computer

A computer performs five major operations or functions irrespective of its size and make. These are

- Accepts data or instructions as input
- Stores data and instruction
- Processes data as per the instructions
- Controls all operations inside a computer
- Gives results in the form of output

INPUT/ OUTPUT UNITS

- An input device can send data to another device, but it cannot receive data from another device.
- An output device can receive data from another device and generate output with that data, but it cannot send data to another device.
- An input/output device can receive data from users, or another device (input), and send data to another device (output).

Fig. 11.1.4: I/O Devices

Hardware and Software

- There are two terms associated with computers – Hardware and Software, both work in co-ordination to give you the desired output.

Hardware	Software
All the physical devices of the computer put together are referred to as Hardware. You can see them and touch them.	It is a set of instructions, called PROGRAM that instructs the hardware what to do and how to do it. Even to start your computer and make it usable, you need a software called the Operating System. Besides the Operating System, there is various software for typing your documents and letters, for making calculations, managing your data, for emails and so on.

Table 11.1.1 Hardware and Software

Parts of Computer

Keyboard: You can enter data in the computer by typing it using the keyboard. The keyboard, therefore, is called an input device.

Monitor: The monitor is the screen that shows or displays the data that is processed. It looks like a small TV screen and is an output device.

Mouse: The mouse is a pointing device. It is used to point and select items on your computer screen. Just like the keyboard and mouse

Speakers: The speakers play sound. They may be built in the system Unit or can be connected through cables. It is an output device.

Headset: A headset is a headphone combined with a microphone. Headsets provide the equivalent functionality of a telephone handset with hands-free operation. Headsets typically come with speakers for both ears.

Printer: The printer displays the required information on paper. It is an output device.

System Unit: The system Unit is also called the cabinet. It houses many internal parts. It is a house to Central Processing Unit also.

Scanner: The scanner is a device that can be attached to the computer. It is used for scanning documents or images. It is an input device.

Hard Disk: The hard disk is a primary storage device. It stores the data permanently. This means that the data does not get erased even when the computer is turned off.

Fig. 11.1.5: Parts of Computer

11.1.5 Maintenance

- Using computers properly requires positive attitudes of care and maintenance, which are reflected in the way users care for and use computers.
- This will not only help care for college computers but will develop a good attitude of care in students beyond the college and with technology generally.

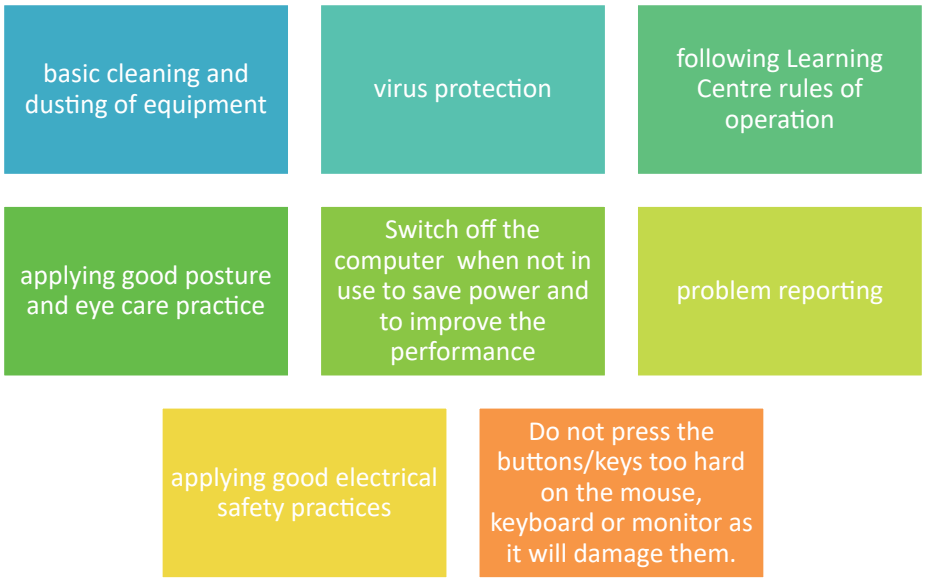

Fig. 11.1.6: Maintenance of a Computer

UNIT 11.2: Basics of MS Office

Unit Objectives

At the end of this unit, you will be able to:

1. Understand about MS Office
2. Discuss the application of MS WORD and EXCEL

11.2.1 Using MS Office

- MS office packages are bundles of programs that help with daily 'office' work.
- It enables writing documents, making extensive calculations, and preparing presentations. In this Unit, you will learn about two programs namely Word and Excel
- Windows provides pictures for all program's user needs to interact with. These small pictures are called icons, which can be clicked to open the desired program.
- As soon as the system is switched on, the interface communicates the status of the operation, which involves switching on or loading of computer processes. For example, the OS displays Starting Windows. The process of opening a computer is called a 'start up'.
- After the start up is complete, Windows displays a dialog box asking to enter a user-name and password. The latter two are unique for every user and is a security feature so that no one else could access your system and inside information. This process is called 'logging in'.
- After you have logged in, you are shown the opening screen of Windows. The opening screen of Windows is called the 'desktop'. There are some icons present on the desktop, which can be clicked.

11.2.2 Using MS Word

- Microsoft Word is a word processor, a program designed to handle a wide variety of pieces of writing.
- It can be used to write a range of documents. It offers a broad range of formatting options and allows us to integrate images, graphs, tables, equations and all sorts of other objects into a document.
- Open Microsoft Word by clicking on its icon on the desktop, or by selecting it from the 'Programs' category of the Start menu.
- Word will start as well if you double-click on any Word document

How will you open a document?	Click Office Button and select Open option.
How will you add text in between the text which already exists?	Place the mouse cursor after the text where you want to add text, enter the text
How will you add a numbered list to your content?	Select the points to which you want to add numbered list, click
How will you add a numbered list to your content?	Select the points to which you want to add a numbered list, click the Numbering button from the Paragraph group.

How will you open a document?	Click Office Button and select Open option.
How will you insert images into your document?	Click the Picture option from the Insert tab. Select the image that you want to add and click the Insert button.
How will you exit from a document?	Click the Office Button and select Exit Word option.
How will you change the font style and font size?	Select the text which you want to change the font style and size. Click Font drop-down list from the Font group select the font style which you want to apply. Click the font size drop-down list and select the font size.
I want to highlight a line in my document, how can I do it?	Select the line to be highlighted, select the Text Highlight Colour option.
How will you set a page margin?	Click the Page Layout tab, click the Page Setup dialog box, set the Top, Bottom, Left, and Right margins.

Table 11.2.1 Basic Functionality of MS Word

11.2.3 Using MS Excel

- Microsoft Excel is a spreadsheet program, a program that allows you to enter all sorts of information, relate the individual bits of information to another, and to use them for calculations and analysis.
- To start Excel, double-click on the Microsoft Excel icon on the desktop. Alternatively, Microsoft Excel appears in the Start menu under 'Programs'.

What is a workbook?	A collection of worksheets is a workbook.
Where do you enter the data?	Data is entered into the cells.
What can you do in Excel?	In Excel, you can calculate data using formulas, analyse them using charts.
Where will you enter the formula and how to enter a formula?	The formula is entered in the Formula Bar, use an equal symbol to start typing your formula.
How will you save an Excel file?	Press CTRL key together to save an Excel file
How will you exit from Excel?	Click the Office Button and select the Exit Excel option.

Table 11.2.2 Basic Functionality of MS Excel

11.2.4 Organizing the System

A file is a computerized document that contains information or data. A folder contains files, programs, and even other folders. While a user has used a system exhaustively, one would create several documents and spreadsheets, etc. Therefore, it becomes important to organize the latter into files and folders so that they can be easily accessed whenever needed. Remember that, the computer can store magnanimous quantities of data. If not organized well, it is very likely for the user to lose important information in this huge pile.

File:

- All the information in a computer is stored as files.
- A file can contain text, graphics or images.
- A file has two parts namely, primary name and extension.
- The primary name is used to identify the file and can be changed.
- The extension of a file is used to identify the application in which the file has been created.
- All files, which are of the same category, can be stored in one location.

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UNIT 11.3: Typing Tutor

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss the basic methodology of typing.
2. Identify different types of keys.

11.3.1 Introduction

- To develop typing skills, one should be familiar with the computer keyboard.
- A computer keyboard has an alphabetic, numeric, function and other special keys.

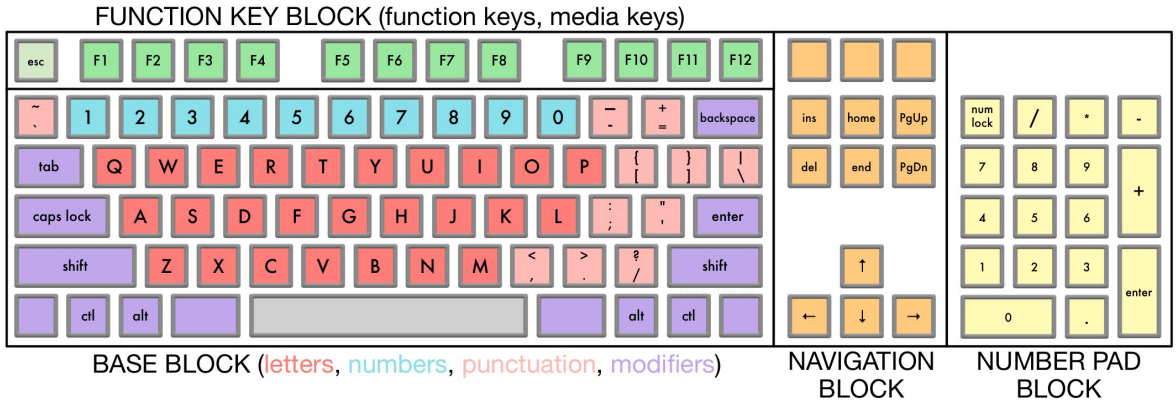

Fig. 11.3.1: Keys on Keyboard

Alphabetical Keys on Keyboard

- The alphabetical keys occupy three rows on the keyboard.
- Use both hands while typing.
- The alphabetical keys correspond to the letters in the English language.

Fig. 11.3.2: Alphabetical Keys and Corresponding Typing Figures

Numeric Keys on keyboard

- The numeric keys on the keyboard enable to enter numbers.
- These keys are used while doing numerical jobs like - some calculations or enter any numbers.
- The numbers keys are located on the Numpad on the right corner of the keyboard. It contains numbers from 0 to 9.

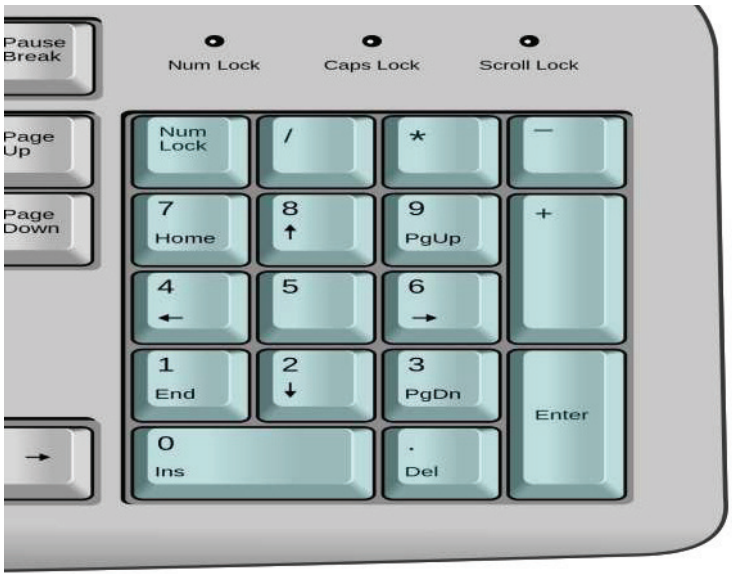

Fig. 11.3.3: Numeric Keys

- Some keys work in combination with numbers keys:
  - Num Lock: The Num Lock is a key that helps to lock or unlock the number keys. A small light on the keyboard next to Num Lock indicates whether the Num Lock is enabled or disabled.

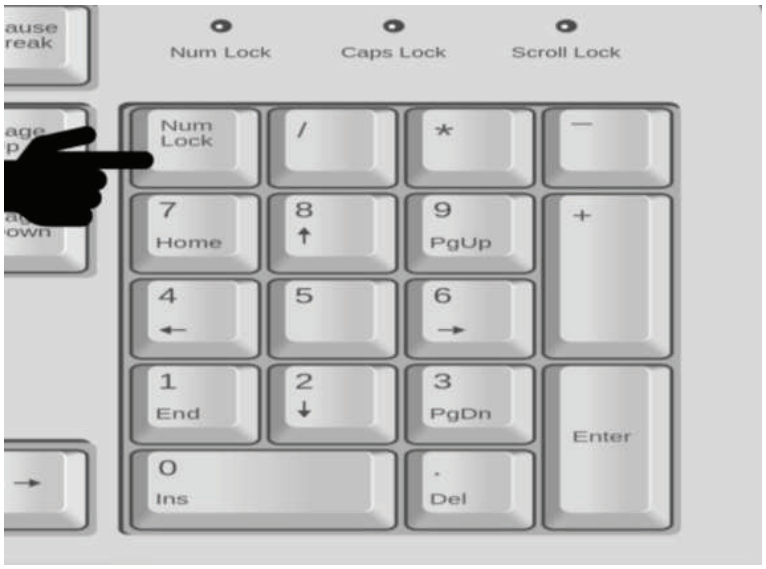

Fig. 11.3.4: Num-Lock Key

- Keys for Calculation, including the decimal point: To make calculations that involve addition, subtraction, multiplication, and division you can use the +, -, *, and / keys, respectively

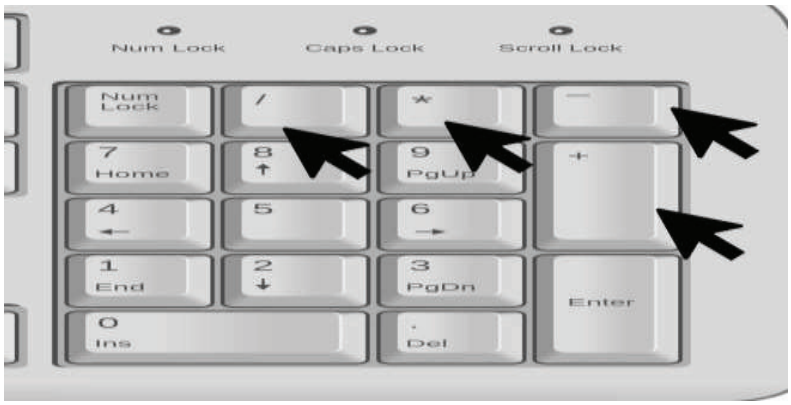

Fig. 11.3.5: Calculation Keys

- Keys with Special Characters: There are some special characters like $, *, &, %, @ they are in the second row on the numeric keys. To use these characters first press Shift key followed immediately followed by pressing the character key.

Fig. 11.3.6: Special Character Keys

Navigation Keys

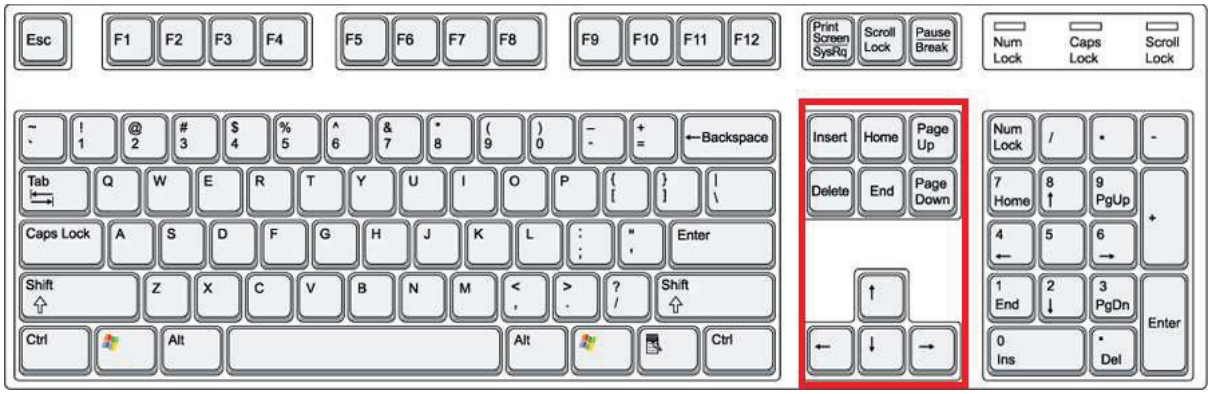

Fig. 11.3.7: Navigation Keys

- **Home:** This key allows you to place the cursor at the beginning of the line.
- **End:** Pressing this key allows you to reach the end of the line.
- **Insert:** This is a toggle key, like Num Lock. By default, the key allows you to insert text or numbers between the lines where the cursor is currently located. However, when the Insert is on, the character where the cursor is blinking will be over-written.
- **Page Up:** Allows you to reach the beginning of the document in which you are working.

- **Page Down:** Allows you to reach the end of the document in which you are currently working.
- **Arrow Keys:** Use the upward arrow key to move one line up, the downward arrow key to move one line down, the right arrow key to move one character towards the right and the left arrow key to move one character towards left.

Editing Keys

- Typing mistakes can be corrected using either the delete or the backspace key.

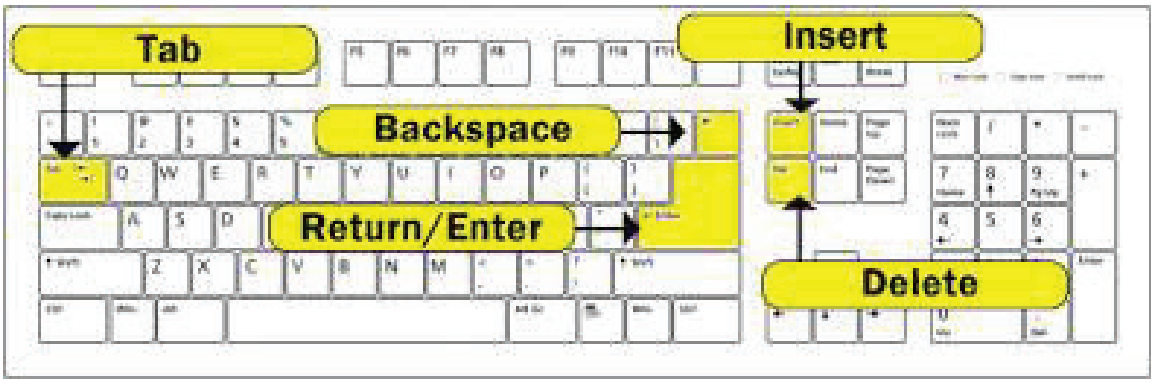

Fig. 11.3.8: Editing Keys

- **Delete Key:** This key allows us to delete the text entered.
- **Backspace Key:** Backspace key is used to delete the text/word. This key deletes the text on the left of the current cursor location.
- **Tab Key** Provides for larger equivalent spacing between words or hops cells.
- **Enter:** To finish the sentence

Exercise

1. Label the parts of a computer

2. What is a difference between a laptop and a desktop?
3. What is MS Word and MS Excel used for?
4. Name any two navigation keys and their functions.

5. List the keys used for editing and their functions.
6. Match the Following:

Headset	Is a pointing device
Printer	Displays data on screen
Hard disk	Permanent storage device
Monitor	Types input
Mouse	Display information on paper
Keyboard	Allows handsfree operation

Activity

1. Try creating a file in all Word and Excel. Then save the file in a folder. Practice by creating at least 3 files and folders for each program.
2. Type the following paragraph in one minute and check for errors. Earlier computer keyboards had been based either on teletype machines or keypunches. There were many electromechanical steps in transmitting data between the keyboard and the computer that slowed things down. By the late '70s and early '80s, all computers used electronic keyboards and VDTs.

Microbiology Practicals

1. Aerobic Mesophilic Plate count

Indicates microbial counts for quality assessment of foods[32]

1.1 Medium:

- Plate count agar;
- Peptone water 0.1%,

1.2 Procedure:

1.2.1 Preparation of food homogenate[33]

- Make a 1:10 dilution of the well mixed sample, by aseptically transferring sample to the desired volume of diluent.
- Measure non-viscous liquid samples (i.e., viscosity not greater than milk) volumetrically and mix thoroughly with the appropriate volume of diluent (11 ml into 99 ml, or 10 ml into 90 ml or 50ml into 450 ml).
- Weigh viscous liquid sample and mix thoroughly with the appropriate volume of diluent (11 + 0.1 g into 99 ml; 10+ 0.1 g into 90ml or 50+0.1 g into 450 ml).
- Weigh 50+ 0.1g of solid or semi-solid sample into a sterile blender jar or into a stomacher bag. Add 450 ml of diluent. Blend for 2 minutes at low speed (approximately 8000 rpm) or mix in the stomacher for 30-60 seconds.
- Powdered samples may be weighed and directly mixed with the diluent. Shake vigorously (50 times through 30 cm arc).

In most of the food samples particulate matter floats in the dilution water. In such cases allow the particles to settle for two to three minutes and then draw the diluent from that portion of dilution where food particles are minimum and proceed.

1.2.2 Dilution:

If the count is expected to be more than 2.5 x 103 per ml or g, prepare decimal dilutions as follows. Shake each dilution 25 times in 30 cm arc. For each dilution use fresh sterile pipette. Alternately use auto pipette. Pipette 1 ml of food homogenate into a tube containing 9 ml of the diluent. From the first dilution transfer 1ml to second dilution tube containing 9 ml of the diluent.

Repeat using a third, fourth or more tubes until the desired dilution is obtained.

1.2.3 Pour plating:

Label all Petri plates with the sample number, dilution, date and any other desired information. Pipette 1ml of the food homogenate and of such dilutions which have been selected for plating into a petri dish in duplicate. Pour into each petri dish 10 to 12 ml of the molten PCA (cooled to 42-45^{O}C) within 15 min from the time of preparation of original dilution. Mix the media and dilutions by swirling gently clockwise, anti-clockwise, backward and forward thrice and taking care that the contents do not touch the lid. Allow to set.

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[32] FSSAI Laboratory Manual "Manual of Methods of Analysis of foods- Microbiological Testing" (https://old.fssai.gov.in/Portals/0/Pdf/15Manuals/MICROBIOLOGY%20MANUAL.pdf)

[33] Official Methods of Analysis of AOAC International (1995). 16th Edition. Edited by Patricia Cuniff. Published by AOAC International. Virginia. USA. Test 17.2.01 p.3-4.

1.3 Incubation:

Incubate the prepared dishes, inverted at 35^{O}C for 48+2 hours. (Or the desired temperature as per food regulation e.g., in case of packaged drinking water).

1.4 Counting Colonies:

Following incubation count all colonies on dishes containing 30-300 colonies and record the results per dilution counted.

1.5 Calculation

In dishes which contain 30-300 colonies count the actual number in both plates of a dilution and as per the formula given below:

$$N = \frac{\sum C}{(N1 + 0.1N2)D}$$

∑ C is the sum of colonies counted on all the dishes retained N1 is the no. of dishes retained in the first dilution

N2 is the no. of dishes retained in the second dilution D is the dilution factor corresponding to first dilution

E.g.

At the first dilution retained (10-2):165 & 218 colonies at the second dilution retained (10-3) 15 & 24

$$N = \frac{165 + 218 + 15 + 24}{\left[2 + (0.1 \times 2) \times 10 \times -2\right]} = \frac{422}{0.022} = 19182$$

Rounding the result to first two digits gives 19000 CFU.

Expression of Result

Aerobic (Mesophilic) Plate Count = 19000 CFU/g or 1.9x104 CFU/g or

If plates from all dilutions have no colonies and inhibitory substances have not been detected, the result is expressed as less than 1 x 101 CFU per g or ml.[34]

If plates from the lowest dilutions contain less than 30 colonies, record the actual number and calculate as above but express results as CFU per g or ml.

Note: - This method, as all other methods, has some limitations. Microbial cells often occur as clumps, clusters, chains or pairs in foods, and may not be well distributed irrespective of the mixing and dilution of the sample. Moreover, the single agar medium used, the conditions of incubation, aeration etc., are not conducive to the growth of various populations of bacteria that may be present in a food sample.

[34] Microbiology- General guidance for the enumeration of Microorganisms-Colony count technique at 350C (first revision) IS5402-2002, ISO4833:1991. Bureau of Indian Standards, Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002

For statistical reasons alone, in 95% of cases the confidence limits of this test vary from ± 12% to ± 37%. In practice even greater variation may be found specially among results obtained by different microbiologists[35]

Aerobic Plate Count Record

Sample number _____ Food type _____

Date received _____ Date analysis initiated _____

Aerobic plate count/g _____ Date reported _____

Dilution	Aerobic plate count	
	Plate 1	Plate 2
10^{-1}		
10^{-2}		
10^{-3}		
10^{-4}		
10^{-5}		
10^{-6}		
10^{-7}		

Record 1: Aerobic Plate Count Record Sample

2. To Determine and Confirm Aciduric Flat Sour Spore Formers in Foods

The organism of this group is Bacillus coagulans. It is responsible for spoilage of canned products.

2.1 Culture Media:

Dextrose tryptone agar (with bromocresol purple)

2.2. Procedure:

Weighed samples or dilutions of the sample are taken in a test tube and heat shocked at 880C for 5 min. The sample tubes are immediately cooled and one ml of the heat shocked sample or decimal volume is transferred to petri plates. 18 to 20 ml of melted bromocresol purple agar is added. After mixing the plates are incubated at 55^{O}C for 48h.[36]

[35] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser Eds. Washington D.C. p. 75-87.

[36] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser Eds. Washington.D.C.p.291-295.

Surface colonies on dextrose tryptone agar will appear slightly moist, usually slightly convex and pale yellow. Subsurface colonies on this medium are compact with fluffy edges. Colonies are surrounded by a yellow zone. Suspected colonies are counted and expressed as number per g of the sample.

2.3 Calculation

Average plate count x dilution factor = X

2.4 Expression of Result[37]

Aciduric flat sour spore formers = X/g

3. Detection and Determination of Bacillus cereus in Foods, and Beverages

3.1 Culture media and reagents

- Mannitol-egg yolk-polymyxin (MYP) agar
- Trypticase-soy-polymyxin broth
- Phenol red dextrose broth
- Nitrate broth
- Nutrient agar slants and plates
- Nutrient agar with L-tyrosine
- Nutrient broth with lysozyme
- Modified Voges- Proskauer medium (VP)
- Motility medium
- Nitrate test reagents
- Voges- Proskauer test reagents

3.2 Procedure

3.2.1 Preparation of food homogenate[38]

Prepare as directed in 3.2.2

3.2.2.1 Dilution

Prepare decimal dilutions by pouring 1ml in 9 ml of dilution water.

3.2.2.2 Most Probable Number Method

This procedure is suitable for the examination of foods which are expected to contain fewer than 1000 B. cereus per g.

[37] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser Eds. Washington.D.C.p.291-295.

[38] Official Methods of Analysis of AOAC International (1995). 16th Edition. Edited by Patricia Cuniff. Published by AOAC International. Virginia. USA Test 17.8.01 p.52-54.

- Inoculate each of three tubes of trypticase-soy-polymyxin broth with 1 ml food homogenate and its dilutions.
- Incubate at 30°C for 48 hours.
- Examine for dense growth typical of B. cereus
- Vortex-mix and using a 3mm loop transfer one loopful from each growth positive tube to dried MYP medium plates. Streak to obtain isolated colonies.
- Incubate at 30°C for 48 hours
- Pick one or more eosin pink (mannitol fermentation positive) colonies surrounded by precipitate zone (due to lecithinase activity) from each plate and transfer to nutrient agar slants for confirmation tests.
- The confirmed B. cereus count is determined using the MPN Table 4 of Test No. 10 for coliform count. On the basis of the number of tubes at each dilution in which B. cereus was detected and reported as MPN of B. cereus per gram.

3.2.2.3 Plate Count Techniques

This procedure is suitable for the examination of foods expected to contain more than 1000 B. cereus per gram.

Inoculate duplicate MYP agar plates with the homogenate and each dilution of homogenate by spreading 0.1 ml evenly on to each plate in duplicate with sterile bent glass streaking rods (hockey sticks). Incubate plates 24 hours at 30°C.

3.2.2.3 Counting Colonies

The number of eosin pink colonies surrounded by lecithinase zone are counted. If reactions are not clear, incubate plates for added 24 hours before counting. Plates must ideally have 15-150 colonies. Five or more colonies of presumptive B. cereus are picked from plates and transferred to nutrient agar slants for confirmation (3.5).

3.2.2 Confirmation Techniques Gram Stain

Incubate the streaked nutrient agar slant either from for confirmation for 24 hours at 30oC. Make Gram stain and examine under microscope. B. cereus will appear as large Gram-positive bacilli in short to long chains; spores are ellipsoidal, central to sub-terminal and do not swell sporangium.

Biochemical tests[39]

Transfer 3 mm loopful of this culture to a tube containing 0.5ml sterile diluent. Vortex mix. Inoculate (or streak) the suspended culture into the following media and read the biochemical reaction.

[39] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser Eds. Washington. D.C. p.593 – 603.

Media	Incubation at 35°C	Typical Reaction
Phenol red dextrose broth	Incubate anaerobically for 24 hours	Acid produced (color changes from red to yellow).
Nitrate broth	For 24 hours	Reduces nitrates to nitrites
Modified VP Medium	For 48 hours	Positive
Nutrient agar with Tyrosine	For 48 hours	Positive
Nutrient broth with lysozyme	For 24 hours	Growth positive

Table 3: Biochemical tests

3.3. Reporting:

After confirmation, the number of B. cereus colonies is multiplied by the reciprocal of the dilution that the countable plate represents (It should be noted that the dilution factor is 10-fold higher than the sample dilution since only 0.1 ml was plated) and report as B. cereus/gram.

3.4 Expression of Results[40]:

Bacillus cereus= Present/Absent

4. Detection and Determination of Anaerobic Mesophilic Spore formers

4.1 Media

Tryptone sulfite cycloserine agar (TSC), Cooked meat medium

4.2 Procedure[41]

Inoculate 2 g of food sample into 15 to 20 ml of cooked meat medium in duplicates. Incubate at 35o for 24 h.

Positive tubes showing turbidity and gas production are streaked on to TSC agar plates. Overlay with TSC agar. Incubate plates upright, anaerobically for 18 to 20 h at 35°C.

Count all colonies that are black in color surrounded by a zone of precipitate.

4.3 Confirmation[42]

Inoculate a portion of the selected black colony from TSC agar on to motility nitrate agar and lactose gelatin agar by stabbing. Also inoculate a tube of fluid thioglycolate medium. Incubate at 35°C for 24 h.

[40] Bacteriological Analytical Manual (1992) 6th Edn. Arlingon. V.A. Published by Association of Official Analytical Chemists for FDA, Washington.D.C.p.191-198.

[41] Official Methods of Analysis of AOAC International (1995). 16th Edition. Edited by Patricia Cuniff. Published by AOAC International. Virginia. USA. Test No. 17.7.02 p. 48 – 50.

[42] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 623 – 635.

Observe microscopically the culture growing in thioglycolate media for the presence of large gram-positive rods. The culture is non-motile and growth therefore occurs only along the line of inoculum in mobility nitrate agar, and they are positive for reduction of nitrate to nitrite which is indicated by the development of red or orange color of the medium. On lactose gelatin medium, the culture shows positive reaction for fermentation of lactose as indicated by gas bubbles and change in color of medium from red to yellow. Gelatin is liquified by C. perfringens.

4.4 Calculation

NA

4.5 Expression of Result[43]

Clostridium perfringens = present/absent

5. Detection, Determination and Confirmation of Coliforms, Fecal coliforms and Escherichia coli in Foods and Beverages.

5.1 Procedure

5.1.1 Test for Coliforms

Coliforms in foods may be enumerated by the solid medium method or by the Most Probable Number (MPN) method.

5.1.1.1 Solid medium method

Preparation of food homogenate Prepare as directed under 1.4.1

5.1.1.2 Dilutions

Prepare as directed under 1.4.2

5.1.1.3 Pour Plating

Pipette 1ml of the food homogenate (prepared sample) and of each dilution into each of the appropriately marked duplicate petri dishes.

Pour into each petri-dish 10-12 ml of VRBA (tempered to 48^{O}C) and swirl plates to mix. Allow to solidify. Overlay with 3 to 5 ml VRBA and allow to solidify.

Incubate the dishes, inverted at 35^{O}C for 18 to 24 hours.

5.1.1.4 Counting the colonies

Following incubation, count all colonies that are purple red in color,

0.5 mm in diameter or larger and are surrounded by a zone of precipitated bile acids. Optimally the plates should have 30 to 100 colonies.

5.1.1.5 Calculation

Multiply the total number of colonies per plate with the reciprocal of the dilution used and report as coliforms per g or ml.

[43] Bacteriological Analytical Manual (1992) 6th Edn. Arlington. V.A. Association of Official Analytical Chemists for FDA, WashingtonDC.p.209–214.

5.1.1.6 Most Probable Number method

This method is valuable in those samples where coliform density is low because higher quantity of sample can be used for examination. It is based on probability statistics wherein aliquots of decimal volumes/dilutions of the sample are transferred to several (1 to 5) tubes of specific medium. Positive tubes are scored and the MPN estimate is directly made using the Table 5.

5.1.1.7 Preparation of food homogenate

Prepare as directed under 1.4.1

5.1.1.8 Dilutions:

Prepare as directed under 1.4.2

5.1.1.9 Inoculation

Inoculate each of 3 tubes of LST broth (containing inverted Durham tubes) with 1ml of food homogenate (1:10).

Carry out the same operation from the first (1 in 100) and the second (1 in 1000) dilution tubes. Using a fresh sterile pipette for each dilution.

5.1.1.10 Incubation

Incubate the LST tubes at 35+0.5^{O}C for 24 and 48 hours.

5.2 Presumptive test for coliforms

Record tubes showing gas production after 24 hours and re-incubate negative tubes for further 24 hours. Then record tubes showing gas production.

5.3 Confirmed test for coliforms

Transfer a loopful from each gas positive tube of LST to a separate tube of BGLB broth.

Incubate the BGLB broth tubes at 35+0.5^{O}C for 48+2h.

The formation of gas confirms the presence of coliform bacteria. Record the number of positive tubes that were confirmed as positive for coliform.

5.4 Calculation

Note the MPN appropriate to the number of positive tubes from the table 5.4.

5.5 For example:

3 in 1:10; 1 in 1:100 and 0 in 1:1000. The table shows that MPN = 43 coliforms per g or ml.

Coliforms= present/absent per g

Positive tubes				Positive Tubes				Positive tubes				Positive tubes			
0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN
0	0	0	<3	1	0	0	3.6	2	0	0	9.1	3	0	0	23
0	0	1	3	1	0	1	7.2	2	0	1	14	3	0	1	39
0	0	2	6	1	0	2	11	2	0	2	20	3	0	2	64

Positive tubes				Positive Tubes				Positive tubes				Positive tubes			
0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN	0.1	0.01	0.001	MPN
0	0	3	9	1	0	3	15	2	0	3	26	3	0	3	95
0	1	0	3	1	1	0	7.3	2	1	0	15	3	1	0	43
0	1	1	6.1	1	1	1	11	2	1	1	20	3	1	1	75
0	1	2	9.2	1	1	2	15	2	1	2	27	3	1	2	120
0	1	3	12	1	1	3	19	2	1	3	34	3	1	3	160
0	2	0	6.2	1	2	0	11	2	2	0	21	3	2	0	93
0	2	1	9.3	1	2	1	15	2	2	1	28	3	2	1	150
0	2	2	12	1	2	2	20	2	2	2	35	3	2	2	210
0	2	3	16	1	2	3	24	2	2	3	42	3	2	3	290
0	3	0	9.4	1	3	0	16	2	3	0	29	3	3	0	240
0	3	1	13	1	3	1	20	2	3	1	36	3	3	1	460
0	3	2	16	1	3	2	24	2	3	2	44	3	3	2	1100
0	3	3	19	1	3	3	29	2	3	3	53	3	3	3	>1100

Table 5. Most Probable Number (MPN) per 1 g of sample, using 3 tubes with each of 0.1, 0.01, and 0.001 g portions.

5.6 Test for faucal Coliforms

Proceed as directed from 5.5

Transfer a loopful from each gas positive tube of LST to a separate tube of EC broth.

Incubate the EC tubes at 45.5+0.2°C in water bath for 24+2 hours.

Submerge broth tubes so that water level is above highest level of medium.

Record tubes showing gas production.

5.7 Calculations:

As directed under the test for coliforms.

5.8 Test for Escherichia coli

- Proceed as directed under test for fecal coliforms.

  Streak one plate L-EMB from each positive BGLB tube in a way to obtain discrete colonies.

  Incubate inverted plates at 35 +0.5° C for 24+2 hours.

  Examine plates for typical nucleated dark centered colonies with or without sheen. If typical colonies are present pick two from each EMB plate by touching needle to the center of the colony and transfer to a PCA slant.

  Incubate slants at 35+0.5° C for 18 to 24 hours

  Transfer growth from PCA slants to the following broth for biochemical tests (vide Chapter 4 under Biochemical Tests).

  Tryptone broth: Incubate 24+2 hours at 35+0.5° C and test for indole.

  MR-VP Medium: Incubate 48+2 hours at 35+0.5° C. Aseptically transfer 1ml of culture to a 13x100 mm tube and perform the Voges Proskauer test. Incubate the remainder of MR-VP

culture an additional 48h and test for methyl red reaction.

Koser citrate broth: Incubate 96 hours at 35+0.5° C and record as + or – for growth.

LST broth: Incubate 48+2 hours at 35+0.5° C and examine for gas formation.

Gram stain: Perform the Gram stain in a smear prepared from 18 hours PCA slant. Presence of small red colored rods confirm Escherichia coli.

Compute MPN of E. coli per g or ml considering gram negative, non- spore forming rods producing gas in lactose and classify biochemical types as follows (IMViC) (Table 5.1).

Indole	MR	VP	Citrate	Type
+	+	-	-	Typical E. coli.
-	+	-	-	Atypical E. coli.
+	+	-	+	Typical intermediate
-	+	-	+	Atypical Intermediate
-	-	+	+	Typical Enterobacter aerogenes
+	-	+	+	Atypical Enterobacter aerogenes

Table 5.1: Micro-organism & IMVIC

5.9 Calculations

As per MPN table

5.10 Interpretation

Escherichia coli= x MPN/g

6. Direct Microscopic Count in Tomato Puree, Sauce, Paste, Chutney

- Howard Mold Count
- Bacterial Count
- Yeast and Bacterial Spore Count

Special Equipment

- Howard mould counting slide
- Haemocytometer

The Howard mold counting slide is a thick glass slide with a flat plane of rectangle of 20x15 mm in the middle of the slide, surrounded by a moat flanked on each side by shoulders 0.1mm higher than flat plane surface. The cover glass when placed is supported on the shoulders and leaves a depth of 0.1mm between underside of cover glass and plane surface. In the case of Haemocytometer the flat plane surface is ruled in the form of a square with sides measuring 1mm each. This square is divided into 25 medium size squares and 400 small size squares.

Procedure[44]:

Mold Count

Preparation of sample

Tomato juice: Use juice as it comes from container

Catsup (Ketchup) or sauce: Place 50ml stabilizer solution in 100 ml graduated cylinder, add 50ml well mixed sample by displacement and mix thoroughly.

Stabilizer solution: 0.5% Sodium Carboxy Methyl Cellulose (NaCMC) – place 500ml boiling water in high-speed blender. With blender running add 2.5gms NaCMC and 10ml formalin and blend for 1 minute. Keep in a stoppered bottle (handle the blender carefully because hot materials in the blender create pressure on closure with blender lid).

Puree and Paste: Dilute the sample with stabilizer solution and mix thoroughly so that the refractive index of 1.3448 to 1.3454 at 20oC (or 1.3442 to 1.3448 at 25oC) is obtained.

Preparation of slide

Clean Howard slide so that Newton's rings are produced between slide and cover glass. Remove cover and with knife, blade or scalpel, place portion of well mixed sample upon central disk. Spread evenly over disk and cover with cover glass to give uniform distribution. Discard any mount showing uneven distribution or absence of Newton's ring or spillage of liquid into moat.

Mold count

Place slide under microscope and examine with such adjustments that each field of view covers 1.5 sq.mm obtained by so adjusting draw-tube that diameter of field becomes 1.382 mm2. When such adjustment is not possibly making use of accessory drop in ocular diaphragm with aperture accurately cut to necessary size. Diameter of area of field of view can be determined by use of stage micrometer. When instrument is properly adjusted, volume of liquid examined per field is 0.15 mm^3. Use magnification of 90-125X. Use approximately 200X magnification to confirm identity of mold filament.

Prepare two mounts and count only 25 fields from each, observing in such a manner as to be representative of all sections of mount. Observe each field noting presence or absence of mold filament and recording results as positive when aggregate length of not less than 3 filaments present exceeds 1/6 of diameter of field. In case a single filament is traversing several fields of microscope it is counted as one positive field. For calculations refer 6.3.

Bacterial count

Preparation of sample for bacterial count in the case of a homogeneous food sample such as catsup and sauce involve proper dilutions to facilitate easy identification and counting. Normally a 1:5 dilution would serve the purpose. To 20ml of distilled water in a 25 ml graduated cylinder add 5 ml of sample by displacement and shake thoroughly.

Place the haemocytometer slide under microscope and using 400 to 500 magnification count four small size squares from each corner of ruled chamber and the central medium square (total 20 small squares). For calculations refer 6.3.

[44] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 97-104.

Yeast and Bacterial spore count

The same slide prepared for bacterial counts is used and a total of 200 squares comprising of 80, 40 and 80 from the top, middle and base of ruled chamber respectively is counted. For calculations refer 6.3.

Calculations

Calculation 6.2.A for Mould Count

Calculate proportions of positive fields from results of examination of all observed field and report as percent fields containing mold filaments.

No. of positive fields

Percent positive fields = ---------- 100

No. of fields observed

Calculation 6.2.B for Bacterial count

No. of bacteria in 20 small squares = B

No. of bacteria in 400 small square= (B x 400) / 20 That is - 20 B bacteria

1.0 mm^3 contains - 20 x 10B

1.0 cc contains - 20 x 10 x 10^3 B or 2 x 10^5 B

If the material is diluted five times then the number of bacteria per ml of sample is

=5 x 2 x 10^5B or 10 x 10^5B or 10^6B or B million/cc.

e.g. If B = 20 then the count will be 20 million per cc.

Calculation 6.2.C for yeast and spores

Calculate number of yeasts/bacterial spores per 1/60 mm^3 as follows:

No. of yeasts/spores in 200 small squares = Y

No. of yeast/spores in 400 small squares = (400 x Y)/200 or = 2Y or 0.1 mm^3 contains = 2Y yeast

1.0 mm^3 contains = 2 x 10 Y yeasts

1/60 mm^3 = (2 x 10 x 1 Y yeast)/60

Or 1/3 Y yeasts

If diluted 5 times than 5 x 1/3Y; or

5/3 Y yeasts/bacterial spores per 1/60 mm^3 of the sample.

Expression of Results

Mold Hyphae positive fields =

10^6 per cc Yeast and Bacterial spores=

% Microscopic Bacterial Count =

1/60 mm^3

7. Fermentation Test (Incubation test)

To determine commercial sterility of processed canned foods.

Media:

- Tryptone broth
- Cooked meat medium
- Orange serum broth
- Potato dextrose agar
- APT broth

Procedure[45]

The most reliable test for determining commercial sterility of a container of a product is to incubate that container in an appropriate temperature, long enough to allow any significant microorganisms contained therein to grow and to manifest their presence. This is the incubation or fermentation test.

Routine Production Monitoring

For low acid products destined for storage at temperatures above 40^{O}C, containers from each sampling period or retort load should be incubated at 55^{O}C for 5 to 7 days.

For all other low-acid products incubate at 30^{O}C to 35^{O}C for 10 days. For acid or acidified foods incubate at 25^{O} to 30^{O}C for 10 days.

Examination

Containers may be removed from the incubator whenever outward manifestations of microbial growth appear (e.g., swells or with transparent containers, noticeable product change). At the end of the incubation period, some containers should be opened to detect possible flat sour spoilage by measure of reduced pH as compared to good packs.

Weigh each suspect container to the nearest gram. Subtract the average tare weight of the empty container and determine net weight.

Before opening, the container must be cleaned with detergent and water, rinsed and wiped dry with clean paper towels.

Containers are opened employing aseptic techniques with extra precautions. Note abnormal odor, consistency changes, and frothiness. Measure pH electrometrically or calorimetrically.

Sub culturing of Product Samples

Transfer about 2g of product from each container to media mentioned below. Tubes for anaerobes should be exhausted in flowing steam for an exposure of 20 min and cooled to 55oC prior to inoculation if not freshly prepared and autoclaved. For detection of molds in high acid foods, potato dextrose agar pour plates are prepared. Measure pH of the product and observe product odor and appearance.

[45] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds.WashingtonD.C.p.265-274.

Interpretation of Data

The development of swelled containers may indicate microbial activity. Growth must be confirmed by demonstrating excessive microorganisms by direct smear or by sub culturing or abnormal product (pH, texture, odor, discoloration, evolution of gas).

Swelling may also be due to overfilling; low filling temperatures, improper vacuum closing procedures, incipient spoilage and chemical swells.

Expression of Results

Incubation test Negative/positive when incubated at 30oC/35oC for a period of 10 days.

8. Rope Producing Spores in Flours.

Requirements of the procedure

Culture Media:

Dextrose tryptone agar

Procedure:

Fifty grams of the sample is weighed and transferred to 450 ml of sterile 0.1% peptone water in a blender jar for mixing. Alternately a stomacher may also be used for mixing.

Ten- and one-ml volumes of the peptone water suspension are pipetted into separate 100ml portions of melted dextrose tryptone agar contained in 250 ml flasks and held at 45^{O}C. The flasks and a control flask are submerged in a boiling water bath for 15 mins.

After heating, the flask contents are cooled to about 45^{O}C and contents of each flask is poured into 5 sterile plates in approximately equal volumes. When the agar has solidified, the plates are inverted and incubated at 35^{O}C for 48h.

Calculation

Count as rope producing organisms, the surface colonies that are grey- white, vesicle like, becoming at first drier and finally wrinkled. Add to this count any subsurface colony that displays stringiness when tested. The total colonies on the set of 5 plates from the flask that received 10ml suspension are considered as rope spores per gm of sample.

Expression of Results

Rope spores = /g

9. Detection and Confirmation of Salmonella species in foods.

Culture Media:

- Lactose broth
- Trypticase Soy Broth
- Trypticase Soy Broth Containing Potassium Sulfite at a final concentration of 0.5%.
- Reconstituted Non-Fat Dry Milk
- 1% aqueous Brilliant Green Dye Solution.

- Selenite Cystine Broth
- Tetrathionate Broth
- Xylose Lysine Deoxycholate (XLD) Agar
- Hektoen Enteric Agar (HEA)
- Bismuth Sulphite Agar (BSA)
- Triple Sugar Iron (TSI) Agar
- Lysine Iron Agar (LIA)
- Urea Broth
- Phenol Red Dulcitol Broth
- Phenol Red Lactose Broth
- Tryptone Broth
- KCN Broth
- Malonate Broth
- Buffered Glucose (MR-VP) Medium
- Brain Heart Infusion (BHI) Broth
- Buffered Peptone Water

Procedure:

Preparation of sample and pre-enrichment

Aseptically open the sample container and weigh 25g sample into a sterile empty wide mouth container with screw cap or suitable closure.

Add 225ml of sterile lactose broth to the sample. Buffered peptone water, Trypticase soy broth, and nutrient broth can also be used for pre- enrichment. Make a uniform suspension by blending if necessary. Cap container and let stand at room temperature for 60 min. Instead of lactose broth the recommended pre-enrichment broth for the following food samples is as follows:

Nonfat dry milk and dry whole milk – Sterile distilled water. Add

0.45 ml of 1% aqueous brilliant green dye before incubation. Dried active yeast – Trypticase soy broth

Onion-garlic powder – Trypticase soy broth containing potassium sulfite at a final concentration of 0.5%

Milk Chocolate – Reconstituted nonfat dry milk.

Shake and adjust pH (if necessary) to 6.8±0.2 with sterile 1N NaOH or 1N HCl.

Incubate at 35^{O}C for 24±2 hours

Selective enrichment

Gently shake incubated sample mixture and transfer 1 ml to 10 ml of selenite cystine broth and an additional 1 ml to tetrathionate broth. Incubate 24±2 hours at 35^{O}C.

Selective media plating

Vortex – mix and streak 3 mm loopful of incubated selenite cystine broth on selective media plates of XLD, HEA and BSA. Repeat with 3mm loopful of incubated tetrathionate broth.

Incubate plates at 35^{O}C for 24±2 hours and 48±2 hours. Observe plates for typical Salmonella colonies

On XLD (after 24h) - Pink colonies with or without black centers.

On HEA (after 24h) - Blue green to blue colonies with or without black centers.

On BSA (after 24 to 48h) – Brown, grey or black colonies sometimes with metallic sheen. Surrounding medium is usually brown at first, turning black with increasing incubation time.

Treatment of typical or suspicious colonies

Pick with needle typical or suspicious colonies (if present) from each XLD, HEA and BSA plates. Inoculate portion of each colony first into a TSI agar slant, streaking slant and stabbing butt and then do the same into a LIA slant.

Incubate TSI and LIA slants at 35oC for 24+2 hours and 48+2h respectively. Cap tubes loosely to prevent excessive H2S production.

A Typical Salmonella reaction are:

	TSI	LIA
Slant	Alkaline (red)	Alkaline (Purple)
Butt	Acid (Yellow)	Alkaline (Purple)
H_2S production (blackening in butt)	+ or -	+

A culture is treated as presumptive positive if the reactions are typical on either or both TSI and LIA slants.

Biochemical tests

Using sterile needle inoculate a portion of the presumptive positive culture on TSI slant into the following broths. Incubate at 35^{O}C for the specified period of days and read for Salmonella typical reactions[46].

Biochemical tests

Broth/ Media	Time of incubation	Results
Urea broth	24+2h	Negative (no change in yellow color of medium)
Phenol	red	lactose

[46] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p.371-422.

Broth/ Media	Time of incubation	Results
Broth	48+2h	*Negative for gas and/or acid reaction
Phenol	red	sucrose
Broth	48+2h	*Negative for gas and/or acid reaction
Phenol	red	dulcitol
Broth	48+2h	*Positive for gas and/or acid reaction
Tryptone broth	24+2h	Negative for indole test
KCN broth	48+2h	Negative (no turbidity)
Malonate broth	48+2h	*Negative (green color unchanged)
MR-VP medium	48+2h	Negative for VP test but positive for MR test.

Note: Majority of S. arizonae are atypical for these reactions).

Criteria for discarding Non-Salmonella Cultures

Test(s) or Substrate(s)	Results
Urease test	Positive (purple-red)
Indole test	Positive (red)
Flagellar test (Polyvalent or spicer- Edwards	Negative (no agglutination)
Lysine decarboxylase test	Negative (yellow)
KCN broth	Positive (growth)
Phenol red lactose broth*	Positive (acid and/or gas) **
Lysine decarboxylase test	Negative (yellow)
Phenol red sucrose broth	Positive (acid and/or gas) **
Lysine decarboxylase test	Negative (yellow)
KCN broth	Positive (growth)
Voges-Proskauer test	Positive (red)
Methyl red test	Negative (yellow)

Malonate broth positive cultures are tested further to determine if they are Salmonella arizonae

** Do not discard positive broth cultures if corresponding LI agar cultures give typical Salmonella reactions; test further to determine if they are Salmonella sp. (vide 9).

Serological Tests

To reduce number of presumptive positive cultures (TSI positive and urease negative) carried through biochemical identification tests, the following serological flagellar (H) screening test may be carried out.

Transfer 3mm loopful of culture into 5ml of BHI broth and incubate at 35^{O}C until visible growth occurs (About 4-6 hours).

Add about 2.5ml formalized physiological saline solution.

Test with Salmonella flagellar (H) antisera. Positive cultures show visible agglutination.

Further confirmation can be made by using Salmonella Polyvalent (O) antiserum.

Calculation:

NA

Expression of Result[47]:

Salmonella = Present/Absent per 25 g

10. Detection and Confirmation of Shigella species

Culture media:

- Gram Negative (GN) Broth
- MacConkey agar
- Xylose Lysine Deoxycholate (XLD) Agar
- Triple Sugar Iron (TSI) Agar slants
- Urea Broth
- Acetate Agar Slants
- Carbohydrate Fermentation Media
- Tryptone Broth (for Indole test)
- Buffered Glucose (MR-VP) Medium
- Koser's Citrate Broth
- Decarboxylase Test Media with Lysine or Ornithine
- Motility Test Medium
- Thornley's Semi-Solid Arginine Medium.

Procedure[48]:

Enrichment:

Using aseptic techniques mix or blend if necessary 25 g sample with 225 ml of gram-negative broth. Transfer to a sterile 500 ml bottle.

Adjust pH (if necessary) to 6.0 - 7.0 with sterile 1N NaOH or 1N HCl.

Incubate at 35-37^{O}C for 18 hours.

[47] Bacteriological Analytical Manual (1992) 6th Edn. Arlington. V.A. Association of Official Analytical Chemists for FDA, Washington, D.C.p.51–69.

[48] Bacteriological Analytical Manual (1992) 6th Edn. Arlingon. V.A. Association of Official Analytical Chemists for FDA, Washington, D.C. p. 71 – 76.

Selective streaking:

Transfer a 5 mm loopful of the enrichment broth culture to the surface of MacConkey agar and XLD agar plates and streak to obtain isolated colonies.

Invert and incubate plates at 35-370C for 24+2h. Typical Shigella colonies on XLD agar appear as red or pink colonies usually about 1mm in diameter and on MacConkey agar as opaque or transparent colonies.

Inoculate each suspected colony into TSI agar slant by streaking the slant and stabbing the butt. After overnight incubation at 35-37^{O}C, typical Shigella reaction is alkaline (red) slant and acid (yellow) butt with no H_2S or gas production:

Other Biochemical tests to confirm Shigella

Perform the following biochemical tests on a portion of the suspected culture on the TSI slant noted in 9.7 & 9.8

Test	Reaction
Urease	-
Motility	-
Acetate utilization	-
Gas from glucose	-
IMVIC Reaction	+ + - - or - + - -
Lysine decarboxylase	-
Arginine di- hydrolase	- or +
Ornithine decarboxylase	+ or -

Expression of Results[49]

Shigella = Present / Absent per 25 g of sample

11. Detection, Determination and Confirmation of Staphylococcus aureus.

Culture media:

- Trypticase (tryptic) soy broth with 10% sodium chloride and 1% sodium pyruvate.
- Baird Parker (BP) Medium
- Brain Heart Infusion (BHI) Broth
- Desiccated Coagulase Plasma (rabbit) with EDTA
- Butterfields Buffered Phosphate Diluent
- Plate Count Agar (PCA)

[49] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 423 – 431.

Procedure:

Preparation of food homogenate:

Aseptically weigh 50 g food sample into the sterile blender jar. Add 450ml of diluent (1:10) and homogenize 2 min at high speed (16000-18000 rpm).

Alternately use stomacher for sample preparation

Dilution:

Pipette 10ml of the food homogenate into 90ml of diluent (or 1ml to 9ml) to make a 1:100 dilution. Mix well using a vortex-mixer.

Transfer 1ml from this dilution to a fresh tube of 9ml to give a 1:1000 dilution. Repeat until the desired dilution is obtained.

Most probable number method:

This procedure is recommended for testing processed foods likely to contain a small number of S. aureus.

Inoculation:

Inoculate each of 3 tubes of tryptose soy broth (with 10% sodium chloride and 1% sodium pyruvate) with 1ml of food homogenate.

Carry out the same operation from the first and subsequent dilutions using a fresh sterile pipette each time. Maximum dilution of sample must be high enough to yield negative end point. Incubate at 35^{O}C for 48h.

Surface Streaking:

Vortex mix the tubes from.A.1 and then using 3mm loop transfer one loopful from each growth positive tube to dried BP medium plates. Streak so as to obtain isolated colonies. Incubate at 35-37^{O}C for 48 hours.

Interpretation:

Colonies of S. aureus are typically grey black to jet black, circular, smooth, convex, moist and 2-3 mm diameter on uncrowded plates. Frequently there is a light colored (off-white) margin, surrounded by opaque zone (precipitate) and frequently with outer opaque zone (precipitate) and frequently with outer clear zone; colonies have buttery to gummy consistency when touched with the inoculating needle.

Confirmation techniques:

Using a sterile needle, transfer (noting the dilution) at least one suspected colony from each plate to tubes containing 5ml BHI and to PCA slants.

Incubate BHI cultures and slants at 35^{O}C for 18-24 h.

Perform coagulase test on the BHI cultures. Retain slant cultures for repeat tests.

Reporting:

Coagulase positive cultures are considered to be S. aureus. Now record number of positive tubes (and the respective dilutions) of S. aureus. Report most probable number (MPN) of S. aureus per gram from Table 4 of MPN values.

Surface Plating method:

This method is applicable for general purpose use in testing foods expected to contain > 10 cells of S. aureus per g.

Transfer 1ml of the food homogenate (1:10 dilution) and other dilutions to triplicate plates of BP medium and equitably distribute 1ml inoculum over the triplicate plates. Spread inoculum over agar surface using sterile bent glass streaking rods (hockey sticks).

Incubate plates in upright position in the 35-37^{O}C incubator for about 1 hour or until inoculum is absorbed by medium. Then invert plates and incubate 45-48 hours.

Counting colonies:

Count colonies of typical S. aureus appearance (as described in 19.5.3.3). Test for coagulase production on suspected colonies. Add number of colonies on triplicate plates represented by colonies giving positive coagulate test. Multiply the count obtained by inverse of corresponding sample dilution. Report as S. aureus per gm or ml of the sample.

Expression of result[50]:

Staphylococcus aureus = x/g

Bacteriological Analytical Manual (1992) 6th Edn. Arlingon. V.A. Association of Official Analytical Chemists for FDA, Washington D.C. p. 161 – 165.

12. Detection and Confirmation of Sulfide Spoilage Spore formers in Processed Foods.

Culture Media:

Sulfite agar

Procedure:

For sample preparation and heat treatment follow the steps mentioned for anaerobic thermophilic spore formers. (Test No. 4)

Inoculations of the prepared sample are placed into the sulfite agar medium with a nail. Incubate at 55^{O}C for 24 to 48h in anaerobic jar.

D. nigrificans will appear as jet-black spherical areas, the color due to the formation of iron sulfide. No gas is produced. Colonies can be counted and reported as spores/g of sample.

Calculation:

Number of colonies x dilution factor

[50] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. WashingtonD.C.p.317-323.

Expression of Result

Spores of sulfide spoilage/g

13. Detection and Determination of Thermophilic Flat Sour Spore formers

Culture Media:

Dextrose Tryptone Agar.

Procedure[51]:

Weighed samples or dilution are heat treated at 100^{O}C for 30 min followed by rapid cooling. Aliquots of these solutions are then transferred to petri plates. Dextrose tryptone agar is added and swirled gently to distribute the inoculum. Allowed to solidify. The inverted plates are incubated at 55^{O}C for 48 to 72 hr.

In case of starch samples, the dilutions are added directly to sterile dextrose tryptone agar (100 ml) contained in flasks. The flasks are autoclaved at 5lb for 10min. The flasks are then gently agitated while cooling as rapidly as possible. The entire mixture is distributed equally into 5 plates and allowed to harden. It is then layered with a thin layer of sterile plain 2% agar in water and allowed to harden. The inverted plates are incubated at 50^{O}C to 55^{O}C for 48 to 72 hr.

Flat sour colonies are round, are 2 to 5mm in diameter, show a dark, opaque center and usually are surrounded by a yellow halo in a field of purple.

The colonies are counted and expressed in terms of number of spores per g of the sample.

Calculation:

=Number of colonies x dilution factor

Expression of Result[52]:

Thermophilic flat sour bacteria = x/g

14. Detection and Determination of Pathogenic Vibrio's in Foods

Culture Medium:

- Thiosulphate Citrate Bile Salts Sucrose Agar
- Gelatin Phosphate Salt Broth and Agar.
- Kligler Iron Agar.
- T1 N1 Agar.

Procedure:

Enrichment

Weigh 25g sample and transfer to 225ml of GPS broth. Incubate at 35^{O}C for 6 to 8 h.

[51] Official Methods of Analysis of AOAC International (1995). 16th Edition. Edited by Patricia Cuniff. Published by AOAC International. Virginia. USA

[52] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 299 – 307

Plating:

Prepare dried plates of TCBS and GPS agar medium. Transfer a loopful of the surface growth of the broth culture to the surface of the two-plating medium and streak in a manner that will yield isolated colonies.

Incubate plating medium for 18 to 24 h at 35^{O}C.

Interpretation:

Typical colonies of V. cholerae on TCBS agar are large (2 to 3 mm in diameter) smooth, yellow (occasional slow sucrose fermenters are green), and slightly flattened with opaque centers and translucent peripheries. On GPS agar the colonies have a cloudy zone around them that becomes more definite after a few minutes of refrigeration. In oblique light, the colonies appear iridescent green to bronze colored and finely granular.

Typical colonies of V. parahaemolyticus on TCBS agar appear round, opaque, green or bluish colonies, 2 to 3 mm in diameter.

Confirmation:

Subculture all suspect colonies of V. cholerae on to T1N1 agar and incubate at 35^{O}C for 24h. Stab streak a KIA slant with the culture and incubate the KIA slant overnight at 35^{O}C. V. cholerae cultures have an alkaline (red) slant and an acid (yellow) butt, no gas and no blackening in the butt. Also perform the string test on suspect cultures as follows. Emulsify a large inoculum from the T_1 N_1 agar culture in a large drop of 0.5% sodium deoxycholate in 0.85% saline solution. Within 60 seconds, a mucoid mass forms and this material strings when a loopful is lifted (up to 2 to 3 cm) from the slide. Further confirmation is by serological reactions.

Stab streak suspect colonies of Vibrio on the TSI slant and incubate overnight at 35^{O}C. Typical reaction of V. parahaemolyticus is an alkaline slant and an acid butt but no gas or H_2S production

Results:

Test for pathogenic Vibrio's = Positive/ Negative

Reference:

Official Methods of Analysis of AOAC International (1995). 16th Edition. Edited by Patricia Cuniff. Published by AOAC International. Virginia. USA, Test No. 17.11.01 p. 108 – 110.

Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 451 – 473.

Bacteriological Analytical Manual (1992) 6th Edn. Arlington. V.A. Association of Official Analytical Chemists for FDA, Washington D.C.p.111–121.

15. Estimation of Yeasts and Molds in Foods and Beverages

Media:

- Potato Dextrose Agar
- Mycophilic Agar
- Antibiotic Solution

Procedure[53]:

Prepare food homogenate and decimal dilutions as directed under1.4.1 and 1.4.2 respectively.

Pour plating:

Label all petri plates with the sample number, dilution, date and any other described information.

Pipette 1ml of the food homogenate of such dilutions which have been selected for plating into a petri dish in duplicate.

Acidify PDA or malt agar with sterile 10% tartaric acid to pH 3.5+0.1. Do not reheat medium once acid has been added. Pour 10-12 ml of the agar medium (tempered to 45^{O}C). Mix by swirling and allow to solidify.

(OR)

Add 2ml antibiotic solution to 100ml of plate count, Mycophil or malt agar. Mix and pour 10-12ml of the agar medium tempered to 45^{O}C. Mix by swirling and allow to solidify.

Incubation[54]:

Invert plates and incubate at 20 or 25^{O}C for 2 to 5 to 7 days. Discard plates after seven days of if growth is not observed, observe plates every day and mark the colonies because some time fungal growth spreads to entire plate and mask the colonies. Do not open the plates which are showing fungal sporangia.

Counting colonies:

Count colonies, multiply by the inverse of the corresponding dilution and report as yeast or mold count per g or ml.

Reporting:

Yeast and Mold count = x/g

[53] Compendium of Methods for the Microbiological Examination of Foods. (1992) Carl Vanderzant and Don F. Splittstoesser. Eds. Washington D.C. p. 239 – 249.

[54] Bacteriological Analytical Manual (1992) 6th Edn. Arlington. V.A. Association of Official Analytical Chemists for FDA, Washington D.C. p.227-230.

Annexure-I

Objective: Surfaces Monitoring - Swab Contact Method

Method

- Cut cellulose sponges into pieces approximately 5 x 5 cm and autoclave in individual paper bags.
- Moisten sterilized sponge with approximately 10 ml of nutrient broth or 0.1 % peptone water.
- Using aseptic technique, hold moistened sterile sponge with sterile tongs or sterile gloves and vigorously swab 1 square meter of designated area.
- Place sponge in a sterile plastic bag and add 100 ml of diluent.
- Vigorously massage sponge for 1 minute to release microorganisms.
- Transfer duplicate 1-ml aliquots to plate count agar using the pour plate procedure. Make further dilutions as required.
- Incubate plates at 35° for 48 ± 2 hours.
- Calculate number of microorganisms based on area swabbed, amount of diluent used, and volume of inoculum plated. For example, if 80 colonies are counted from a 1-ml inoculum obtained from a sponge in 100 ml of diluent which swabbed an area of 1 square meter, the count is reported as 8,000 colony forming units per square meter.
- Record these data in a hard-bound record book.

Objective: Surfaces Monitoring - Replicate Organism Direct Agar Contact (RODAC)

Method

- RODAC plates may either be obtained commercially or prepared in the laboratory. To prepare in the laboratory, fill 15 x 100 mm petri plates with plate count agar so that meniscus of agar medium is above the rim of the plate.
- Remove cover of the petri plate and press agar surface to the surface area to be sampled.
- A rolling pressure on the back of the plate is needed to be certain that the entire agar meniscus contacts the sampling area.
- Replace the cover of the petri plate and incubate plates at 35° for 48 +. 2 hours.
- Count colonies and report as number of colonies par sq cm of surface area.

Annexure-II

Objective: Calibration of Microscope

Methods

- Place an eyepiece micrometer grid, 1 mm grid, with lines 10 /µm apart into one of the microscope oculars (10X magnification).
- Place a stage micrometer grid, 2 mm grid, with lines 10 µm apart onto microscope stage.
- Using lowest power microscope objective, focus ocular micrometer onto stage micrometer.
- Align the two grids so that the far-left lines of each are superimposed.
- Count the number of stage micrometer lines that are covered by the 100 lines of the ocular micrometer.
- If at 10X magnification, the 100 lines of the ocular micrometer cover 60 lines (600 µm) of the stage micrometer, the distance between each line of the ocular micrometer is 6 /µm.
- If at 40X magnification, the 100 lines of the ocular micrometer cover 15 lines (150 µm) of the stage micrometer, the distance between each line of the ocular micrometer is 1.5 /µm.
- If at 100X magnification, the 100 lines of the ocular micrometer cover 6.5 lines (65 /µm) of the stage micrometer, the distance between each line of the ocular micrometer is 0.65 µm.
- If a microbiological specimen is observed at 100X magnification to have a length spanning 4 ocular micrometer lines and a width covering 2.5 ocular micrometer lines, its length and width are 2.6 / µm and 1.63 µm, respectively.

Annexure-III

Objective: Determination of Bacteriostatic/Bactericidal Residue on Laboratory Glassware Surfaces

Method:

- Wash six petri dishes according to the normal washing routine of the laboratory, and designate these dishes as Group A.
- Wash six additional dishes as above, rinse 12 times with distilled water, and designate as Group B.
- Wash another six dishes according to the laboratory's normal procedure, dry without further rinsing, and designate as Group C.
- Sterilize petri dishes in Groups A, B, and C by the laboratory's normal procedure.
- If testing of pre-sterilized plastic petri dishes is desired, designate six sterile dishes as Group D.
- To each petri dish add 1 ml of a pure culture dilution of Enterobacter aerogenes that will yield 50-150 colonies per plate.
- To each plate, add 20 ml of plate count agar and mix thoroughly with inoculum.
- After solidification, incubate plates at 35° for 48 ±2 hours and then count.
- Interpret counts as follows:
    - Less than 15% difference in the average plate counts for plates of Groups A, B, C, and D indicates no detergent residual with bacteriostatic or bactericidal properties or that the pre-sterilized plates are acceptable.
    - A difference in colony counts of more than 15% between Groups A and B or D and B indicates the presence of an inhibitory detergent residue.
    - A difference in counts of less than 15% between Groups A and B and more than 15% between Groups A and C indicates that the detergent has inhibitory properties that are removed during routine washing.

Annexure-IV

Record for Cleaning and Disinfection of Microbiology Lab

Date: _____

Area	Cleaned With	Disinfected by	Disinfectant Ref. No.	Done By/ Time	Checked by	Remarks
Microbiology Entry Air Lock						
General Corridor						
Sterilization Area						
Media Preparation Room						
Washing Area						
Sterility Room						
Change Room						
Sub-culture room						

Annexure-V

Nutrient Agar

Objective: Preparation of PDA Media

Ingredients Required:

- Infusions from potatoes: 200 ml
- Dextrose: 20g
- Agar: 15g
- Distilled Water: 1.00 Litre

Method:

- Suspend ingredients in distilled water and heat mixture to boiling point to dissolve.
- Distribute into tubes or flasks, and autoclave 15 minutes at 121^{O}C (15 lb. pressure).
- When used as planting medium for yeasts and molds, melt into flowing steam of water, cool and acidify to pH 3.5 with sterile 10 percent tartaric acid solution. (For use in cultivation of yeasts and molds, adjust to the desired pH id different from pH 3.5.)
- Mix thoroughly and pour into plates.
- To preserve solidify properties of the agar do not heat medium after the addition of tartaric acid.

Nutrient Broth

Objective: Preparation of Nitrate Broth

Ingredients Required:

- Beef Extract: 3.0 g
- Peptone: 5.0g
- Potassium Nitrate: 15.0g
- Distilled Water: 1.0 litre

Method:

- Dissolve all the ingredients in distilled water.
- Distribute in tubes and sterilize for 15 minutes at 121^{O}C.
- Check the pH of the broth with pH meter. It should be neutral.

Skill India
कौशल भारत-कुशल भारत

सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation
Transforming the skill landscape

12. Employability & Entrepreneurship Skills

FICSI
Food Industry Capacity and Skill Initiative

Key Learning Outcomes

At the end of this module, you will be able to:

1. Explain the meaning of health
2. List common health issues
3. Discuss tips to prevent common health issues
4. Explain the meaning of hygiene
5. Discuss the purpose of Swacch Bharat Abhiyan
6. Explain the meaning of habit
7. Discuss ways to set up a safe work environment
8. Discuss critical safety habits to be followed by employees
9. Explain the importance of self-analysis
10. Discuss motivation with the help of Maslow's Hierarchy of Needs
11. Discuss the meaning of achievement motivation
12. List the characteristics of entrepreneurs with achievement motivation
13. List the different factors that motivate you
14. Discuss the role of attitude in self-analysis
15. Discuss how to maintain a positive attitude
16. List your strengths and weaknesses
17. Discuss the qualities of honest people
18. Describe the importance of honesty in entrepreneurs
19. Discuss the elements of a strong work ethic
20. Discuss how to foster a good work ethic
21. List the characteristics of highly creative people
22. List the characteristics of highly innovative people
23. Discuss the benefits of time management
24. List the traits of effective time managers
25. Describe effective time management technique
26. Discuss the importance of anger management
27. Describe anger management strategies
28. Discuss tips for anger management
29. Discuss the causes of stress
30. Discuss the symptoms of stress
31. Discuss tips for stress management
32. Identify the basic parts of a computer
33. Identify the basic parts of a keyboard
34. Recall basic computer terminology
35. Recall the functions of basic computer keys
36. Discuss the main applications of MS Office
37. Discuss the benefits of Microsoft Outlook
38. Discuss the different types of e-commerce
39. List the benefits of e-commerce for retailers and customers
40. Discuss how the Digital India campaign will help boost e-commerce in India
41. Describe how you will sell a product or service on an e-commerce platform

42. Discuss the importance of saving money
43. Discuss the benefits of saving money
44. Discuss the main types of bank accounts
45. Describe the process of opening a bank account
46. Differentiate between fixed and variable costs
47. Describe the main types of investment options
48. Describe the different types of insurance products
49. Describe the different types of taxes
50. Discuss the uses of online banking
51. Discuss the main types of electronic funds transfers
52. Discuss the steps to prepare for an interview
53. Discuss the steps to create an effective Resume
54. Discuss the most frequently asked interview questions
55. Discuss how to answer the most frequently asked interview questions
56. Discuss basic workplace terminology
57. Discuss the concept of entrepreneurship
58. Discuss the importance of entrepreneurship
59. Describe the characteristics of an entrepreneur
60. Describe the different types of enterprises
61. List the qualities of an effective leader
62. Discuss the benefits of effective leadership
63. List the traits of an effective team
64. Discuss the importance of listening effectively
65. Discuss how to listen effectively
66. Discuss the importance of speaking effectively
67. Discuss how to speak effectively
68. Discuss how to solve problems
69. List important problem solving traits
70. Discuss ways to assess problem solving skills
71. Discuss the importance of negotiation
72. Discuss how to negotiate
73. Discuss how to identify new business opportunities
74. Discuss how to identify business opportunities within your business
75. Explain the meaning of entrepreneur
76. Describe the different types of entrepreneurs
77. List the characteristics of entrepreneurs
78. Recall entrepreneur success stories
79. Discuss the entrepreneurial process
80. Describe the entrepreneurship ecosystem
81. Discuss the purpose of the Make in India campaign
82. Discuss key schemes to promote entrepreneurs
83. Discuss the relationship between entrepreneurship and risk appetite
84. Discuss the relationship between entrepreneurship and resilience

85. Describe the characteristics of a resilient entrepreneur
86. Discuss how to deal with failure
87. Discuss how market research is carried out
88. Describe the 4 Ps of marketing
89. Discuss the importance of idea generation
90. Recall basic business terminology
91. Discuss the need for CRM
92. Discuss the benefits of CRM
93. Discuss the need for networking
94. Discuss the benefits of networking
95. Discuss the importance of setting goals
96. Differentiate between short-term, medium-term and long-term goals
97. Discuss how to write a business plan
98. Explain the financial planning process
99. Discuss ways to manage your risk
100. Describe the procedure and formalities for applying for bank finance
101. Discuss how to manage your own enterprise
102. List important questions that every entrepreneur should ask before starting an enterprise

UNIT 12.1: Personal Strengths & Value Systems

Unit Objectives

At the end of this unit, you will be able to:

1. Explain the meaning of health
2. List common health issues
3. Discuss tips to prevent common health issues
4. Explain the meaning of hygiene
5. Understand the purpose of Swacch Bharat Abhiyan
6. Explain the meaning of habit
7. Discuss ways to set up a safe work environment
8. Discuss critical safety habits to be followed by employees
9. Explain the importance of self-analysis
10. Understand motivation with the help of Maslow's Hierarchy of Needs
11. Discuss the meaning of achievement motivation
12. List the characteristics of entrepreneurs with achievement motivation
13. List the different factors that motivate you
14. Discuss how to maintain a positive attitude
15. Discuss the role of attitude in self-analysis
16. List your strengths and weaknesses
17. Discuss the qualities of honest people
18. Describe the importance of honesty in entrepreneurs
19. Discuss the elements of a strong work ethic
20. Discuss how to foster a good work ethic
21. List the characteristics of highly creative people
22. List the characteristics of highly innovative people
23. Discuss the benefits of time management
24. List the traits of effective time managers
25. Describe effective time management technique
26. Discuss the importance of anger management
27. Describe anger management strategies
28. Discuss tips for anger management
29. Discuss the causes of stress
30. Discuss the symptoms of stress
31. Discuss tips for stress management

12.1.1 Health, Habits, Hygiene: What is Health

As per the World Health Organization (WHO), health is a "State of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity." This means being healthy does not simply mean not being unhealthy – it also means you need to be at peace emotionally, and feel fit physically. For example, you cannot say you are healthy simply because you do not have any physical ailments like a cold or cough. You also need to think about whether you are feeling calm, relaxed and happy.

Common Health Issues

Some common health issues are:

- Allergies
- Asthma
- Skin Disorders
- Depression and Anxiety
- Diabetes
- Cough, Cold, Sore Throat
- Difficulty Sleeping
- Obesity

12.1.1.1 Tips to Prevent Health Issues

Taking measures to prevent ill health is always better than curing a disease or sickness. You can stay healthy by:

- Eating healthy foods like fruits, vegetables and nuts
- Cutting back on unhealthy and sugary foods
- Drinking enough water everyday
- Not smoking or drinking alcohol
- Exercising for at least 30 minutes a day, 4-5 times a week
- Taking vaccinations when required
- Practicing yoga exercises and meditation

How many of these health standards do you follow? Tick the ones that apply to you.

1. Get minimum 7-8 hours of sleep every night. ☐
2. Avoid checking email first thing in the morning and right before you go to bed at night. ☐
3. Don't skip meals – eat regular meals at correct meal times. ☐
4. Read a little bit every single day. ☐
5. Eat more home cooked food than junk food ☐
6. Stand more than you sit. ☐
7. Drink a glass of water first thing in the morning and have at least 8 glasses of water through the day. ☐
8. Go to the doctor and dentist for regular checkups. ☐
9. Exercise for 30 minutes at least 5 days a week. ☐
10. Avoid consuming lots of aerated beverages. ☐

12.1.1.2 What is Hygiene?

As per the World Health Organization (WHO), "Hygiene refers to conditions and practices that help to maintain health and prevent the spread of diseases." In other words, hygiene means ensuring that you do whatever is required to keep your surroundings clean, so that you reduce the chances of spreading germs and diseases.

For instance, think about the kitchen in your home. Good hygiene means ensuring that the kitchen is always spick and span, the food is put away, dishes are washed and dustbins are not overflowing with garbage. Doing all this will reduce the chances of attracting pests like rats or cockroaches, and prevent the growth of fungus and other bacteria, which could spread disease.

How many of these health standards do you follow? Tick the ones that apply to you.

1. Have a bath or shower every day with soap – and wash your hair with shampoo 2-3 times a week.
2. Wear a fresh pair of clean undergarments every day.
3. Brush your teeth in the morning and before going to bed.
4. Cut your fingernails and toenails regularly.
5. Wash your hands with soap after going to the toilet.
6. Use an anti-perspirant deodorant on your underarms if you sweat a lot.
7. Wash your hands with soap before cooking or eating.
8. Stay home when you are sick, so other people don't catch what you have.
9. Wash dirty clothes with laundry soap before wearing them again.
10. Cover your nose with a tissue/your hand when coughing or sneezing.

See how healthy and hygienic you are, by giving yourself 1 point for every ticked statement! Then take a look at what your score means.

Your Score

- **0-7/20:** You need to work a lot harder to stay fit and fine! Make it a point to practice good habits daily and see how much better you feel!
- **7-14/20:** Not bad, but there is scope for improvement! Try and add a few more good habits to your daily routine.
- **14-20/20:** Great job! Keep up the good work! Your body and mind thank you!

12.1.1.3 Swachh Bharat Abhiyan

We have already discussed the importance of following good hygiene and health practices for ourselves. But, it is not enough for us to be healthy and hygienic. We must also extend this standard to our homes, our immediate surroundings and to our country as a whole.

The 'Swachh Bharat Abhiyan' (Clean India Mission) launched by Prime Minister Shri Narendra Modi on 2nd October 2014, believes in doing exactly this. The aim of this mission is to clean the streets and roads of India and raise the overall level of cleanliness. Currently this mission covers 4,041 cities and towns across the country. Millions of our people have taken the pledge for a clean India. You should take the pledge too, and do everything possible to keep our country clean!

12.1.1.4 What are Habits?

A habit is a behaviour that is repeated frequently. All of us have good habits and bad habits. Keep in mind the phrase by John Dryden: "We first make our habits, and then our habits make us." This is why it is so important that you make good habits a way of life, and consciously avoid practicing bad habits.

Some good habits that you should make part of your daily routine are:

- Always having a positive attitude
- Making exercise a part of your daily routine
- Reading motivational and inspirational stories
- Smiling! Make it a habit to smile as often as possible
- Making time for family and friends
- Going to bed early and waking up early

Some bad habits that you should quit immediately are:

- Skipping breakfast
- Snacking frequently even when you are not hungry
- Eating too much fattening and sugary food
- Smoking, drinking alcohol and doing drugs
- Spending more money than you can afford
- Worrying about unimportant issues
- Staying up late and waking up late

12.1.1.5 Tips 

1. Following healthy and hygienic practices every day will make you feel good mentally and physically.
2. Hygiene is two-thirds of health – so good hygiene will help you stay strong and healthy!

12.1.2 What are Habits?

Every employer is obligated to ensure that his workplace follows the highest possible safety protocol. When setting up a business, owners must make it a point to:

- Use ergonomically designed furniture and equipment to avoid stooping and twisting
- Provide mechanical aids to avoid lifting or carrying heavy objects
- Have protective equipment on hand for hazardous jobs
- Designate emergency exits and ensure they are easily accessible
- Set down health codes and ensure they are implemented
- Follow the practice of regular safety inspections in and around the workplace
- Ensure regular building inspections are conducted
- Get expert advice on workplace safety and follow it

12.1.2.1 Non-Negotiable Employee Safety Habits

Every employer is obligated to ensure that his workplace follows the highest possible safety protocol. When setting up a business, owners must make it a point to:

- Immediately report unsafe conditions to a supervisor
- Recognize and report safety hazards that could lead to slips, trips and falls
- Report all injuries and accidents to a supervisor
- Wear the correct protective equipment when required
- Learn how to correctly use equipment provided for safety purposes
- Be aware of and avoid actions that could endanger other people
- Take rest breaks during the day and some time off from work during the week

12.1.2.2 Tips 

1. Be aware of what emergency number to call at the time of a workplace emergency
2. Practice evacuation drills regularly to avoid chaotic evacuations

12.1.3 Self Analysis – Attitude, Achievement Motivation

To truly achieve your full potential, you need to take a deep look inside yourself and find out what kind of person you really are. This attempt to understand your personality is known as self-analysis. Assessing yourself in this manner will help you grow, and will also help you to identify areas within yourself that need to be further developed, changed or eliminated. You can better understand yourself by taking a deep look at what motivates you, what your attitude is like, and what your strengths and weaknesses are.

12.1.3.1 What is Motivation?

Very simply put, motivation is your reason for acting or behaving in a certain manner. It is important to understand that not everyone is motivated by the same desires – people are motivated by many, many different things. We can understand this better by looking at Maslow's Hierarchy of Needs.

12.1.3.2 Maslow's Hierarchy of Needs

Famous American psychologist Abraham Maslow wanted to understand what motivates people. He believed that people have five types of needs, ranging from very basic needs (called physiological needs) to more important needs that are required for self-growth (called self- actualization needs). Between the physiological and self-actualization needs are three other needs – safety needs, belongingness and love needs, and esteem needs. These needs are usually shown as a pyramid with five levels and are known as Maslow's Hierarchy of Needs.

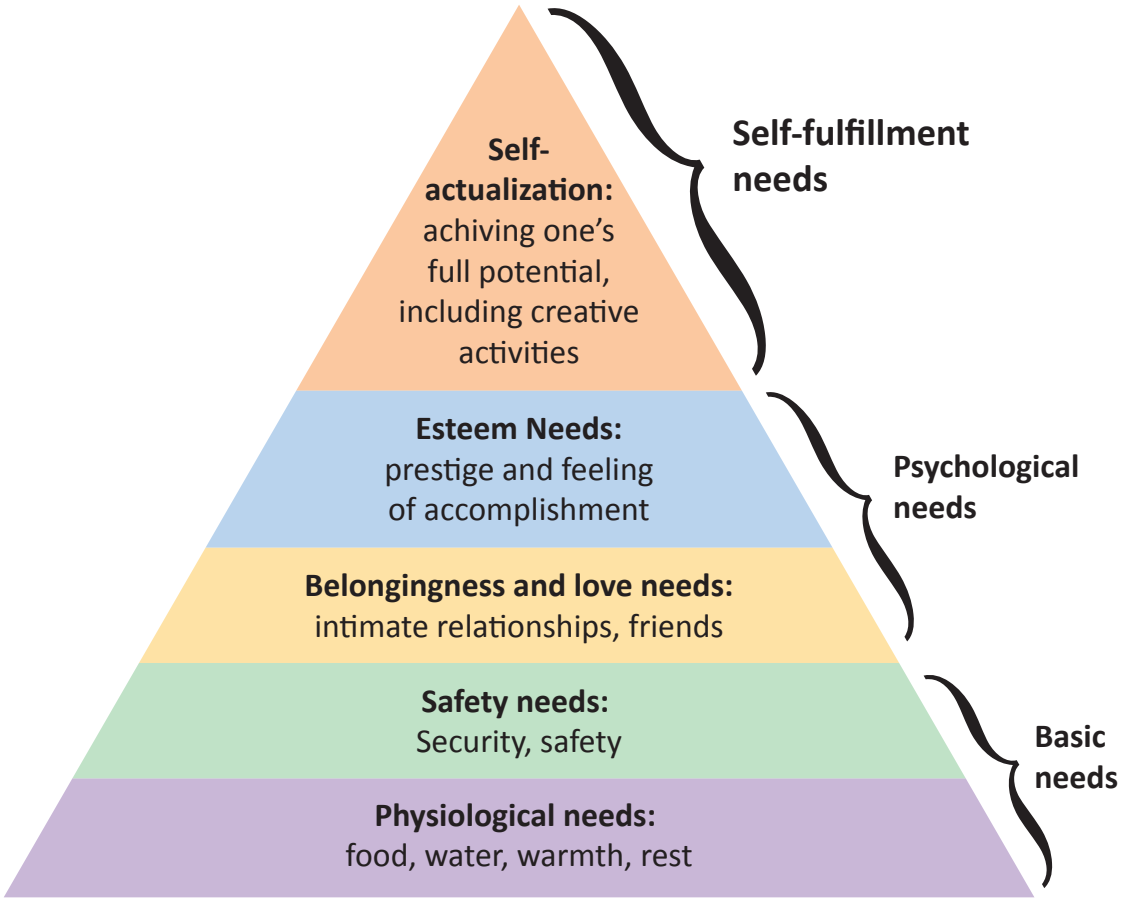

Fig. 12.1.1: Mashlow's Hierarchy of Needs

As you can see from the pyramid, the lowest level depicts the most basic needs. Maslow believed that our behaviour is motivated by our basic needs, until those needs are met. Once they are fulfilled, we move to the next level and are motived by the next level of needs. Let's understand this better with an example.

Rupa comes from a very poor family. She never has enough food, water, warmth or rest. According to Maslow, until Rupa is sure that she will get these basic needs, she will not even think about the next level of needs – her safety needs. But, once Rupa is confident that her basic needs will be met, she will move to the next level, and her behaviour will then be motivated by her need for security and safety. Once these new needs are met, Rupa will once again move to the next level, and be motivated by her need for relationships and friends. Once this need is satisfied, Rupa will then focus on the fourth level of needs – her esteem needs, after which she will move up to the fifth and last level of needs – the desire to achieve her full potential.

12.1.3.3 Understanding Achievement Motivation

We now know that people are motivated by basic, psychological and self-fulfillment needs. However, certain people are also motivated by the achievement of highly challenging accomplishments. This is known as Achievement Motivation, or 'need for achievement'.

The level of motivation achievement in a person differs from individual to individual. It is important that entrepreneurs have a high level of achievement motivation – a deep desire to accomplish something important and unique. It is equally important that they hire people who are also highly motivated by challenges and success.

What Motivates You?

What are the things that really motivate you? List down five things that really motivate you. Remember to answer honestly!

I am motivated by:

Characteristics of Entrepreneurs with Achievement Motivation

- Entrepreneurs with achievement motivation can be described as follows:
- Unafraid to take risks for personal accomplishment
- Love being challenged Future-oriented Flexible and adaptive
- Value negative feedback more than positive feedback
- Very persistent when it comes to achieving goals
- Extremely courageous
- Highly creative and innovative
- Restless - constantly looking to achieve more
- Feel personally responsible for solving problems

Think about it:

- How many of these traits do you have?
- Can you think of entrepreneurs who display these traits?

12.1.3.4 How to Cultivate a Positive Attitude

The good news is attitude is a choice. So it is possible to improve, control and change our attitude, if we decide we want to! The following tips help foster a positive mindset:

- Remember that you control your attitude, not the other way around
- Devote at least 15 minutes a day towards reading, watching or listening to something positive
- Avoid negative people who only complain and stop complaining yourself
- Expand your vocabulary with positive words and delete negative phrases from your mind
- Be appreciative and focus on what's good in yourself, in your life, and in others
- Stop thinking of yourself as a victim and start being proactive
- Imagine yourself succeeding and achieving your goals

12.1.3.5 What is Attitude?

Now that we understand why motivation is so important for self-analysis, let's look at the role our attitude plays in better understanding ourselves. Attitude can be described as your tendency (positive or negative), to think and feel about someone or something. Attitude is the foundation for success in every aspect of life. Our attitude can be our best friend or our worst enemy. In other words:

"The only disability in life is a bad attitude."

When you start a business, you are sure to encounter a wide variety of emotions, from difficult times and failures to good times and successes. Your attitude is what will see you through the tough times and guide you towards success. Attitude is also infectious. It affects everyone around you, from your customers to your employees to your investors. A positive attitude helps build confidence in the workplace while a negative attitude is likely to result in the demotivation of your people.

12.1.3.6 What Are Your Strengths and Weaknesses

Another way to analyze yourself is by honestly identifying your strengths and weaknesses. This will help you use your strengths to your best advantage and reduce your weaknesses.

Note down all your strengths and weaknesses in the two columns below. Remember to be honest with yourself!

Strengths	Weaknesses

12.1.3.7 Tips

1. Achievement motivation can be learned.
2. Don't be afraid to make mistakes.
3. Train yourself to finish what you start.
4. Dream big.

12.1.4 Honesty & Work Ethics: What is Honesty?

Honesty is the quality of being fair and truthful. It means speaking and acting in a manner that inspires trust. A person who is described as honest is seen as truthful and sincere, and as someone who isn't deceitful or devious and doesn't steal or cheat. There are two dimensions of honesty – one is honesty in communication and the other is honesty in conduct.

Honesty is an extremely important trait because it results in peace of mind and builds relationships that are based on trust. Being dishonest, on the other hand, results in anxiety and leads to relationships full of distrust and conflict.

12.1.4.1 Qualities of Honest People

Honest individuals have certain distinct characteristics. Some common qualities among honest people are:

- They don't worry about what others think of them. They believe in being themselves – they don't bother about whether they are liked or disliked for their personalities.
- They stand up for their beliefs. They won't think twice about giving their honest opinion, even if they are aware that their point of view lies with the minority.
- They are think skinned. This means they are not affected by others judging them harshly for their honest opinions.
- They forge trusting, meaningful and healthy friendships. Honest people usually surround themselves with honest friends. They have faith that their friends will be truthful and upfront with them at all times.

They are trusted by their peers. They are seen as people who can be counted on for truthful and objective feedback and advice.

- **Honesty and employees:** When entrepreneurs build honest relationships with their employees, it leads to more transparency in the workplace, which results in higher work performance and better results.
- **Honesty and investors:** For entrepreneurs, being honest with investors means not only sharing strengths but also candidly disclosing current and potential weaknesses, problem areas and solution strategies. Keep in mind that investors have a lot of experience with startups and are aware that all new companies have problems. Claiming that everything is perfectly fine and running smoothly is a red flag for most investors.
- **Honesty with oneself:** The consequences of being dishonest with oneself can lead to dire results, especially in the case of entrepreneurs. For entrepreneurs to succeed, it is critical that they remain realistic about their situation at all times, and accurately judge every aspect of their enterprise for what it truly is.

12.1.4.2 Importance of Honesty in Entrepreneurs

One of the most important characteristics of entrepreneurs is honesty. When entrepreneurs are honest with their customers, employees and investors, it shows that they respect those that they work with. It is also important that entrepreneurs remain honest with themselves. Let's look at how being honest would lead to great benefits for entrepreneurs.

- **Honesty and customers:** When entrepreneurs are honest with their customers it leads to stronger relationships, which in turn results in business growth and a stronger customer network.

12.1.4.3 What are Work Ethics?

Being ethical in the workplace means displaying values like honesty, integrity and respect in all your decisions and communications. It means not displaying negative qualities like lying, cheating and stealing.

Workplace ethics play a big role in the profitability of a company. It is as crucial to an enterprise as high morale and teamwork. This is why most companies lay down specific workplace ethic guidelines that must compulsorily be followed by their employees. These guidelines are typically outlined in a company's employee handbook.

12.1.4.4 Elements of a Strong Work Ethic

An entrepreneur must display strong work ethics, as well as hire only those individuals who believe in and display the same level of ethical behavior in the workplace. Some elements of a strong work ethic are:

- **Professionalism:** This involves everything from how you present yourself in a corporate setting to the manner in which you treat others in the workplace.
- **Respectfulness:** This means remaining poised and diplomatic regardless of how stressful or volatile a situation is.
- **Dependability:** This means always keeping your word, whether it's arriving on time for a meeting or delivering work on time.

- **Dedication:** This means refusing to quit until the designated work is done, and completing the work at the highest possible level of excellence.
- **Determination:** This means embracing obstacles as challenges rather than letting them stop you, and pushing ahead with purpose and resilience to get the desired results.
- **Accountability:** This means taking responsibility for your actions and the consequences of your actions, and not making excuses for your mistakes.
- **Humility:** This means acknowledging everyone's efforts and had work, and sharing the credit for accomplishments.

12.1.4.5 How to Foster a Good Work Ethic

As an entrepreneur, it is important that you clearly define the kind of behaviour that you expect from each and every team member in the workplace. You should make it clear that you expect employees to display positive work ethics like:

- **Honesty:** All work assigned to a person should be done with complete honesty, without any deceit or lies.
- Good attitude: All team members should be optimistic, energetic, and positive.
- **Reliability:** Employees should show up where they are supposed to be, when they are supposed to be there.
- **Good work habits:** Employees should always be well groomed, never use inappropriate language, conduct themselves professionally at all times, etc.
- **Initiative:** Doing the bare minimum is not enough. Every team member needs to be proactive and show initiative.
- **Trustworthiness:** Trust is non-negotiable. If an employee cannot be trusted, it's time to let that employee go.
- **Respect:** Employees need to respect the company, the law, their work, their colleagues and themselves.
- **Integrity:** Each and every team member should be completely ethical and must display above board behaviour at all times.
- **Efficiency:** Efficient employees help a company grow while inefficient employees result in a waste of time and resources.

12.1.4.6 Tips

1. Don't get angry when someone tells you the truth and you don't like what you hear.
2. Always be willing to accept responsibility for your mistakes.

12.1.5 Creativity & Innovation

What is Creativity

Creativity means thinking outside the box. It means viewing things in new ways or from different perspectives, and then converting these ideas into reality. Creativity involves two parts: thinking and producing. Simply having an idea makes you imaginative, not creative. However, having an idea and acting on it makes you creative.

Characteristics of Highly Creative People

Some characteristics of creative people are:

- They are imaginative and playful
- They see issues from different angles
- They notice small details
- They have very little tolerance for boredom
- They detest rules and routine
- They love to daydream
- They are very curious

What is Innovation?

There are many different definitions of innovation. In simple terms, innovation means turning an idea into a solution that adds value. It can also mean adding value by implementing a new product, service or process, or significantly improving on an existing product, service or process.

Characteristics of Highly Innovative People

- Some characteristics of highly innovative people are:
- They embrace doing things differently
- They don't believe in taking shortcuts
- They are not afraid to be unconventional
- They are highly proactive and persistent
- They are organized, cautious and risk-averse

12.1.5.1 Tips

1. Take regular breaks from your creative work to recharge yourself and gain fresh perspective.
2. Build prototypes frequently, test them out, get feedback, and make the required changes.

12.1.6 Time Management

Management is the process organizing your time, and deciding how to allocate your time between different activities. Good time management is the difference between working smart (getting more done in less time) and working hard (working for more time to get more done).

Effective time management leads to an efficient work output, even when you are faced with tight deadlines and high pressure situations. On the other hand, not managing your time effectively results in inefficient output and increases stress and anxiety.

Benefits of Time Management

Time management can lead to huge benefits like:

- Greater productivity
- Higher efficiency
- Better professional reputation
- Reduced stress

- Higher chances for career advancement
- Greater opportunities to achieve goals

Not managing time effectively can result in undesirable consequences like:

- Missing deadlines
- Inefficient work output
- Substandard work quality
- Poor professional reputation
- Stalled career
- Increase in stress and anxiety

12.1.6.1 Traits of Effective Time Managers

Some traits of effective time managers are:

- They begin projects early They set daily objectives
- They modify plans if required, to achieve better results
- They are flexible and open-minded
- They inform people in advance if their help will be required
- They know how to say no
- They break tasks into steps with specific deadlines
- They continually review long term goals
- They think of alternate solutions if and when required
- They ask for help when required They create backup plans

12.1.6.2 Effective Time Management Techniques

You can manage your time better by putting into practice certain time management techniques. Some helpful tips are:

- **Plan out your day as well as plan for interruptions.** Give yourself at least 30 minutes to figure out your time plan. In your plan, schedule some time for interruptions.
- **Put up a "Do Not Disturb" sign** when you absolutely have to complete a certain amount of work.
- **Close your mind to all distractions.** Train yourself to ignore ringing phones, don't reply to chat messages and disconnect from social media sites.
- **Delegate your work.** This will not only help your work get done faster, but will also show you the unique skills and abilities of those around you.
- **Stop procrastinating.** Remind yourself that procrastination typically arises due to the fear of failure or the belief that you cannot do things as perfectly as you wish to do them.
- **Prioritize.** List each task to be completed in order of its urgency or importance level. Then focus on completing each task, one by one.
- **Maintain a log of your work activities.** Analyze the log to help you understand how efficient you are, and how much time is wasted every day.
- **Create time management goals** to reduce time wastage.

12.1.6.3 Tips

1. Always complete the most important tasks first.
2. Get at least 7 – 8 hours of sleep every day.
3. Start your day early.
4. Don't waste too much time on small, unimportant details.
5. Set a time limit for every task that you will undertake.
6. Give yourself some time to unwind between tasks.

12.1.7 Anger Management

Anger management is the process of:

1. Learning to recognize the signs that you, or someone else, is becoming angry.
2. Taking the best course of action to calm down the situation in a positive way Anger management does not mean suppressing anger.

Importance of Anger Management

Anger is a perfectly normal human emotion. In fact, when managed the right way, anger can be considered a healthy emotion. However, if it is not kept in check, anger can make us act inappropriately and can lead to us saying or doing things that we will likely later regret.

Extreme anger can:

- **Hurt you physically:** It leads to heart disease, diabetes, a weakened immune system, insomnia, and high blood pressure.
- **Hurt you mentally:** It can cloud your thinking and lead to stress, depression and mental health issues.
- **Hurt your career:** It can result in alienating your colleagues, bosses, clients and lead to the loss of respect.
- **Hurt your relationships:** It makes it hard for your family and friends to trust you, be honest with you and feel comfortable around you.

This is why anger management, or managing anger appropriately, is so important.

12.1.7.1 Anger Management Strategies

Here are some strategies that can help you control your anger:

Strategy 1: Relaxation: Something as simple as breathing deeply and looking at relaxing images works wonders in calming down angry feelings. Try this simple breathing exercise:

- Take a deep breath from your diaphragm (don't breathe from your chest)
- Visualize your breath coming up from your stomach
- Keep repeating a calming word like 'relax' or 'take it easy' (remember to keep breathing deeply while repeating the word)
- Picture a relaxing moment (this can be from your memory or your imagination)

Follow this relaxation technique daily, especially when you realize that you're starting to feel angry.

Strategy 2: Cognitive Restructuring: Cognitive restructuring means changing the manner in which you think. Anger can make you curse, swear, exaggerate and act very dramatically. When this happens, force yourself to replace your angry thoughts with more logical ones. For instance, instead of thinking 'Everything is ruined' change your mindset and tell yourself 'It's not the end of the world and getting angry won't solve this'.

Strategy 3: Problem Solving: Getting angry about a problem that you cannot control is a perfectly natural response. Sometimes, try as you may, there may not be a solution to the difficulty you are faced with. In such cases, stop focusing on solving the problem, and instead focus on handling and facing the problem. Remind yourself that you will do your best to deal with the situation, but that you will not blame yourself if you don't get the solution you desire.

Strategy 4: Better Communication: When you're angry, it is very easy to jump to inaccurate conclusions. In this case, you need to force yourself to stop reacting, and think carefully about what you want to say, before saying it. Avoid saying the first thing that enters your head. Force yourself to listen carefully to what the other person is saying. Then think about the conversation before responding.

Strategy 5: Changing Your Environment: If you find that your environment is the cause of your anger, try and give yourself a break from your surroundings. Make an active decision to schedule some personal time for yourself, especially on days that are very hectic and stressful. Having even a brief amount of quiet or alone time is sure to help calm you down.

12.1.7.2 Tips for Anger Management

- The following tips will help you keep your anger in check:
- Take some time to collect your thoughts before you speak out in anger.
- Express the reason for your anger in an assertive, but non-confrontational manner once you have calmed down.
- Do some form of physical exercise like running or walking briskly when you feel yourself getting angry.
- Make short breaks part of your daily routine, especially during days that are stressful. Focus on how to solve a problem that's making you angry, rather than focusing on the fact that the problem is making you angry.

12.1.8 Stress Management

We say we are 'stressed' when we feel overloaded and unsure of our ability to deal with the pressures placed on us. Anything that challenges or threatens our well-being can be defined as a stress. It is important to note that stress can be good and bad. While good stress keeps us going, negative stress undermines our mental and physical health. This is why it is so important to manage negative stress effectively.

Causes of Stress

Stress can be caused by internal and external factors.

Internal causes of stress:

- Constant worry
- Rigid thinking
- Unrealistic expectations
- Pessimism
- Negative self-talk
- All in or all out attitude

External causes of stress:

- Major life changes
- Difficulties with relationships
- Having too much to do
- Difficulties at work or in school
- Financial difficulties
- Worrying about one's children and/or family

12.1.8.1 Symptoms of Stress

Stress can manifest itself in numerous ways. Take a look at the cognitive, emotional, physical and behavioral symptoms of stress.

Cognitive Symptoms	Emotional Symptoms
• Memory problems • Concentration issues • Lack of judgement • Pessimism • Anxiety • Constant worrying	• Depression • Agitation • Irritability • Loneliness • Anxiety • Anger

Physical Symptoms	Behavioral Symptoms
• Aches and pain • Diarrhea or constipation • Nausea • Dizziness • Chest pain and/or rapid heartbeat • Frequent cold or flu like feelings	• Increase or decrease in appetite • Over sleeping or not sleeping enough • Withdrawing socially • Ignoring responsibilities • Consumption of alcohol or cigarettes • Nervous habits like nail biting, pacing etc.

12.1.8.2 Tips for Stress Management

The following tips can help you manage your stress better:

- Note down the different ways in which you can handle the various sources of your stress.
- Remember that you cannot control everything, but you can control how you respond.
- Discuss your feelings, opinions and beliefs rather than reacting angrily, defensively or passively.
- Practice relaxation techniques like meditation, yoga or tai chi when you start feeling stressed.
- Devote a part of your day towards exercise.
- Eat healthy foods like fruits and vegetables. Avoid unhealthy foods especially those containing large amounts of sugar.
- Plan your day so that you can manage your time better, with less stress.
- Say no to people and things when required.
- Schedule time to pursue your hobbies and interests.
- Ensure you get at least 7-8 hours of sleep.
- Reduce your caffeine intake.
- Increase the time spent with family and friends.

UNIT 12.2: Digital Literacy: A Recap

Unit Objectives

At the end of this unit, you will be able to:

1. Identify the basic parts of a computer
2. Identify the basic parts of a keyboard
3. Recall basic computer terminology
4. Recall basic computer terminology
5. Recall the functions of basic computer keys
6. Discuss the main applications of MS Office
7. Discuss the benefits of Microsoft Outlook
8. Discuss the different types of e-commerce
9. List the benefits of e-commerce for retailers and customers
10. Discuss how the Digital India campaign will help boost e-commerce in India
11. Describe how you will sell a product or service on an e-commerce platform

12.2.1 Computer and Internet basics: Basic Parts of a Computer

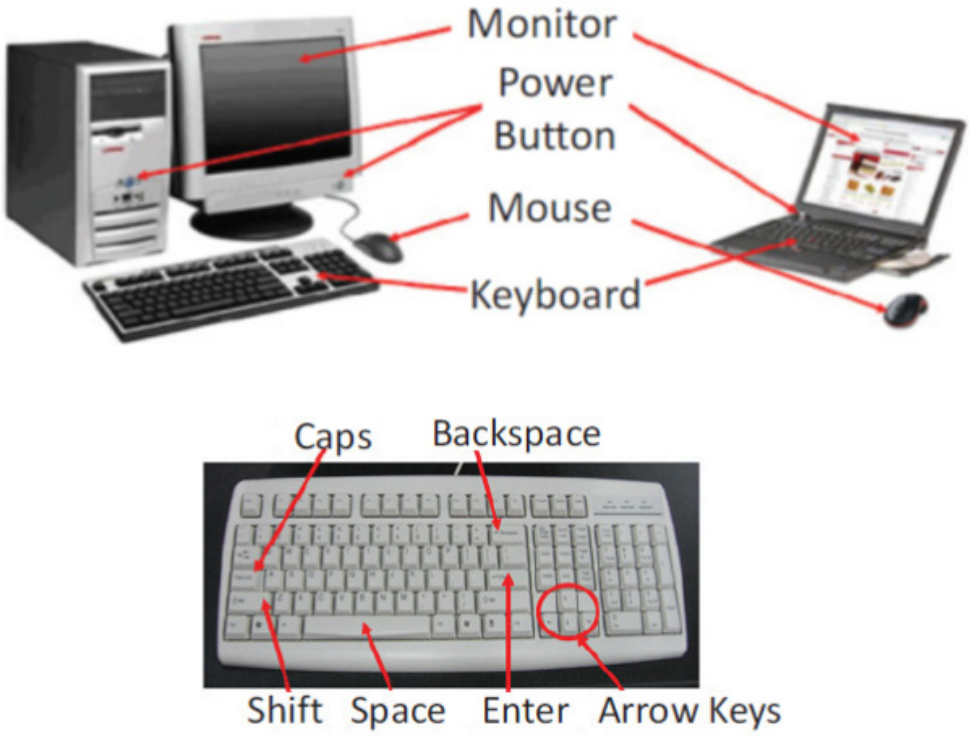

Fig. 12.2.1: Computer and Internet Basics

12.2.1.1 Basic Parts of a Computer

1. **Central Processing Unit (CPU):** The brain of the computer. It interprets and carries out program instructions.
2. **Hard Drive:** A device that stores large amounts of data.
3. **Monitor:** The device that contains the computer screen where the information is visually displayed.
4. **Desktop:** The first screen displayed after the operating system loads.
5. **Background:** The image that fills the background of the desktop.
6. **Mouse:** A hand-held device used to point to items on the monitor.
7. **Speakers:** Devices that enable you to hear sound from the computer.
8. **Printer:** A device that converts output from a computer into printed paper documents.
9. **Icon:** A small picture or image that visually represents something on your computer.
10. **Cursor:** An arrow which indicates where you are positioned on the screen.
11. **Program Menu:** A list of programs on your computer that can be accessed from the Start menu.
12. **Taskbar:** The horizontal bar at the bottom of the computer screen that lists applications that are currently in use.
13. **Recycle Bin:** A temporary storage for deleted files.

12.2.1.2 Basic Internet Terms

- **The Internet:** Avast, international collection of computer networks that transfers information.
- **The World Wide Web:** A system that lets you access information on the Internet.
- **Website:** A location on the World Wide Web (and Internet) that contains information about a specific topic.
- **Homepage:** Provides information about a website and directs you to other pages on that website.
- **Link/Hyperlink:** A highlighted or underlined icon, graphic, or text that takes you to another file or object.
- **Web Address/URL:** The address for a website.
- **Address Box:** A box in the browser window where you can type in a web address.

12.2.1.3 Basic Computer Keys

- **Arrow Keys:** Press these keys to move your cursor.
- **Space bar:** Adds a space.
- **Enter/Return:** Moves your cursor to a new line.
- **Shift:** Press this key if you want to type a capital letter or the upper symbol of a key.
- **Caps Lock:** Press this key if you want all the letters you type to be capital letters. Press it again to revert back to typing lowercase letters.
- **Backspace:** Deletes everything to the left of your cursor.

12.2.1.4 Tips

1. When visiting a .com address, there no need to type http:// or even www. Just type the name of the website and then press Ctrl + Enter. (Example: Type 'apple' and press Ctrl + Enter to go to www.apple.com)
2. Press the Ctrl key and press the + or - to increase and decrease the size of text.
3. Press F5 or Ctrl + R to refresh or reload a web page.

12.2.2 MS Office and Email

About MS Office

MS Office or Microsoft Office is a suite of computer programs developed by Microsoft. Although meant for all users, it offers different versions that cater specifically to students, home users and business users. All the programs are compatible with both, Windows and Macintosh.

Most Popular Office Products

Some of the most popular and universally used MS Office applications are:

1. **Microsoft Word:** Allows users to type text and add images to a document.
2. **Microsoft Excel:** Allows users to enter data into a spreadsheet and create calculations and graphs.
3. **Microsoft PowerPoint:** Allows users to add text, pictures and media and create slideshows and presentations.
4. **Microsoft Outlook:** Allows users to send and receive email.
5. **Microsoft OneNote:** Allows users to make drawings and notes with the feel of a pen on paper.
6. **Microsoft Access:** Allows users to store data over many tables.

Why Choose Microsoft Outlook

A popular email management choice especially in the workplace, Microsoft Outlook also includes an address book, notebook, web browser and calendar. Some major benefits of this program are:

- **Integrated search function:** You can use keywords to search for data across all Outlook programs.
- **Enhanced security:** Your email is safe from hackers, junk mail and phishing website email.
- **Email syncing:** Sync your mail with your calendar, contact list, notes in One Note and…your phone!
- **Offline access to email:** No Internet? No problem! Write emails offline and send them when you're connected again.

12.2.2.1 Tips

1. Press Ctrl+R as a shortcut method to reply to email.
2. Set your desktop notifications only for very important emails.
3. Flag messages quickly by selecting messages and hitting the Insert key.
4. Save frequently sent emails as a template to reuse again and again.
5. Conveniently save important emails as files.

12.2.3 E-Commerce: What is E-Commerce?

What is E-Commerce

E-commerce is the buying or selling of goods and services, or the transmitting of money or data, electronically on the internet. E-Commerce is the short form for "electronic commerce."

Examples of E-Commerce:

- Online shopping Online auctions
- Online ticketing
- Electronic payments
- Internet banking

Types of E-Commerce

E-commerce can be classified based on the types of participants in the transaction. The main types of e-commerce are:

- **Business to Business (B2B):** Both the transacting parties are businesses.
- **Business to Consumer (B2C):** Businesses sell electronically to end-consumers.
- **Consumer to Consumer (C2C):** Consumers come together to buy, sell or trade items to other consumers.
- **Consumer-to-Business (C2B):** Consumers make products or services available for purchase to companies looking for exactly those services or products.
- **Business-to-Administration (B2A):** Online transactions conducted between companies and public administration.
- **Consumer-to-Administration (C2A):** Online transactions conducted between individuals and public administration.

12.2.3.1 Benefits of E-Commerce

The e-commerce business provides some benefits for retailers and customers.

Benefits for retailers:

- Establishes an online presence
- Reduces operational costs by removing overhead costs
- Increases brand awareness through the use of good keywords
- Increases sales by removing geographical and time constraints

Benefits for customers:

- Offers a wider range of choice than any physical store
- Enables goods and services to be purchased from remote locations
- Enables consumers to perform price comparisons

12.2.3.2 Digital India Campaign

Prime Minister Narendra Modi launched the Digital India campaign in 2015, with the objective of offering every citizen of India access to digital services, knowledge and information. The campaign aims to improve the country's online infrastructure and increase internet connectivity, thus boosting the e-commerce industry.

Currently, the majority of online transactions come from tier 2 and tier 3 cities. Once the Digital India campaign is in place, the government will deliver services through mobile connectivity, which will help deliver internet to remote corners of the country. This will help the e-commerce market to enter India's tier 4 towns and rural areas.

E-Commerce Activity

Choose a product or service that you want to sell online. Write a brief note explaining how you will use existing e-commerce platforms, or create a new e-commerce platform, to sell your product or service.

12.2.3.3 Tips

1. Before launching your e-commerce platform, test everything.
2. Pay close and personal attention to your social media.

UNIT 12.3: Money Matters

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss the importance of saving money
2. Discuss the benefits of saving money
3. Discuss the main types of bank accounts
4. Describe the process of opening a bank account
5. Differentiate between fixed and variable costs
6. Describe the main types of investment options
7. Describe the different types of insurance products
8. Describe the different types of taxes
9. Discuss the uses of online banking
10. Discuss the main types of electronic funds transfers

12.3.1 Personal Finance – Why to Save

Importance of Saving

We all know that the future is unpredictable. You never know what will happen tomorrow, next week or next year. That's why saving money steadily through the years is so important. Saving money will help improve your financial situation over time. But more importantly, knowing that you have money stashed away for an emergency will give you peace of mind. Saving money also opens the door to many more options and possibilities.

Benefits of Saving

Inculcating the habit of saving leads to a vast number of benefits. Saving helps you:

- **Become financially independent:** When you have enough money saved up to feel secure you can start making your choices, from taking a vacation whenever you want, to switching careers or starting your own business.
- **Invest in yourself through education:** Through saving, you can earn enough to pay up for courses that will add to your professional experience and ultimately result in higher paying jobs.
- **Get out of debt:** Once you have saved enough as a reserve fund, you can use your savings to pay off debts like loans or bills that have accumulated over time.
- **Be prepared for surprise expenses:** Having money saved enables you to pay for unforeseen expenses like sudden car or house repairs, without feeling financially stressed.
- **Pay for emergencies:** Saving helps you deal with emergencies like sudden health issues or emergency trips without feeling financially burdened.
- **Afford large purchases and achieve major goals:** Saving diligently makes it possible to place down payments towards major purchases and goals, like buying a home or a car.
- **Retyre:** The money you have saved over the years will keep you comfortable when you no longer have the income you would get from your job.

12.3.1.1 Tips

1. Break your spending habit. Try not spending on one expensive item per week, and put the money that you would have spent into your savings.
2. Decide that you will not buy anything on certain days or weeks and stick to your word.

12.3.2 Types of Bank Accounts

In India, banks offer four main types of bank accounts. These are:

1. Current Accounts
2. Savings Accounts
3. Recurring Deposit Accounts
4. Fixed Deposit Accounts

Current Accounts

Current accounts offer the most liquid deposits and thus, are best suited for businessmen and companies. As these accounts are not meant for investments and savings, there is no imposed limit on the number or amount of transactions that can be made on any given day. Current account holders are not paid any interest on the amounts held in their accounts. They are charged for certain services offered on such accounts.

Savings Accounts

Savings accounts are meant to promote savings, and are therefore the number one choice for salaried individuals, pensioners and students. While there is no restriction on the number and amount of deposits made, there are usually restrictions on the number and amount of withdrawals. Savings account holders are paid interest on their savings.

Recurring Deposit Accounts

Recurring Deposit accounts, also called RD accounts, are the accounts of choice for those who want to save an amount every month, but are unable to invest a large sum at one time. Such account holders deposit a small, fixed amount every month for a pre-determined period (minimum 6 months). Defaulting on a monthly payment results in the account holder being charged a penalty amount. The total amount is repaid with interest at the end of the specified period.

Fixed Deposit Accounts

Fixed Deposit accounts, also called FD accounts, are ideal for those who wish to deposit their savings for a long term in return for a high rate of interest. The rate of interest offered depends on the amount deposited and the time period, and also differs from bank to bank. In the case of an FD, a certain amount of money is deposited by the account holder for a fixed period of time. The money can be withdrawn when the period expires. If necessary, the depositor can break the fixed deposit prematurely. However, this usually attracts a penalty amount which also differs from bank to bank.

12.3.2.1 Opening a Bank Account

Opening a bank account is quite a simple process. Take a look at the steps to open an account of your own:

Step 1: Fill in the Account Opening Form

This form requires you to provide the following information:

- Personal details (name, address, phone number, date of birth, gender, occupation, address)
- Method of receiving your account statement (hard copy/email)
- Details of your initial deposit (cash/cheque)
- Manner of operating your account (online/mobile banking/traditional via cheque, slip books) Ensure that you sign wherever required on the form.

Step 2: Affix your Photograph

Stick a recent photograph of yourself in the allotted space on the form.

Step 3: Provide your Know Your Customer (KYC) Details

KYC is a process that helps banks verify the identity and address of their customers. To open an account, every individual needs to submit certain approved documents with respect to photo identity (ID) and address proof. Some Officially Valid Documents (OVDs) are:

- Passport
- Driving License
- Voters' Identity Card
- PAN Card
- UIDAI (Aadhaar) Card

Step 4: Submit All your Documents

Submit the completed Account Opening Form and KYC documents. Then wait until the forms are processed and your account has been opened!

12.3.2.2 Tips 

1. Select the right type of account.
2. Fill in complete nomination details.
3. Ask about fees.
4. Understand the rules.
5. Check for online banking – it's convenient!
6. Keep an eye on your bank balance.

12.3.3 Costs: Fixed vs Variable

What are Fixed and Variable Costs

- Fixed costs and variable costs together make up a company's total cost. These are the two types of costs that companies have to bear when producing goods and services.
- A fixed cost does not change with the volume of goods or services a company produces. It always remains the same.

- A variable cost, on the other hand, increases and decreases depending on the volume of goods and services produced. In other words, it varies with the amount produced.

Differences Between Fixed and Variable Costs

Let's take a look at some of the main differences between fixed and variable costs:

Criteria	Fixed Costs	Variable Costs
Meaning	A cost that stays the same, regardless of the output produced.	A cost that changes when the
Nature	Time related.	Incurred
Incurred	Incurred irrespective of units being produced.	Incurred only when units are produced.
Unit cost	Inversely proportional to the number of units produced.	Remains the same, per unit.
Examples	Depreciation, rent, salary, insurance, tax etc.	Material consumed, wages, commission on sales, packing expenses, etc.

12.3.3.1 Tips

1. When trying to determine whether a cost is fixed or variable, simply ask the following question: Will the particular cost change if the company stopped its production activities? If the answer is no, then it is a fixed cost. If the answer is yes, then it is probably a variable cost.

12.3.4 Investment, Insurance and Taxes

Investment

Investment means that money is spent today with the aim of reaping financial gains at a future time. The main types of investment options are as follows:

- **Bonds:** Bonds are instruments used by public and private companies to raise large sums of money – too large to be borrowed from a bank. These bonds are then issued in the public market and are bought by lenders.
- **Stocks:** Stocks or equity are shares that are issued by companies and are bought by the general public.
- **Small Savings Schemes:** Small Savings Schemes are tools meant to save money in small amounts. Some popular schemes are the Employees Provident Fund, Sukanya Samriddhi Scheme and National Pension Scheme.
- **Mutual Funds:** Mutual Funds are professionally managed financial instruments that invest money in different securities on behalf of investors.
- **Fixed Deposits:** A fixed amount of money is kept aside with a financial institution for a fixed amount of time in return for interest on the money.
- **Real Estate:** Loans are taken from banks to purchase real estate, which is then leased or sold with the aim of making a profit on the appreciated property price.

- **Hedge Funds:** Hedge funds invest in both financial derivatives and/or publicly traded securities.
- **Private Equity:** Private Equity is trading in the shares of an operating company that is not publicly listed and whose shares are not available on the stock market.
- **Venture Capital:** Venture Capital involves investing substantial capital in a budding company in return for stocks in that company.

Insurance

There are two types of insurance:

1. Life Insurance
2. Non-Life or General Insurance.

Life Insurance Products

The main life insurance products are:

- **Term Insurance:** This is the simplest and cheapest form of insurance. It offers financial protection for a specified tenure, say 15 to 20 years. In the case of your death, your family is paid the sum assured. In the case of your surviving the term, the insurer pays nothing.
- **Endowment Policy:** This offers the dual benefit of insurance and investment. Part of the premium is allocated towards the sum assured, while the remaining premium gets invested in equity and debt. It pays a lump sum amount after the specified duration or on the death of the policyholder, whichever is earlier.
- **Unit-Linked Insurance Plan (ULIP):** Here part of the premium is spent on the life cover, while the remaining amount is invested in equity and debt. It helps develop a regular saving habit.
- **Money Back Life Insurance:** While the policyholder is alive, periodic payments of the partial survival benefits are made during the policy tenure. On the death of the insured, the insurance company pays the full sum assured along with survival benefits.
- **Whole Life Insurance:** It offers the dual benefit of insurance and investment. It offers insurance cover for the whole life of the person or up to 100 years whichever is earlier.

General Insurance

General Insurance deals with all insurance covering assets like animals, agricultural crops, goods, factories, cars and so on.

General Insurance Products:

- **Motor Insurance:** This can be divided into Four Wheeler Insurance and Two Wheeler Insurance.
- **Health Insurance:** The main types of health insurance are individual health insurance, family floater health insurance, comprehensive health insurance and critical illness insurance.
- **Travel Insurance:** This can be categorised into Individual Travel Policy, Family Travel Policy, Student Travel Insurance and Senior Citizen Health Insurance.
- **Home Insurance:** This protects the house and its contents from risk.
- **Marine Insurance:** This insurance covers goods, freight, cargo etc. against loss or damage during transit by rail, road, sea and/or air.

Taxes

There are two types of taxes:

1. Direct Taxes
2. Indirect Taxes.

Direct Tax

Direct taxes are levied directly on an entity or a person and are non-transferrable. Some examples of Direct Taxes are:

- **Income Tax:** This tax is levied on your earning in a financial year. It is applicable to both, individuals and companies.
- **Capital Gains Tax:** This tax is payable whenever you receive a sizable amount of money. It is usually of two types – short term capital gains from investments held for less than 36 months and long term capital gains from investments held for longer than 36 months.
- **Securities Transaction Tax:** This tax is added to the price of a share. It is levied every time you buy or sell shares.
- **Perquisite Tax:** This tax is levied is on perks that have been acquired by a company or used by an employee.
- **Corporate Tax:** Corporate tax is paid by companies from the revenue they earn.

Indirect Tax

Indirect taxes are levied on goods or services. Some examples of Indirect Taxes are:

- **Sales Tax:** Sales Tax is levied on the sale of a product.
- **Service Tax:** Service Tax is added to services provided in India.
- **Value Added Tax:** Value Added Tax is levied at the discretion of the state government. The tax is levied on goods sold in the state. The tax amount is decided by the state.
- **Customs Duty & Octroi:** Customs Duty is a charge that is applied on purchases that are imported from another country. Octroi is levied on goods that cross state borders within India.
- **Excise Duty:** Excise Duty is levied on all goods manufactured or produced in India.

12.3.4.1 Tips

1. Think about how quickly you need your money back and pick an investment option accordingly.
2. Ensure that you are buying the right type of insurance policy for yourself.
3. Remember, not paying taxes can result in penalties ranging from fines to imprisonment.

12.3.5 Online Banking, NEFT, RTGS, etc.

What is Online Banking

Internet or online banking allows account holders to access their account from a laptop at any location. In this way, instructions can be issued. To access an account, account holders simply need to use their unique customer ID number and password.

Internet banking can be used to:

- Find out an account balance
- Transfer amounts from one account to another
- Arrange for the issuance of cheques
- Instruct payments to be made
- Request for a cheque book
- Request for a statement of accounts
- Make a fixed deposit

Electronic Funds Transfers

Electronic funds transfer is a convenient way of transferring money from the comfort of one's own home, using integrated banking tools like internet and mobile banking.

Transferring funds via an electronic gateway is extremely convenient. With the help of online banking, you can choose to:

- Transfer funds into your own accounts of the same bank.
- Transfer funds into different accounts of the same bank.
- Transfer funds into accounts in different banks, using NEFT.
- Transfer funds into other bank accounts using RTGS.
- Transfer funds into various accounts using IMPS.

NEFT

NEFT stands for National Electronic Funds Transfer. This money transfer system allows you to electronically transfer funds from your respective bank accounts to any other account, either in the same bank or belonging to any other bank. NEFT can be used by individuals, firms and corporate organizations to transfer funds between accounts.

In order to transfer funds via NEFT, two things are required:

- A transferring bank
- A destination bank

Before you can transfer funds through NEFT, you will need to register the beneficiary who will be receiving the funds. In order to complete this registration, you will require the following

- Recipient's name
- Recipient's account number
- Recipient's bank's name
- Recipient's bank's IFSC code

RTGS

RTGS stands for Real Time Gross Settlement. This is a real time funds transfer system which enables you to transfer funds from one bank to another, in real time or on a gross basis. The transferred amount is immediately deducted from the account of one bank, and instantly credited to the other bank's account. The RTGS payment gateway is maintained by the Reserve Bank of India. The transactions between banks are made electronically.

RTGS can be used by individuals, companies and firms to transfer large sums of money. Before remitting funds through RTGS, you will need to add the beneficiary and his bank account details via your online banking account. In order to complete this registration, you will require the following information:

- Name of the beneficiary
- Beneficiary's account number
- Beneficiary's bank address
- Bank's IFSC code

IMPS

IMPS stands for Immediate Payment Service. This is a real-time, inter-bank, electronic funds transfer system used to transfer money instantly within banks across India. IMPS enables users to make instant

electronic transfer payments using mobile phones through both, Mobile Banking and SMS. It can also be used through ATMs and online banking. IMPS is available 24 hours a day and 7 days a week. The system features a secure transfer gateway and immediately confirms orders that have been fulfilled.

To transfer money through IMPS, the you need to:

- Register for IMPS with your bank
- Receive a Mobile Money Identifier (MMID) from the bank
- Receive a MPIN from the bank

Once you have both these, you can login or make a request through SMS to transfer a particular amount to a beneficiary.

For the beneficiary to receive the transferred money, he must:

- Link his mobile number with his respective account
- Receive the MMID from the bank

In order to initiate a money transfer through IMPS, you will need to enter the following information:

- The beneficiary's mobile number
- The beneficiary's MMID
- The transfer amount
- Your MPIN

As soon as money has been deducted from your account and credited into the beneficiary's account, you will be sent a confirmation SMS with a transaction reference number, for future reference.

12.3.5.1 Differences Between NEFT, RTGS & IMPS

Criteria	NEFT	RTGS	IMPS
Settlement	Done in Batches	Real-Time	Real-Time
Full Form	national Electronic Fund Transfer	Real Time Gross Settlement	Immediate Payment Service
Timing on Monday to Friday	8.00 am - 6.30 pm	9.00 am - 4.30 pm	24x7
Timing on Saturday	8.00 am - 7.00 p.m.	9.00 am - 1.30 pm	24x7
Minimum amount of money transfer limit	`1	`2 lacs	`1
Maximum amount of money transfer limit	`10 lacs	`10 lacs per day	`2 lacs
Maximum charges as per RBI	Upto 10,000 - `2.5 above 10,000 - `1 lac - `5 above 1-2 lacs - `15 above 2-5 lacs - `25 above 5-10 lacs - `25	above 2-5 lacs - `25 above 5-10 lacs - `50	Upto 10,000 - `5 above 10,000 - `1 lac - `5 above 1-2 lacs - `15

12.3.5.2 Tips 

1. Never click on any links in any e-mail message to access your online banking website.
2. You will never be asked for your credit or debit card details while using online banking.
3. Change your online banking password regularly.

UNIT 12.4: Preparing for Employment & Self Employment

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss the steps to prepare for an interview
2. Discuss the steps to create an effective Resume
3. Discuss the most frequently asked interview questions
4. Discuss how to answer the most frequently asked interview questions
5. Discuss basic workplace terminology

12.4.1 Interview Preparation: How to Prepare for an Interview

The success of your getting the job that you want depends largely on how well your interview for that job goes. Therefore, before you go in for your interview, it is important that you prepare for it with a fair amount of research and planning. Take a look at the steps to follow in order to be well prepared for an interview:

1. **Research the organization that you are having the interview with.**
   - Studying the company beforehand will help you be more prepared at the time of the interview. Your knowledge of the organization will help you answer questions at the time of the interview, and will leave you looking and feeling more confident. This is sure to make you stand out from other, not as well informed, candidates.
   - Look for background information on the company. Ty and find an overview of the company and its industry profile.
   - Visit the company website to get a good idea of what the company does. A company website offers a wealth of important information. Read and understand the company's mission statement. Pay attention to the company's products/services and client list. Read through any press releases to get an idea of the company's projected growth and stability.
   - Note down any questions that you have after your research has been completed.
2. **Think about whether your skills and qualifications match the job requirements.**
   - Carefully read through and analyze the job description.
   - Make a note of the knowledge, skills and abilities required to fulfill the job requirements.
   - Take a look at the organization hierarchy. Figure out where the position you are applying for fits into this hierarchy.
3. **Go through the most typical interview questions asked, and prepare your responses.**
   - Remember, in most interviews a mix of resume-based, behavioral and case study questions are asked.
   - Think about the kind of answers you would like to provide to typical questions asked in these three areas.
   - Practice these answers until you can express them confidently and clearly.
4. **Plan your attyre for the interview.**
   - It is always safest to opt for formal business attyre, unless expressly informed to dress in business casual (in which case you should use your best judgement).

- Ensure that your clothes are clean and well-ironed. Pick neutral colours – nothing too bright or flashy.
- The shoes you wear should match your clothes, and should be clean and suitable for an interview.
- Remember, your aim is to leave everyone you meet with the impression that you are a professional and highly efficient person.

5. **Ensure that you have packed everything that you may require during the interview.**
   - Carry a few copies of your resume. Use a good quality paper for your resume print outs.
   - Always take along a notepad and a pen.
   - Take along any information you may need to refer to, in order to fill out an application form.
   - Carry a few samples of your work, if relevant.
6. **Remember the importance of non-verbal communication.**
   - Practice projecting confidence. Remind yourself to smile and make eye contact. Practice giving a firm handshake.
   - Keep in mind the importance of posture. Practice sitting up straight. Train yourself to stop nervous gestures like fidgeting and foot-tapping.
   - Practice keeping your reactions in check. Remember, your facial expressions provide a good insight into your true feelings. Practice projecting a positive image.
7. **Make a list of questions to end the interview with.**
   - Most interviews will end with the interviewer(s) asking if you have any questions. This is your chance to show that you have done your research and are interested in learning more about the company.
   - If the interviewer does not ask you this question, you can inform him/her that you have some queries that you would like to discuss. This is the time for you to refer to the notes you made while studying the company.
   - Some good questions to ask at this point are:What do you consider the most important criteria for success in this job?
     - How will my performance be evaluated?
     - What are the opportunities for advancement?
     - What are the next steps in the hiring process?
   - Remember, never ask for information that is easily available on the company website.

12.4.1.1 Tips

1. Ask insightful and probing questions.
2. When communicating, use effective forms of body language like smiling, making eye contact, and actively listening and nodding. Don't slouch, play with nearby items, fidget, chew gum, or mumble.

12.4.2 Preparing an Effective Resume

A resume is a formal document that lists a candidate's work experience, education and skills. A good resume gives a potential employer enough information to believe the applicant is worth interviewing. That's why it is so important to create a résumé that is effective. Take a look at the steps to create an effective resume:

Step 1: Write the Address Section: The Address section occupies the top of your resume. It includes information like your name, address, phone number and e-mail address. Insert a bold line under the

section to separate it from rest of your resume.

Example:

Jasmine Watts
Breach Candy, mumbai - India
Contact No. +91 2223678270
Email: jasmine.watts@gmail.com

Step 2: Add the Profile Summary Section: This part of your resume should list your overall experiences, achievements, awards, certifications and strengths. You can make your summary as short as 2-3 bullet points or as long as 8-10 bullet points.

Example:

Profile Summary

- A Content Writer gratuated from University of Strathclyde having 6 years of experience in writing website copy.
- Core expertise lies in content creation for e-learning courses, specifically for the k-12 segment.

Step 3: Include Your Educational Qualifications: When listing your academic records, first list your highest degree. Then add the second highest qualification under the highest one and so on. To provide a clear and accurate picture of your educational background, it is critical that include information on your position, rank, percentage or CPI for every degree or certification that you have listed.

If you have done any certifications and trainings, you can add a Trainings & Certifications section under your Educational Qualifications section.

Example:

Educetional Qualification

- Masters in International Management (2007) from Columbia University with 7.8 CPI.
- Bachelor of Management Studios (2004) from Mumbai University with 87% marks.
- 10+2 with Math, Stats (2001) from Maharastra Board with 91% marks.
- High School (1999) from Maharastra Board with 93% marks.

Step 4: List Your Technical Skills: When listing your technical skills, start with the skills that you are most confident about. Then add the skills that you do not have as good a command over. It is perfectly acceptable to include just one skill, if you feel that particular skill adds tremendous value to your résumé. If you do not have any technical skills, you can omit this step.

Example:

Technical Skills

- Flash
- Photoshop

Step 5: Insert Your Academic Project Experience

List down all the important projects that you have worked on. Include the following information in this section:

Example:

Project title	Organization	Platform used
Contribution	Description	

Academic Projects
Project Title: Different Communication Skills
Organization: True Blue Solutions
Platform used: Articilate
Contribution: Content writing and graphic zisualization
Description: Development of storyboards for corporate induction & training programs.

Step 6: List Your Strengths: This is where you list all your major strengths. This section should be in the form of a bulleted list.

Example:

Strengths
- Excellent oral, written and presentation skills
- Action-oriented and result-focused
- Great time management skills

Step 7: List Your Extracurricular Activities: It is very important to show that you have diverse interests and that your life consists of more than academics. Including your extracurricular activities can give you an added edge over other candidates who have similar academic scores and project experiences. This section should be in the form of a bulleted list.

Example:

Extracurricular Activities
- Mamber of the Debate Club
- Played tennis at at national level
- Won first prizes in the All India Camel Contest, 2010

Step 8: Write Your Personal Details: The last section of your résumé must include the following personal information:

- Date of birth
- Gender & marital status
- Nationality
- Languages known

Example:

Personal Details
- Date of Birth: 25th May, 1981
- Gender & marital status: Female, Single
- Nationality: Indian
- Languages known: English, Hindi, Tamil, French

12.4.2.1 Tips

1. Keep your resume file name short, simple and informational.
2. Make sure the resume is neat and free from typing errors.
3. Always create your resume on plain white paper.

12.4.3 Interview FAQs

Take a look at some of the most frequently asked interview questions, and some helpful tips on how to answer them.

1. **Can you tell me a little about yourself?**

   Tips to answer:

   - Don't provide your full employment or personal history.
   - Offer 2-3 specific experiences that you feel are most valuable and relevant.
   - Conclude with how those experiences have made you perfect for this specific role.

2. **How did you hear about the position?**

   Tips to answer:

   - Tell the interviewer how you heard about the job – whether it was through a friend (name the friend), event or article (name them) or a job portal (say which one).
   - Explain what excites you about the position and what in particular caught your eye about this role.

3. **What do you know about the company?**

   Tips to answer:

   - Don't recite the company's About Us page.
   - Show that you understand and care about the company's goals.
   - Explain why you believe in the company's mission and values.

4. **Why do you want this job?**

   Tips to answer:

   - Show that you are passionate about the job.
   - Identify why the role is a great fit for you.
   - Explain why you love the company.

5. **Why should we hire you?**

   Tips to answer:

   - Prove through your words that you can not only do the work, but can definitely deliver excellent results.
   - Explain why you would be a great fit with the team and work culture.
   - Explain why you should be chosen over any other candidate.

6. **What are your greatest professional strengths?**

   Tips to answer:

   - Be honest – share some of your real strengths, rather than give answers that you think sound good.
   - Offer examples of specific strengths that are relevant to the position you are applying for.
   - Provide examples of how you've demonstrated these strengths.

7. **What do you consider to be your weaknesses?**

   Tips to answer:

   - The purpose of this question is to gauge your self-awareness and honesty.
   - Give an example of a trait that you struggle with, but that you're working on to improve.

8. **What are your salary requirements?**

   Tips to answer:

   - Do your research beforehand and find out the typical salary range for the job you are applying for.

- Figure out where you lie on the pay scale based on your experience, education, and skills.
- Be flexible. Tell the interviewer that you know your skills are valuable, but that you want the job and are willing to negotiate.

9. **What do you like to do outside of work?**

   Tips to answer:

   - The purpose of this question is to see if you will fit in with the company culture.
   - Be honest – open up and share activities and hobbies that interest and excite you.

10. **If you were an animal, which one would you want to be?**

    Tips to answer:

    - The purpose of this question is to see if you are able to think on your feet.
    - There's no wrong answer – but to make a great impression try to bring out your strengths or personality traits through your answer.

11. **What do you think we could do better or differently?**

    Tips to answer:

    - The purpose of this question is to see if you have done your research on the company, and to test whether you can think critically and come up with new ideas.
    - Suggest new ideas. Show how your interests and expertise would help you execute these ideas.

12. **Do you have any questions for us?**

    Tips to answer:

    - Do not ask questions to which the answers can be easily found on the company website or through a quick online search.
    - Ask intelligent questions that show your ability to think critically.

12.4.3.1 Tips

1. Be honest and confident while answering.
2. Use examples of your past experiences wherever possible to make your answers more impactful.

12.4.4 Work Readiness – Terms & Terminologies

Every employee should be well versed in the following terms:

- **Annual leave:** Paid vacation leave given by employers to employees.
- **Background Check:** A method used by employers to verify the accuracy of the information provided by potential candidates.
- **Benefits:** A part of an employee's compensation package.
- **Breaks:** Short periods of rest taken by employees during working hours.
- **Compensation Package:** The combination of salary and benefits that an employer provides to his/her employees.
- **Compensatory Time (Comp Time):** Time off in lieu of pay.
- **Contract Employee:** An employee who works for one organization that sells said employee's services to another company, either on a project or time basis.
- **Contract of Employment:** When an employee is offered work in exchange for wages or salary, and accepts the offer made by the employer, a contract of employment exists.

- **Corporate Culture:** The beliefs and values shared by all the members of a company, and imparted from one generation of employees to another.
- **Counter Offer/Counter Proposal:** A negotiation technique used by potential candidates to increase the amount of salary offered by a company.
- **Cover Letter:** A letter that accompanies a candidate's resume. It emphasizes the important points in the candidate's resume and provides real examples that prove the candidate's ability to perform the expected job role.
- **Curriculum Vitae (CV)/Resume:** A summary of a candidate's achievements, educational background, work experience, skills and strengths.
- **Declining Letter:** A letter sent by an employee to an employer, turning down the job offer made by the employer to the employee.
- **Deductions:** Amounts subtracted from an employee's pay and listed on the employee's pay slip.
- **Discrimination:** The act of treating one person not as favourably as another person.
- **Employee:** A person who works for another person in exchange for payment.
- **Employee Training:** A workshop or in-house training that an employee is asked to attend by his or her superior, for the benefit of the employer.
- **Employment Gaps:** Periods of unemployed time between jobs.
- **Fixed-Term Contract:** A contract of employment which gets terminated on an agreed-upon date.
- **Follow-Up:** The act of contacting a potential employer after a candidate has submitted his or her resume.
- **Freelancer/Consultant/Independent Contractor:** A person who works for him or herself and pitches for temporary jobs and projects with different employers.
- **Holiday:** Paid time-off from work.
- **Hourly Rate:** The amount of salary or wages paid for 60 minutes of work.
- **Internship:** A job opportunity offered by an employer to a potential employee, called an intern, to work at the employer's company for a fixed, limited time period.
- **Interview:** A conversation between a potential employee and a representative of an employer, in order to determine if the potential employee should be hired.
- **Job Application:** A form which asks for a candidate's information like the candidate's name, address, contact details and work experience. The purpose of a candidate submitting a job application, is to show that candidate's interest in working for a particular company.
- **Job Offer:** An offer of employment made by an employer to a potential employee.
- **Job Search Agent:** A program that enables candidates to search for employment opportunities by selecting criteria listed in the program, for job vacancies.
- **Lay Off:** A lay off occurs when an employee is temporarily let go from his or her job, due to the employer not having any work for that employee.
- **Leave:** Formal permission given to an employee, by his or her employer, to take a leave of absence from work.
- **Letter of Acceptance:** A letter given by an employer to an employee, confirming the offer of employment made by the employer, as well as the conditions of the offer.
- **Letter of Agreement:** A letter that outlines the terms of employment.
- **Letter of Recommendation:** A letter written for the purpose of validating the work skills of a person.
- **Maternity Leave:** Leave taken from work by women who are pregnant, or who have just given birth.
- **Mentor:** A person who is employed at a higher level than you, who offers you advice and guides you in your career.
- **Minimum wage:** The minimum wage amount paid on an hourly basis.

- **Notice:** An announcement made by an employee or an employer, stating that the employment contract will end on a particular date.
- **Offer of Employment:** An offer made by an employer to a prospective employee that contains important information pertaining to the job being offered, like the starting date, salary, working conditions etc.
- **Open-Ended Contract:** A contract of employment that continues till the employer or employee terminates it.
- **Overqualified:** A person who is not suited for a particular job because he or she has too many years of work experience, or a level of education that is much higher than required for the job, or is currently or was previously too highly paid.
- **Part-Time Worker:** An employee who works for fewer hours than the standard number of hours normally worked.
- **Paternity Leave:** Leave granted to a man who has recently become a father.
- **Recruiters/Headhunters/Executive Search Firms:** Professionals who are paid by employers to search for people to fill particular positions.
- **Resigning/Resignations:** When an employee formally informs his or her employer that he or she is quitting his or her job.
- **Self-Employed:** A person who has his or her own business and does not work in the capacity of an employee.
- **Time Sheet:** A form that is submitted to an employer, by an employee, that contains the number of hours worked every day by the employee.

UNIT 12.5: Understanding Entrepreneurship

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss the concept of entrepreneurship
2. Discuss the importance of entrepreneurship
3. Describe the characteristics of an entrepreneur
4. Describe the different types of enterprises
5. List the qualities of an effective leader
6. Discuss the benefits of effective leadership
7. List the traits of an effective team
8. Discuss the importance of listening effectively
9. Discuss how to listen effectively
10. Discuss the importance of speaking effectively
11. Discuss how to speak effectively
12. Discuss how to solve problems
13. List important problem solving traits
14. Discuss ways to assess problem solving skills
15. Discuss the importance of negotiation
16. Discuss how to negotiate
17. Discuss how to identify new business opportunities
18. Discuss how to identify business opportunities within your business
19. Understand the meaning of entrepreneur
20. Describe the different types of entrepreneurs
21. List the characteristics of entrepreneurs
22. Recall entrepreneur success stories
23. Discuss the entrepreneurial process
24. Describe the entrepreneurship ecosystem
25. Discuss the government's role in the entrepreneurship ecosystem
26. Discuss the current entrepreneurship ecosystem in India
27. Understand the purpose of the Make in India campaign
28. Discuss the relationship between entrepreneurship and risk appetite
29. Discuss the relationship between entrepreneurship and resilience
30. Describe the characteristics of a resilient entrepreneur
31. Discuss how to deal with failure

12.5.1 Concept Introduction

Anyone who is determined to start a business, no matter what the risk, is an entrepreneur. Entrepreneurs run their own start-up, take responsibility for the financial risks and use creativity, innovation and vast reserves of self-motivation to achieve success. They dream big and are determined to do whatever it takes to turn their idea into a viable offering. The aim of an entrepreneur is to create an enterprise. The process of creating this enterprise is known as entrepreneurship.

12.5.1.1 Importance of Entrepreneurship

Entrepreneurship is very important for the following reasons:

1. It results in the creation of new organizations
2. It brings creativity into the marketplace
3. It leads to improved standards of living
4. It helps develop the economy of a country

12.5.1.2 Characteristics of Entrepreneurs

All successful entrepreneurs have certain characteristics in common.

They are all:

1. Extremely passionate about their work
2. Confident in themselves
3. Disciplined and dedicated
4. Motivated and driven
5. Highly creative
6. Visionaries
7. Open-minded
8. Decisive

Entrepreneurs also have a tendency to:

1. Have a high risk tolerance
2. Thoroughly plan everything
3. Manage their money wisely
4. Make their customers their priority
5. Understand their offering and their market in detail
6. Ask for advice from experts when required
7. Know when to cut their losses

12.5.1.3 Examples of Famous Entrepreneurs

Some famous entrepreneurs are:

- Bill Gates (Founder of Microsoft)
- Steve Jobs (Co-founder of Apple)
- Mark Zuckerberg (Founder of Facebook)
- Pierre Omidyar (Founder of eBay)

12.5.1.4 Types of Enterprises

As an entrepreneur in India, you can own and run any of the following types of enterprises:

Sole Proprietorship: In a sole proprietorship, a single individual owns, manages and controls the enterprise. This type of business is the easiest to form with respect to legal formalities. The business and the owner have no separate legal existence. All profit belongs to the proprietor, as do all the losses- the liability of the entrepreneur is unlimited.

Partnership: A partnership firm is formed by two or more people. The owners of the enterprise are called partners. A partnership deed must be signed by all the partners. The firm and its partners have no separate legal existence. The profits are shared by the partners. With respect to losses, the liability of the partners is unlimited. A firm has a limited life span and must be dissolved when any one of the partners dies, retyres, claims bankruptcy or goes insane.

Limited Liability Partnership (LLP): In a Limited Liability Partnership or LLP, the partners of the firm enjoy perpetual existence as well as the advantage of limited liability. Each partner's liability is limited to their agreed contribution to the LLP. The partnership and its partners have a separate legal existence.

12.5.1.5 Tips

1. Learn from others' failures.
2. Be certain that this is what you want.
3. Search for a problem to solve, rather than look for a problem to attach to your idea.

12.5.2 Leadership & Teamwork: Leadership and Leaders

Leadership means setting an example for others to follow. Setting a good example means t asking someone to do something that you wouldn't willingly want to do yourself. Leadership is about figuring out what to do in order to win as a team, and as a company.

Leaders believe in doing the right things. They also believe in helping others to do the right things. An effective leader is someone who:

- Creates an inspiring vision of the future.
- Motivates and inspires his team to pursue that vision.

12.5.2.1 Leadership Qualities That All Entrepreneurs Need

Building a successful enterprise is only possible if the entrepreneur in charge possesses excellent leadership qualities. Some critical leadership skills that every entrepreneur must have are:

1. **Pragmatism:** This means having the ability to highlight all obstacles and challenges, in order to resolve issues and reduce risks.
2. **Humility:** This means admitting to mistakes often and early, and being quick to take responsibility for your actions. Mistakes should be viewed as challenges to overcome, not opportunities to point blame.
3. **Flexibility:** It is critical for a good leader to be very flexible and quickly adapt to change. It is equally critical to know when to adapt and when not to.
4. **Authenticity:** This means showing both, your strengths and your weaknesses. It means being human and showing others that you are human.

5. **Reinvention:** This means refreshing or changing your leadership style when necessary. To do this, it's important to learn where your leadership gaps lie and find out what resources are required to close them.
6. **Awareness:** This means taking the time to recognize how others view you. It means understanding how your presence affects those around you.

12.5.2.2 Benefits of Effective Leadership

Effective leadership results in numerous benefits. Great leadership leads to the leader successfully:

- Gaining the loyalty and commitment of the team members
- Motivating the team to work towards achieving the company's goals and objectives
- Building morale and instilling confidence in the team members
- Fostering mutual understanding and team-spirit among team members
- Convincing team members about the need to change when a situation requires adaptability

12.5.2.3 Teamwork and Teams

Teamwork occurs when the people in a workplace combine their individual skills to pursue a common goal. Effective teams are made up of individuals who work together to achieve this common goal. A great team is one who holds themselves accountable for the end result.

12.5.2.4 Importance of Teamwork in Entrepreneurial Success

For an entrepreneurial leader, building an effective team is critical to the success of a venture. An entrepreneur must ensure that the team he builds possesses certain crucial qualities, traits and characteristics. An effective team is one which has:

1. **Unity of purpose:** All the team members should clearly understand and be equally committed to the purpose, vision and goals of the team.
2. **Great communication skills:** Team members should have the ability to express their concerns, ask questions and use diagrams, and charts to convey complex information.
3. **The ability to collaborate:** Every member should feel entitled to provide regular feedback on new ideas.
4. **Initiative:** The team should consist of proactive individuals. The members should have the enthusiasm to come up with new ideas, improve existing ideas, and conduct their own research.
5. **Visionary members:** The team should have the ability to anticipate problems and act on these potential problem before they turn into real problems.
6. **Great adaptability skills:** The team must believe that change is a positive force. Change should be seen as the chance to improve and try new things.
7. **Excellent organizational skills:** The team should have the ability to develop standard work processes, balance responsibilities, properly plan projects, and set in place methods to measure progress and ROI.

12.5.2.5 Tips

1. Don't get too attached to your original idea. Allow it to evolve and change.
2. Be aware of your weaknesses and build a team that will complement your shortfalls.
3. Hiring the right people is not enough. You need to promote or incentivize your most talented people to keep them motivated.
4. Earn your team's respect

12.5.3 Communication Skills

Listening is the ability to correctly receive and understand messages during the process of communication. Listening is critical for effective communication. Without effective listening skills, messages can easily be misunderstood. This results in a communication breakdown and can lead to the sender and the receiver of the message becoming frustrated or irritated.

It's very important to note that listening is not the same as hearing. Hearing just refers to sounds that you hear. Listening is a whole lot more than that. To listen, one requires focus. It means not only paying attention to the story, but also focusing on how the story is relayed, the way language and voice is used, and even how the speaker uses their body language. The ability to listen depends on how effectively one can perceive and understand both, verbal and non-verbal cues.

12.5.3.1 How to Listen Effectively

To listen effectively you should:

- Stop talking
- Stop interrupting
- Focus completely on what is being said
- Nod and use encouraging words and gestures
- Be open-minded
- Think about the speaker's perspective
- Be very, very patient
- Pay attention to the tone that is being used
- Pay attention to the speaker's gestures, facial expressions and eye movements
- Not try and rush the person
- Not let the speaker's mannerisms or habits irritate or distract you
- Be very, very patient
- Pay attention to the tone that is being used
- Pay attention to the speaker's gestures, facial expressions and eye movements
- Not try and rush the person
- Not let the speaker's mannerisms or habits irritate or distract you

12.5.3.2 How to Listen Effectively

How successfully a message gets conveyed depends entyrely on how effectively you are able to get it through. An effective speaker is one who enunciates properly, pronounces words correctly, chooses the right words and speaks at a pace that is easily understandable. Besides this, the words spoken out loud need to match the gestures, tone and body language used.

What you say, and the tone in which you say it, results in numerous perceptions being formed. A person who speaks hesitantly may be perceived as having low self-esteem or lacking in knowledge of the discussed topic. Those with a quiet voice may very well be labelled as shy. And those who speak in commanding tones with high levels of clarity, are usually considered to be extremely confident. This makes speaking a very critical communication skill.

12.5.3.3 How to Speak Effectively

To speak effectively you should:

- Incorporate body language in your speech like eye contact, smiling, nodding, gesturing etc.
- Build a draft of your speech before actually making your speech.
- Ensure that all your emotions and feelings are under control.
- Pronounce your words distinctly with the correct pitch and intensity. Your speech should be crystal clear at all times.
- Use a pleasant and natural tone when speaking. Your audience should not feel like you are putting on an accent or being unnatural in any way.
- Use precise and specific words to drive your message home. Ambiguity should be avoided at all costs.
- Ensure that your speech has a logical flow.
- Be brief. Don't add any unnecessary information.
- Make a conscious effort to avoid irritating mannerisms like fidgeting, twitching etc.
- Choose your words carefully and use simple words that the majority of the audience will have no difficulty understanding.
- Use visual aids like slides or a whiteboard.
- Speak slowly so that your audience can easily understand what you're saying. However, be careful not to speak too slowly because this can come across as stiff, unprepared or even condescending.
- Remember to pause at the right moments.

12.5.3.4 Tips 

1. If you're finding it difficult to focus on what someone is saying, try repeating their words in your head.
2. Always maintain eye contact with the person that you are communicating with, when speaking as well as listening. This conveys and also encourages interest in the conversation.

12.5.4 Problem Solving & Negotiation skills

As per The Concise Oxford Dictionary (1995), a problem is, "A doubtful or difficult matter requiring a solution"

All problems contain two elements:

1. Goals
2. Obstacles

The aim of problem solving is to recognize the obstacles and remove them in order to achieve the goals.

12.5.4.1 How to Solve Problems

Solving a problem requires a level of rational thinking. Here are some logical steps to follow when faced with an issue:

- **Step 1:** Identify the problem
- **Step 2:** Study the problem in detail
- **Step 3:** List all possible solutions
- **Step 4:** Select the best solution
- **Step 5:** Implement the chosen solution
- **Step 6:** Check that the problem has really been solved

12.5.4.2 Important Traits for Problem Solving

Highly developed problem solving skills are critical for both, business owners and their employees. The following personality traits play a big role in how effectively problems are solved:

- Being open minded
- Asking the right questions
- Being proactive
- Not panicking
- Having a positive attitude
- Focusing on the right problem

12.5.4.3 Important Traits for Problem Solving

As an entrepreneur, it would be a good idea to assess the level of problem solving skills of potential candidates before hiring them. Some ways to assess this skill are through:

- **Application forms:** Ask for proof of the candidate's problem solving skills in the application form.
- **Psychometric tests:** Give potential candidates logical reasoning and critical thinking tests and see how they fare.
- **Interviews:** Create hypothetical problematic situations or raise ethical questions and see how the candidates respond.
- **Technical questions:** Give candidates examples of real life problems and evaluate their thought process.

12.5.4.4 What is Negotiation?

Negotiation is a method used to settle differences. The aim of negotiation is to resolve differences through a compromise or agreement while avoiding disputes. Without negotiation, conflicts are likely to lead to resentment between people. Good negotiation skills help satisfy both parties and go a long way towards developing strong relationships.

Why Negotiate

Starting a business requires many, many negotiations. Some negotiations are small while others are critical enough to make or break a startup. Negotiation also plays a big role inside the workplace. As an entrepreneur, you need to know not only know how to negotiate yourself, but also how to train employees in the art of negotiation.

How to Negotiate

Take a look at some steps to help you negotiate:

Step 1: Pre-Negotiation Preparation: Agree on where to meet to discuss the problem, decide who all will be present and set a time limit for the discussion.

Step 2: Discuss the Problem: This involves asking questions, listening to the other side, putting your views forward and clarifying doubts.

Step 3: Clarify the Objective: Ensure that both parties want to solve the same problem and reach the same goal.

Step 4: Aim for a Win-Win Outcome: Try your best to be open minded when negotiating. Compromise and offer alternate solutions to reach an outcome where both parties win.

Step 5: Clearly Define the Agreement: When an agreement has been reached, the details of the agreement should be crystal clear to both sides, with no scope for misunderstandings.

Step 6: Implement the Agreed Upon Solution: Agree on a course of action to set the solution in motion.

12.5.4.5 Tips 

1. Know exactly what you want before you work towards getting it
2. Give more importance to listening and thinking, than speaking
3. Focus on building a relationship rather than winning
4. Remember that your people skills will affect the outcome
5. Know when to walk away – sometimes reaching an agreement may not be possible

12.5.4.6 What is Negotiation?

"The entrepreneur always searches for change, responds to it and exploits it as an opportunity."

Peter Drucker

The ability to identify business opportunities is an essential characteristic of an entrepreneur.

What is an Opportunity?

The word opportunity suggests a good chance or a favourable situation to do something offered by circumstances.

A business opportunity means a good or favourable change available to run a specific business in a given environment, at a given point of time.

Common Questions Faced by Entrepreneurs

A critical question that all entrepreneurs face is how to go about finding the business opportunity that is right for them.

Some common questions that entrepreneurs constantly think about are:

- Should the new enterprise introduce a new product or service based on an unmet need?
- Should the new enterprise select an existing product or service from one market and offer it in another where it may not be available?
- Should the enterprise be based on a tried and tested formula that has worked elsewhere?

It is therefore extremely important that entrepreneurs must learn how to identify new and existing business opportunities and evaluate their chances of success.

When is an Idea an Opportunity?

An idea is an opportunity when:

- It creates or adds value to a customer
- It solves a significant problem, removes a pain point or meets a demand
- Has a robust market and profit margin
- Is a good fit with the founder and management team at the right time and place

Factors to Consider When Looking for Opportunities

- Consider the following when looking for business opportunities:
- Economic trends Changes in funding
- Changing relationships between vendors, partners and suppliers
- Market trends
- Changes in political support
- Shift in target audience

Ways to Identify New Business Opportunities

- **Identify Market Inefficiencies:** When looking at a market, consider what inefficiencies are present in the market. Think about ways to correct these inefficiencies.
- **Remove Key Hassles:** Rather than create a new product or service, you can innovatively improve a product, service or process.
- **Create Something New:** Think about how you can create a new experience for customers, based on existing business models.
- **Pick a Growing Sector/Industry:** Research and find out which sectors or industries are growing and think about what opportunities you can tap in the same.
- **Think About Product Differentiation:** If you already have a product in mind, think about ways to set it apart from the existing ones.

Ways to Identify Business Opportunities Within Your Business

SWOT Analysis: An excellent way to identify opportunities inside your business is by creating a SWOT analysis. The acronym SWOT stands for strengths, weaknesses, opportunities, and threats. SWOT analysis framework:

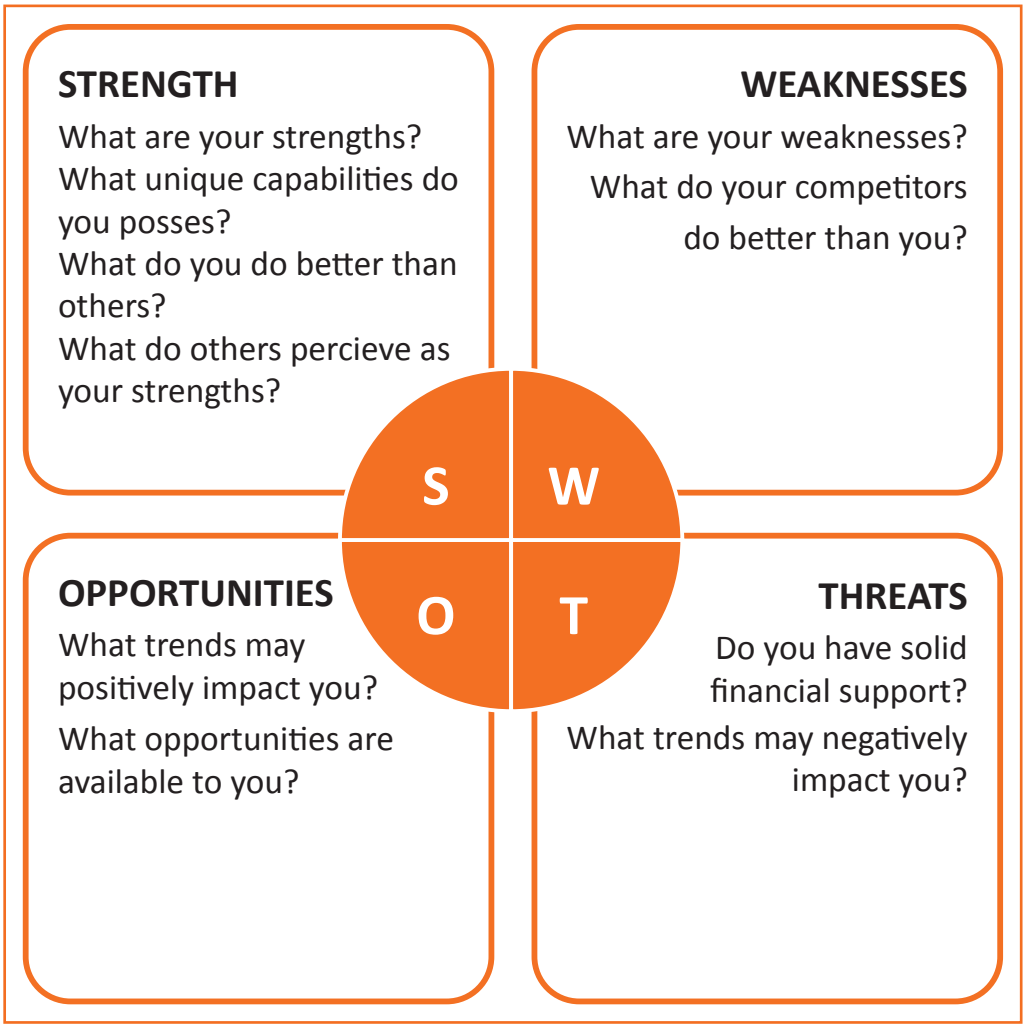

Fig. 12.5.1: SWOT

Consider the following when looking for business opportunities:

By looking at yourself and your competitors using the SWOT framework, you can uncover opportunities that you can exploit, as well as manage and eliminate threats that could derail your success.

Establishing Your USP

Establish your USP and position yourself as different from your competitors. Identify why customers should buy from you and promote that reason.

Opportunity Analysis

Once you have identified an opportunity, you need to analyze it. To analyze an opportunity, you must:

- Focus on the idea
- Focus on the market of the idea
- Talk to industry leaders in the same space as the idea
- Talk to players in the same space as the idea

12.5.4.7 Tips

1. Remember, opportunities are situational.
2. Look for a proven track record.
3. Avoid the latest craze.
4. Love your idea.

12.5.5 Entrepreneurship Support Eco-System

An entrepreneur is a person who:

- Does not work for an employee
- Runs a small enterprise
- Assumes all the risks and rewards of the enterprise, idea, good or service

Types of Entrepreneurs

There are four main types of entrepreneurs:

1. **The Traditional Entrepreneur:** This type of entrepreneur usually has some kind of skill – they can be a carpenter, mechanic, cook etc. They have businesses that have been around for numerous years like restaurants, shops and carpenters. Typically, they gain plenty of experience in a particular industry before they begin their own business in a similar field.
2. **The Growth Potential Entrepreneur:** The desire of this type of entrepreneur is to start an enterprise that will grow, win many customers and make lots of money. Their ultimate aim is to eventually sell their enterprise for a nice profit. Such entrepreneurs usually have a science or technical background.
3. **The Project-Oriented Entrepreneur:** This type of entrepreneur generally has a background in the Arts or psychology. Their enterprises tend to be focus on something that they are very passionate about.
4. **The Lifestyle Entrepreneur:** This type of entrepreneur has usually worked as a teacher or a office assistant. They are more interested in selling something that people will enjoy, rather than making lots of money.

Characteristics of an Entrepreneur

Successful entrepreneurs have the following characteristics:

- They are highly motivated
- They are creative and persuasive
- They are mentally prepared to handle each and every task
- They have excellent business skills – they know how to evaluate their cash flow, sales and revenue
- They are willing to take great risks
- They are very proactive – this means they are willing to do the work themselves, rather than wait for someone else to do it
- They have a vision – they are able to see the big picture
- They are flexible and open-minded
- They are good at making decisions

12.5.5.1 Entrepreneur Success Stories

Dhiru Bhai Ambani

Dhirubhai Ambani began his entrepreneurial career by selling "bhajias" to pilgrims in Mount Girnar on weekends. At 16, he moved to Yemen where he worked as a gas-station attendant, and as a clerk in an oil company. He returned to India with Rs. 50,000 and started a textile trading company. Reliance went on to become the first Indian company to raise money in global markets and the first Indian company to feature in Forbes 500 list.

Dr. Karsanbhai Patel

Karsanbhai Patel made detergent powder in the backyard of his house. He sold his product door-to-door and offered a money back guarantee with every pack that was sold. He charged Rs. 3 per kg when the cheapest detergent at that time was Rs.13 per kg. Dr. Patel eventually started Nirma which became a whole new segment in the Indian domestic detergent market.

12.5.5.2 The Entrepreneurial Process

Let's take a look at the stages of the entrepreneurial process.

- **Stage 1:** Idea Generation. The entrepreneurial process begins with an idea that has been thought of by the entrepreneur. The idea is a problem that has the potential to be solved.
- **Stage 2:** Germination or Recognition. In this stage a possible solution to the identified problem is thought of.
- **Stage 3:** Preparation or Rationalization. The problem is studied further and research is done to find out how others have tried to solve the same problem.
- **Stage 4:** Incubation or Fantasizing. This stage involves creative thinking for the purpose of coming up with more ideas. Less thought is given to the problem areas.
- **Stage 5:** Feasibility Study: The next step is the creation of a feasibility study to determine if the idea will make a profit and if it should be seen through.
- **Stage 6:** Illumination or Realization. This is when all uncertain areas suddenly become clear. The entrepreneur feels confident that his idea has merit.
- **Stage 7:** Verification or Validation. In this final stage, the idea is verified to see if it works and if it is useful.

Take a look at the diagram below to get a better idea of this process.

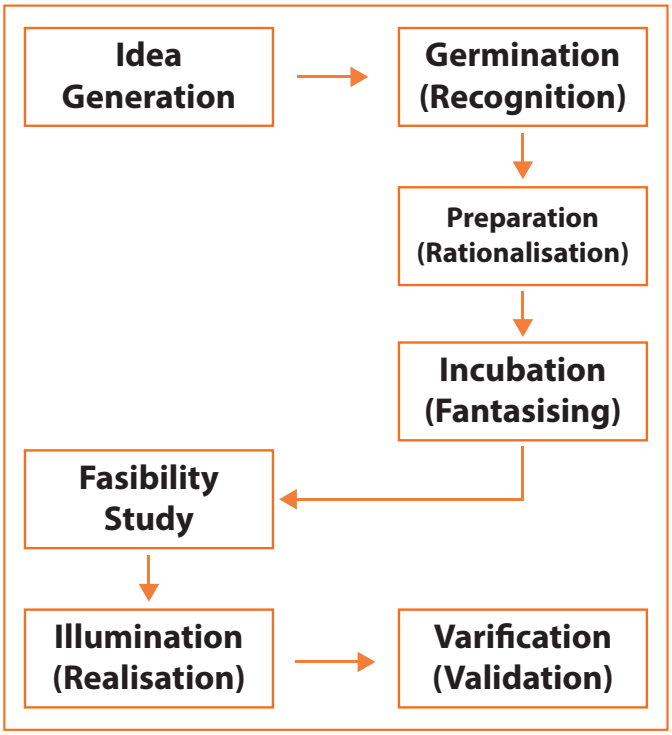

Fig. 12.5.2: Stages of the entrepreneurial process

12.5.5.3 What is an Entrepreneur?

The entrepreneurship support ecosystem signifies the collective and complete nature of entrepreneurship. New companies emerge and flourish not only because of the courageous, visionary entrepreneurs who launch them, but they thrive as they are set in an environment or 'ecosystem' made of private and public participants. These players nurture and sustain the new ventures, facilitating the entrepreneurs' efforts.

An entrepreneurship ecosystem comprises of the following six domains:

1. **Favourable Culture:** This includes elements such as tolerance of risk and errors, valuable networking and positive social standing of the entrepreneur.
2. **Facilitating Policies & Leadership:** This includes regulatory framework incentives and existence of public research institutes.
3. **Financing Options:** Angel financing, venture capitalists and micro loans would be good examples of this.
4. **Human Capital:** This refers to trained and untrained labour, entrepreneurs and entrepreneurship training programmes, etc.
5. **Conducive Markets for Products & Services:** This refers to an existence or scope of existence of a market for the product/service.
6. **Institutional & Infrastructural Support:** This includes legal and financing advisers, telecommunications, digital and transportation infrastructure, and entrepreneurship networking programmes.

These domains indicate whether there is a strong entrepreneurship support ecosystem and what actions should the government put in place to further encourage this ecosystem. The six domains and their various elements have been graphically depicted.

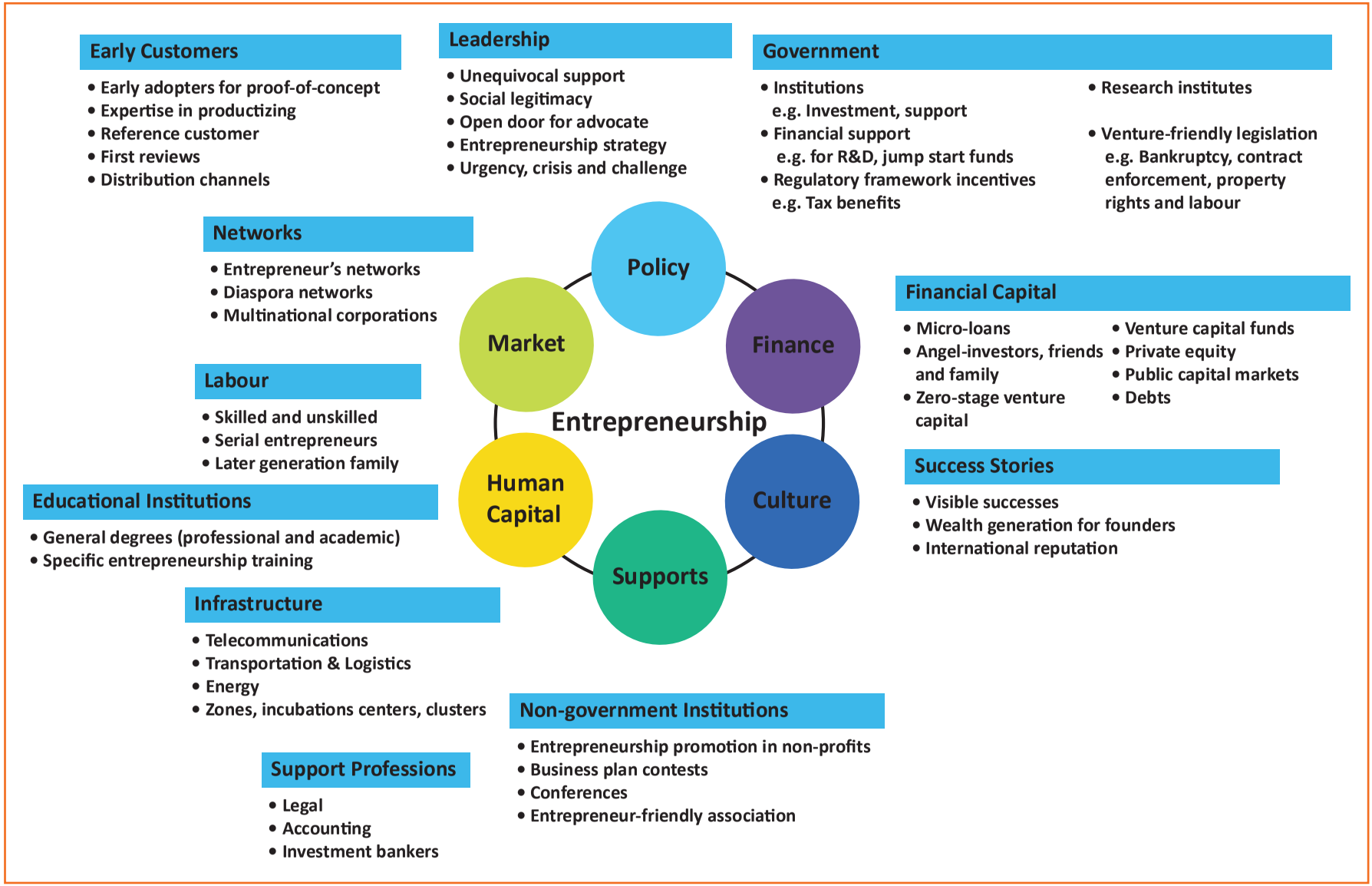

Fig. 12.5.3: Entrepreneurship support ecosystem

Every entrepreneurship support ecosystem is unique and all the elements of the ecosystem are interdependent. Although every region's entrepreneurship ecosystem can be broadly described by the above features, each ecosystem is the result of the hundred elements interacting in highly complex and particular ways.

Entrepreneurship ecosystems eventually become (largely) self-sustaining. When the six domains are resilient enough, they are mutually beneficial. At this point, government involvement can and should be significantly minimized. Public leaders do not need to invest a lot to sustain the ecosystem. It is imperative that the entrepreneurship ecosystem incentives are formulated to be self-liquidating, hence focusing on sustainability of the environment.

12.5.5.4 Make in India Campaign

Every entrepreneur has certain needs. Some of their important needs are:

- To easily get loans
- To easily find investors
- To get tax exemptions
- To easily access resources and good infrastructure
- To enjoy a procedure that is free of hassles and is quick
- To be able to easily partner with other firms

The Make in India campaign, launched by Prime Minister Modi aims to satisfy all these needs of young, aspiring entrepreneurs. Its objective is to:

- Make investment easy
- Support new ideas
- Enhance skill development
- Safeguard the ideas of entrepreneurs
- Create state-of-the-art facilities for manufacturing goods

12.5.5.5 Key Schemes to Promote Entrepreneurs

The government offers many schemes to support entrepreneurs. These schemes are run by various Ministries/ Departments of Government of India to support First Generation Entrepreneurs.Take a look at a few key schemes to promote entrepreneurship:

Name of the Scheme

1. Pradhan Mantri MUDRA Yojana - Micro Units Development and Refinance Agency (MUDRA),
2. STAND UP INDIA
3. Prime Minister Employment Generation Programme (PMEGP)
4. International Cooperation
5. Performance and Credit Rating
6. Marketing Assistance Scheme
7. Reimbursement of Registration Fee for Bar Coding
8. Enable Participation of MSMEs in State/District level Trade Fairs and Provide Funding Support
9. Capital Subsidy Support on Credit for Technology up gradation
10. Credit Guarantee Fund for Micro and Small Enterprise (CGFMSE)
11. Reimbursement of Certification Fees for Acquiring ISO Standards

12. Agricultural Marketing
13. Small Agricultural Marketing
14. Mega Food Park
15. Adivasi Mahila Sashaktikaran Yojana

Pradhan Mantri MUDRA Yojana, - Micro Units Development and Refinance Agency (MUDRA)

Under the aegis support of Pradhan Mantri MUDRA Yojana, MUDRA has already created its initial products/ schemes. The interventions have been named 'Shishu', 'Kishor' and 'Tarun' to signify the stage of growth/ development and funding needs of the beneficiary micro unit/entrepreneur and also provide a reference point for the next phase of graduation/growth to look forward to:

- **Shishu:** Covering loans upto Rs.50,000/-
- **Kishor:** Covering loans above Rs. 50,000/- and upto Rs.5 lakh
- **Tarun:** Covering loans above Rs. 5 lakh to Rs.10 lakh

Who can apply?: Any Indian citizen who has a business plan for a non-farm sector income generating activity such as manufacturing, processing, trading or service sector and whose credit need is less than Rs.10 lakh can approach either a Bank, MFI, or NBFC for availing of MUDRA loans under Pradhan Mantri Mudra Yojana (PMMY).

Stand Up India

The objective of the Standup India scheme is to facilitate bank loans between Rs.10 lakh and Rs.1 crore to at least one Schedule Caste (SC) or Scheduled Tribe (ST) borrower and at least one woman borrower per bank branch for setting up a Greenfield enterprise. This enterprise may be in manufacturing, services or the trading sector. In case of non-Individual enterprises at least 51% of the shareholding and controlling stake should be held be either an SC/ST or Woman Entrepreneur.

Who can apply?: ST, SC &Women

Prime Minister Employment Generation Programme (PMEGP)

The Scheme is implemented by Khadi and Village Industries Commission (KVIC), as the nodal agency at the National level. At the State level, the Scheme is implemented through State KVIC Directorates, State Khadi and Village Industries Boards (KVIBs) and District Industries Centres (DICs) and banks. The Government subsidy under the Scheme is routed. by KVIC through identified banks for eventual distribution to the beneficiaries/ entrepreneurs in their bank accounts.

Nature of assistance: The maximum cost of the project/unit admissible under manufacturing sector is Rs.25 lakh and under business/service sector is Rs.10 lakh. Levels of funding under PMEGP

Categories of beneficiaries under PMEGP	Beneficiary's contribution (of project cost)	Rate of Subsidy (of project cost)
Area (location of project/unit)		Urban Rural
General Category	10%	15% 25%
Special (including SC / ST / OBC / Minorities / Women, Ex- servicemen, Physically handicapped, NER, Hill and Border areas, etc.	05%	25% 35%

The balance amount of the total project cost will be provided by Banks as term loan as well as working capital.

Who can apply?: Any individual, above 18 years of age. At least VIII standard pass for projects costing above Rs.10 lakh in the manufacturing sector and above Rs.5 lakh in the business/service sector. Only new projects are considered for sanction under PMEGP. Self Help Groups (including those belonging to BPL provided that they have not availed benefits under any other Scheme), Institutions registered under Societies Registration Act,1860; Production Co-operative Societies, and Charitable Trusts are also eligible. Existing Units (under PMRY, REGP or any other scheme of Government of India or State Government) and the units that have already availed Government Subsidy under any other scheme of Government of India or State Government are NOT eligible.

International Cooperation Description

The Scheme would cover the following activities:

- Deputation of MSME business delegations to other countries for exploring new areas of technology infusion/ upgradation, facilitating joint ventures, improving market of MSMEs products, foreign collaborations, etc.
- Participation by Indian MSMEs in international exhibitions, trade fairs and buyer-seller meets in foreign countries as well as in India, in which there is international participation.
- Holding international conferences and seminars on topics and themes of interest to the MSME.

Nature of assistance: IC Scheme provides financial assistance towards the airfare and space rent of entrepreneurs. Assistance is provided on the basis of size and the type of the enterprise.

Who can apply?:

- State/Central Government Organisations;
- Industry/Enterprise Associations; and
- Registered Societies/Trusts and Organisations associated with the promotion and development of MSMEs

Performance and Credit Rating for Micro and Small Enterprises Description

The objective of the Scheme is to create awareness amongst micro & small enterprises about the strengths and weaknesses of their operations and also their credit worthiness.

Nature of assistance:

Turn Over	Fee to be reimbursed by Ministry of MSME
Up to Rs.50 lacs	75% of the fee charged by the rating agency subject to a ceiling Rs.15,000/-
Above Rs.50 lacs to Rs.200 lacs	75% of the fee charged by the rating agency subject to a ceiling of Rs.30,0001-
Above Rs.200 lacs	75% of the fee charged by the rating agency subject

Who can apply?: Any enterprise registered in India as a micro or small enterprise is eligible to apply.

Marketing Assistance Scheme Description

The assistance is provided for the following activities:

- Organizing exhibitions abroad and participation in international exhibitions/trade fairs
- Co-sponsoring of exhibitions organized by other organisations/industry associations/agencies
- Organizing buyer-seller meets, intensive campaigns and marketing promotion events

Nature of assistance: Financial assistance of up to 95% of the airfare and space rent of entrepreneurs. Assistance is provided on the basis of size and the type of the enterprise. Financial assistance for co-sponsoring would be limited to 40% of the net expenditure, subject to maximum amount of Rs.5 lakh.

Who can apply?: MSMEs, Industry Associations and other organizations related to MSME sector.

Reimbursement of Registration Fee for Bar Coding Description

The financial assistance is provided towards 75% reimbursement of only one-time registration fee and 75% of annual recurring fee for first three years paid by MSEs to GS1 India for using bar coding.

Nature of assistance: Funding support for reimbursement of 75% of one time and recurring bar code registration fees.

Who can apply?: All MSMEs with EM registration.

Enabling Participation of MSMEs in State/District Level Trade Fairs and Provide Funding Support

Provide marketing platform to manufacturing MSMEs by enabling their participation in state/district level exhibitions being organized by state/district authorities/associations.

Nature of assistance:

- Free registration for participating in trade fairs. The selection of participants would be done by the MSME-DIs post the submission of application.
- Reimbursement of 50% of to and fro actual fare by shortest distance/direct train (limited to AC II tier class) from the nearest railway station/bus fare to the place of exhibition and 50% space rental charges for MSMEs (General category entrepreneurs).
- For Women/SC/ST entrepreneurs & entrepreneurs from North Eastern Region Govt. of India will reimburse 80% of items listed above in Point (2).

Note: *The total reimbursement will be max. Rs.30,000/- per unit for the SC/ST/Women/Physically*

Handicapped entrepreneurs, while for the other units the max. limit will be Rs.20,000/- per person per MSME unit.

Note: *The participant is required to submit follow-up proofs post attending the event to claim reimbursement. The proofs can be submitted after logging in online under the section "My Applications" or directly contacting a DI office.*

Who can apply?: All MSMEs with EM registration.

Capital Subsidy Support on Credit for Technology Upgradation Description

MSMEs can get a capital subsidy (~15%) on credit availed for technology upgradation.

Nature of assistance: Financial assistance for availing credit and loan.

Who can apply?:

- Banks and financial institutions can apply to DC-MSME for availing support.
- MSMEs need to directly contact the respective banks for getting credit and capital subsidy.

How to apply?: If you are a financial institution, click on the "Apply Now" button or else you can also directly contact the Office of DC-MSME. You can view the contact details of Office of DC-MSME. If you are an MSME, directly contact the respective banks/financial institutions as listed in the scheme guidelines.

Provision of Collateral Free Credit for MSMEs Description

Banks and financial institutions are provided funding assistance under this scheme so that they can in turn lend collateral free credit to MSMEs.

Nature of assistance: Funding support to banks and financial institutions for lending collateral-free credit to MSMEs.

Who can apply?: Banks and financial institutions can apply to office of DC-MSME/MSME-DIs for availing support. MSMEs need to directly contact the respective banks for getting credit.

Reimbursement of certification fees for acquiring ISO standards - ISO 9000/ISO 14001 Certification Reimbursement

The GoaI assistance will be provided for one-time reimbursement of expenditure to such MSME manufacturing units which acquire ISO 18000/ISO 22000/ISO 27000 certification.

Nature of assistance: Reimbursement of expenditure incurred on acquiring ISO standards.

Who can apply?: MSMEs with EM registration.

Agricultural Marketing Description

A capital investment subsidy for construction/renovation of rural godowns. Creation of scientific storage capacity and prevention of distress sale.

Nature of assistance: Subsidy @ 25% to farmers, 15% of project cost to companies.

Who can apply?: NGOs, SHGs, companies, co-operatives.

Small Agricultural Marketing Description

Business development description provides venture capital assistance in the form of equity, and arranges training and visits of agri-preneurs

Farmers' Agriculture Business Consortium: Business development description provides venture capital assistance in the form of equity, and arranges training and visits of agri-preneurs.

Nature of assistance: Financial assistance with a ceiling of Rs.5 lakh.

Who can apply?: Individuals, farmers, producer groups, partnership/propriety firms, SGHs, agri-preneurs, etc.

Mega Food Park Description

Mechanism to link agricultural production and market to maximize value addition, enhance farmers income, create rural employment.

Nature of assistance: One-time capital grant of 50% of project cost with a limit of Rs.50 crore.

Who can apply?: Farmers, farmer groups, SHGs.

Adivasi Mahila Sashaktikaran Yojana Description

Concessional scheme for the economic development of ST women.

Nature of assistance: Term loan at concessional rates upto 90% of cost of scheme.

Who can apply?: Scheduled Tribes Women.

12.5.5.6 Tips

1. Remember, opportunities are situational.
2. Look for a proven track record.
3. Avoid the latest craze.
4. Love your idea.

12.5.6 Risk Appetite & Resilience

Entrepreneurship and Risk

Entrepreneurs are inherently risk takers. They are path-makers not path-takers. Unlike a normal, cautious person, an entrepreneur would not think twice about quitting his job (his sole income) and taking a risk on himself and his idea.

An entrepreneur is aware that while pursuing his dreams, assumptions can be proven wrong and unforeseen events may arise. He knows that after dealing with numerous problems, success is still not guaranteed. Entrepreneurship is synonymous with the ability to take risks. This ability, called risk-appetite, is an entrepreneurial trait that is partly genetic and partly acquired.

What is Risk Appetite?

Risk appetite is defined as the extent to which a company is equipped to take risk, in order to achieve its objectives. Essentially, it refers to the balance, struck by the company, between possible profits and the hazards caused by changes in the environment (economic ecosystem, policies, etc.). Taking on more risk may lead to higher rewards but have a high probability of losses as well. However, being too conservative may go against the company as it can miss out on good opportunities to grow and reach their objectives.

The levels of risk appetite can be broadly categorized as “low”, “medium” and “high.” The company’s entrepreneur(s) have to evaluate all potential alternatives and select the option most likely to succeed. Companies have varying levels of risk appetites for different objectives. The levels depend on:

- The type of industry
- Market pressures
- Company objectives

For example, a startup with a revolutionary concept will have a very high risk appetite. The startup can afford short term failures before it achieves longer term success. This type of appetite will not remain constant and will be adjusted to account for the present circumstances of the company.167

Risk Appetite Statement

Companies have to define and articulate their risk appetite in sync with decisions made about their objectives and opportunities. The point of having a risk appetite statement is to have a framework that clearly states the acceptance and management of risk in business. It sets risk taking limits within the company. The risk appetite statement should convey the following:

- The nature of risks the business faces.
- Which risks the company is comfortable taking on and which risks are unacceptable.
- How much risk to accept in all the risk categories.
- The desired tradeoff between risk and reward.
- Measures of risk and methods of examining and regulating risk exposures.

Entrepreneurship and Resilience

Entrepreneurs are characterized by a set of qualities known as resilience. These qualities play an especially large role in the early stages of developing an enterprise. Risk resilience is an extremely valuable characteristic as it is believed to protect entrepreneurs against the threat of challenges and changes in the business environment.

What is Entrepreneurial Resilience?

Resilience is used to describe individuals who have the ability to overcome setbacks related to their life and career aspirations. A resilient person is someone who is capable of easily and quickly recovering from setbacks. For the entrepreneur, resilience is a critical trait. Entrepreneurial resilience can be enhanced in the following ways:

- By developing a professional network of coaches and mentors
- By accepting that change is a part of life
- By viewing obstacles as something that can be overcome

Characteristics of a Resilient Entrepreneur

The characteristics required to make an entrepreneur resilient enough to go the whole way in their business enterprise are:

- A strong internal sense of control
- Strong social connections
- Skill to learn from setbacks
- Ability to look at the bigger picture
- Ability to diversify and expand
- Survivor attitude
- Cash-flow conscious habits
- Attention to detail

12.5.6.1 Tips

1. Cultivate a great network of clients, suppliers, peers, friends and family. This will not only help you promote your business, but will also help you learn, identify new opportunities and stay tuned to changes in the market.
2. Don't dwell on setbacks. Focus on what the you need to do next to get moving again.
3. While you should try and curtail expenses, ensure that it is not at the cost of your growth.

12.5.7 Success & Failures

Understanding Successes and Failures in Entrepreneurship

Shyam is a famous entrepreneur, known for his success story. But what most people don't know, is that Shyam failed numerous times before his enterprise became a success. Read his interview to get an idea of what entrepreneurship is really about, straight from an entrepreneur who has both, failed and succeeded.

Interviewer: Shyam, I have heard that entrepreneurs are great risk-takers who are never afraid of failing. Is this true?

Shyam: Ha ha, no of course it's not true! Most people believe that entrepreneurs need to be fearlessly enthusiastic. But the truth is, fear is a very normal and valid human reaction, especially when you are planning to start your own business! In fact, my biggest fear was the fear of failing. The reality is, entrepreneurs fail as much as they succeed. The trick is to not allow the fear of failing to stop you from going ahead with your plans. Remember, failures are lessons for future success!

Interviewer: What, according to you, is the reason that entrepreneurs fail?

Shyam: Well, there is no one single reason why entrepreneurs fail. An entrepreneur can fail due to numerous reasons. You could fail because you have allowed your fear of failure to defeat you. You could fail because you are unwilling to delegate (distribute) work. As the saying goes, "You can do anything, but not everything!" You could fail because you gave up too easily – maybe you were not persistent enough. You could fail because you were focusing your energy on small, insignificant tasks and ignoring the tasks that were most important. Other reasons for failing are partnering with the wrong people,

not being able to sell your product to the right customers at the right time at the right price… and many more reasons!

Interviewer: As an entrepreneur, how do you feel failure should be looked at?

Shyam: I believe we should all look at failure as an asset, rather than as something negative. The way I see it, if you have an idea, you should try to make it work, even if there is a chance that you will fail. That's because not trying is failure right there, anyway! And failure is not the worst thing that can happen. I think having regrets because of not trying, and wondering 'what if' is far worse than trying and actually failing.

Interviewer: How did you feel when you failed for the first time?

Shyam: I was completely heartbroken! It was a very painful experience. But the good news is, you do recover from the failure. And with every subsequent failure, the recovery process gets a lot easier. That's because you start to see each failure more as a lesson that will eventually help you succeed, rather than as an obstacle that you cannot overcome. You will start to realize that failure has many benefits.

Interviewer: Can you tell us about some of the benefits of failing?

Shyam: One of the benefits that I have experienced personally from failing is that the failure made me see things in a new light. It gave me answers that I didn't have before. Failure can make you a lot stronger. It also helps keep your ego in control.

Interviewer: What advice would you give entrepreneurs who are about to start their own enterprises?

Shyam: I would tell them to do their research and ensure that their product is something that is actually wanted by customers. I'd tell them to pick their partners and employees very wisely and cautiously. I'd tell them that it's very important to be aggressive – push and market your product as aggressively as possible. I would warn them that starting an enterprise is very expensive and that they should be prepared for a situation where they run out of money.

I would tell them to create long term goals and put a plan in action to achieve that goal. I would tell them to build a product that is truly unique. Be very careful and ensure that you are not copying another startup. Lastly, I'd tell them that it's very important that they find the right investors.

Interviewer: That's some really helpful advice, Shyam! I'm sure this will help all entrepreneurs to be more prepared before they begin their journey! Thank you for all your insight!

12.5.7.1 Tips

1. Remember that nothing is impossible.
2. Identify your mission and your purpose before you start.
3. Plan your next steps – don't make decisions hastily.

UNIT 12.6: Preparing to be an Entrepreneur

Unit Objectives

At the end of this unit, you will be able to:

1. Discuss how market research is carried out
2. Describe the 4 Ps of marketing
3. Discuss the importance of idea generation
4. Recall basic business terminology
5. Discuss the need for CRM
6. Discuss the benefits of CRM
7. Discuss the need for networking
8. Discuss the benefits of networking
9. Understand the importance of setting goals
10. Differentiate between short-term, medium-term and long-term goals
11. Discuss how to write a business plan
12. Explain the financial planning process
13. Discuss ways to manage your risk
14. Describe the procedure and formalities for applying for bank finance
15. Discuss how to manage your own enterprise
16. List important questions that every entrepreneur should ask before starting an enterprise

12.6.1 Market Study / The 4 Ps of Marketing / Importance of an IDEA: Understanding Market Research

Understanding Market Research

Market research is the process of gathering, analyzing and interpreting market information on a product or service that is being sold in that market. It also includes information on:

- Past, present and prospective customers
- Customer characteristics and spending habits
- The location and needs of the target market
- The overall industry
- Relevant competitors

Market research involves two types of data:

- Primary information. This is research collected by yourself or by someone hired by you.
- Secondary information. This is research that already exists and is out there for you to find and use.

Primary research

Primary research can be of two types:

- **Exploratory:** This is open-ended and usually involves detailed, unstructured interviews.
- **Specific:** This is precise and involves structured, formal interviews. Conducting specific research is the more expensive than conducting exploratory research.

Secondary research

Secondary research uses outside information. Some common secondary sources are:

- **Public sources:** These are usually free and have a lot of good information. Examples are government departments, business departments of public libraries etc.
- **Commercial sources:** These offer valuable information but usually require a fee to be paid. Examples are research and trade associations, banks and other financial institutions etc.
- **Educational institutions:** These offer a wealth of information. Examples are colleges, universities, technical institutes etc.

12.6.1.1 The 4 Ps of Marketing

The 4 Ps of marketing are:

1. Product,
2. Price,
3. Promotion and
4. Place.

Let's look at each of these 4 Ps in detail.

Product

A product can be:

- A tangible good
- An intangible service

Whatever your product is, it is critical that you have a clear understanding of what you are offering, and what its unique characteristics are, before you begin with the marketing process.

Some questions to ask yourself are:

- What does the customer want from the product/service?
- What needs does it satisfy?
- Are there any more features that can be added?
- Does it have any expensive and unnecessary features?
- How will customers use it?
- What should it be called?
- How is it different from similar products?
- How much will it cost to produce?
- Can it be sold at a profit?

Price

Once all the elements of Product have been established, the Price factor needs to be considered. The Price of a Product will depend on several factors such as profit margins, supply, demand and the marketing strategy.

Some questions to ask yourself are:

- What is the value of the product/service to customers?
- Do local products/services have established price points?

- Is the customer price sensitive?
- Should discounts be offered?
- How is your price compared to that of your competitors?

Promotion

Once you are certain about your Product and your Price, the next step is to look at ways to promote it. Some key elements of promotion are advertising, public relations, social media marketing, email marketing, search engine marketing, video marketing and more.

Some questions to ask yourself are:

- Where should you promote your product or service?
- What is the best medium to use to reach your target audience?
- When would be the best time to promote your product?
- How are your competitors promoting their products?

Place

According to most marketers, the basis of marketing is about offering the right product, at the right price, at the right place, at the right time. For this reason, selecting the best possible location is critical for converting prospective clients into actual clients.

Some questions to ask yourself are:

- Will your product or service be looked for in a physical store, online or both?
- What should you do to access the most appropriate distribution channels?
- Will you require a sales force?
- Where are your competitors offering their products or services?
- Should you follow in your competitors' footsteps?
- Should you do something different from your competitors?

Importance of an IDEA

Ideas are the foundation of progress. An idea can be small or ground-breaking, easy to accomplish or extremely complicated to implement. Whatever the case, the fact that it is an idea gives it merit. Without ideas, nothing is possible. Most people are afraid to speak out their ideas, out for fear of being ridiculed. However, if are an entrepreneur and want to remain competitive and innovative, you need to bring your ideas out into the light.173

Some ways to do this are by:

- Establishing a culture of brainstorming where you invite all interested parties to contribute
- Discussing ideas out loud so that people can add their ideas, views, opinions to them
- Being open minded and not limiting your ideas, even if the idea who have seems ridiculous
- Not discarding ideas that you don't work on immediately, but instead making a note of them and shelving them so they can be revisited at a later date.

12.6.1.2 Tips

1. Keep in mind that good ideas do not always have to be unique.
2. Remember that timing plays a huge role in determining the success of your idea.
3. Situations and circumstances will always change, so be flexible and adapt your idea accordingly.

12.6.2 Business Entity Concepts: Basic Business Terminology

If your aim is to start and run a business, it is crucial that you have a good understanding of basic business terms. Every entrepreneur should be well versed in the following terms:

- **Accounting:** A systematic method of recording and reporting financial transactions.
- **Accounts payable:** Money owed by a company to its creditors.
- **Accounts Receivable:** The amount a company is owed by its clients.
- **Assets:** The value of everything a company owns and uses to conduct its business.
- **Balance Sheet:** A snapshot of a company's assets, liabilities and owner's equity at a given moment.
- **Bottom Line:** The total amount a business has earned or lost at the end of a month.
- **Business:** An organization that operates with the aim of making a profit.
- **Business to Business (B2B):** A business that sells goods or services to another business.
- **Business to Consumer (B2C):** A business that sells goods or services directly to the end user.
- **Capital:** The money a business has in its accounts, assets and investments. The two main types of capital are debt and equity.
- **Cash Flow:** The overall movement of funds through a business each month, including income and expenses.
- **Cash Flow Statement:** A statement showing the money that entered and exited a business during a specific period of time.
- **Contract:** A formal agreement to do work for pay.
- **Depreciation:** The degrading value of an asset over time.
- **Expense:** The costs that a business incurs through its operations.
- **Finance:** The management and allocation of money and other assets.
- **Financial Report:** A comprehensive account of a business' transactions and expenses.
- **Fixed Cost:** A one-time expense.
- **Income Statement (Profit and Loss Statement):** Shows the profitability of a business during a period of time.
- **Liabilities:** The value of what a business owes to someone else.
- **Marketing:** The process of promoting, selling and distributing a product or service.
- **Net Income/Profit:** Revenues minus expenses.
- **Net Worth:** The total value of a business.
- **Payback Period:** The amount of time it takes to recover the initial investment of a business.
- **Profit Margin:** The ratio of profit, divided by revenue, displayed as a percentage.
- **Return on Investment (ROI):** The amount of money a business gets as return from an investment.
- **Revenue:** The total amount of income before expenses are subtracted.
- **Sales Prospect:** A potential customer.
- **Supplier:** A provider of supplies to a business.
- **Target Market:** A specific group of customers at which a company's products and services are aimed.
- **Valuation:** An estimate of the overall worth of the business.
- **Variable Cost:** Expenses that change in proportion to the activity of a business.
- **Working Capital:** Calculated as current assets minus current liabilities.
- **Business Transactions:** There are three types of business transactions. These are:
    - **Simple Transactions –** Usually a single transaction between a vendor and a customer. For example: Buying a cup of coffee.

- **Complex Transactions –** These transactions go through a number of events before they can be completed. For example: Buying a house.
- **Ongoing transactions –** These transactions usually require a contract. For example: Contract with a vendor.

12.6.3 Basic Accounting Formulas

Take a look some important accounting formulas that every entrepreneur needs to know.

1. The Accounting Equation: This is value of everything a company owns and uses to conduct its business.
   Formula: Assets = Liability + Owner's Equity
2. Net Income: This is the profit of the company. Formula: Net Income = Revenues – Expenses
3. Break-Even Point: This is the point at which the company will not make a profit or a loss. The total cost and total revenues are equal.
   Formula: Break-Even = Fixed Costs/Sales Price – Variable Cost per Unit
4. Cash Ratio: This tells us about the liquidity of a company. Formula: Cash Ratio = Cash/Current Liabilities
5. Profit Margin: This is shown as a percentage. It shows what percentage of sales are left over after all the expenses are paid by the business.
   Formula: Profit Margin = Net Income/Sales
6. Debt-to-Equity Ratio: This ratio shows how much equity and debt a company is using to finance its assets, and whether the shareholder equity can fulfill obligations to creditors if the business starts making a loss.
   Formula: Debt-to-Equity Ratio = Total Liabilities/Total Equity
7. Cost of Goods Sold: This is the total of all costs used to create a product or service, which has been sold.
   Formula: Cost of Goods Sold = Cost of Materials/Inventory – Cost of Outputs
8. Return on Investment (ROI): This is usually shown as a percentage. It calculates the profits of an investment as a percentage of the original cost.
   Formula: ROI = Net Profit/Total Investment * 100
9. Simple Interest: This is money you can earn by initially investing some money (the principal).
   Formula: A = P(1 + rt); R = r * 100
   Where:
   A = Total Accrued Amount (principal + interest) P = Principal Amount
   I = Interest Amount
   r = Rate of Interest per year in decimal; r = R/100 t = Time Period involved in months or years
10. Annual Compound Interest: The calculates the addition of interest to the principal sum of a loan or deposit.
    Formula:
    A = P (1 + r/n) ^ nt
    Where, A = the future value of the investment/loan, including interest
    P = the principal investment amount (the initial deposit or loan amount) r = the annual interest rate (decimal)
    n=thenumberoftimesthatinterestiscompoundedperyeart=thenumberofyearsthemoneyisinvested or borrowed for.

12.6.4 CRM & Networking

What is CRM?

CRM stands for Customer Relationship Management. Originally the expression Customer Relationship Management meant managing one's relationship with customers. However, today it refers to IT systems and software designed to help companies manage their relationships.

The Need for CRM

The better a company can manage its relationships with its customers, the higher the chances of the company's success. For any entrepreneur, the ability to successfully retain existing customers and expand the enterprise is paramount. This is why IT systems that focus on addressing the problems of dealing with customers on a daily basis are becoming more and more in demand.

Customer needs change over time, and technology can make it easier to understand what customers really want. This insight helps companies to be more responsive to the needs of their customers. It enables them to modify their business operations when required, so that their customers are always served in the best manner possible. Simply put, CRM helps companies recognize the value of their clients and enables them to capitalize on improved customer relations.

Benifits of CRM

CRM has a number of important benefits:

- It helps improve relations with existing customers which can lead to: Increased sales
  - Identification of customer needs
  - Cross-selling of products
  - It results in better marketing of one's products or services
- It enhances customer satisfaction and retention
- It improves profitability by identifying and focusing on the most profitable customers

12.6.4.1 What is Networking?

In business, networking means leveraging your business and personal connections in order to bring in a regular supply of new business. This marketing method is effective as well as low cost. It is a great way to develop sales opportunities and contacts. Networking can be based on referrals and introductions, or can take place via phone, email, and social and business networking websites.

The Need for Networking

Networking is an essential personal skill for business people, but it is even more important for entrepreneurs. The process of networking has its roots in relationship building. Networking results in greater communication and a stronger presence in the entrepreneurial ecosystem. This helps build strong relationships with other entrepreneurs.

Business networking events held across the globe play a huge role in connecting like-minded entrepreneurs who share the same fundamental beliefs in communication, exchanging ideas and converting ideas into realities. Such networking events also play a crucial role in connecting entrepreneurs with potential investors. Entrepreneurs may have vastly different experiences and backgrounds but they all have a common goal in mind – they all seek connection, inspiration, advice, opportunities and mentors. Networking offers them a platform to do just that. Benefits of Networking

Networking offers numerous benefits for entrepreneurs. Some of the major benefits are:

- Getting high quality leads
- Increased business opportunities

- Good source of relevant connections
- Advice from like-minded entrepreneurs
- Gaining visibility and raising your profile
- Meeting positive and enthusiastic people
- Increased self-confidence
- Satisfaction from helping others
- Building strong and lasting friendships

12.6.4.2 Tips

1. Use social media interactions to identify needs and gather feedback.
2. When networking, ask open-ended questions rather than yes/no type questions.

12.6.5 Business Plan: Why Set Goals

Setting goals is important because it gives you long-term vision and short-term motivation. Goals can be short term, medium term and long term.

Short-Term Goals

- These are specific goals for the immediate future. Example: Repairing a machine that has failed. Medium- Term Goals
- These goals are built on your short term goals.
- They do not need to be as specific as your short term goals.

Example: Arranging for a service contract to ensure that your machines don't fail again.

Long-Term Goals

These goals require time and planning. They usually take a year or more to achieve.

Example: Planning your expenses so you can buy new machinery

Why Create a Business Plan

A business plan is a tool for understanding how your business is put together. It can be used to monitor progress, foster accountable and control the fate of the business. It usually offers a 3-5 year projection and outlines the plan that the company intends to follow to grow its revenues. A business plan is also a very important tool for getting the interest of key employees or future investors.

A business plan typically comprises of eight elements.

12.6.5.1 Elements of a Business Plan

Executive Summary

The executive summary follows the title page. The summary should clearly state your desires as the business owner in a short and businesslike way. It is an overview of your business and your plans. Ideally this should not be more than 1-2 pages.

Your Executive Summary should include:

- **The Mission Statement:** Explain what your business is all about.
  Example: Nike's Mission Statement
  Nike's mission statement is "To bring inspiration and innovation to every athlete in the world."
- **Company Information:** Provide information like when your business was formed, the names and roles of the founders, the number of employees, your business location(s) etc.
- **Growth Highlights:** Mention examples of company growth. Use graphs and charts where possible.
- **Your Products/Services:** Describe the products or services provided.
- **Financial Information:** Provide details on current bank and investors.
- **Summarize future plans:** Describe where you see your business in the future.

Business Description

The second section of your business plan needs to provide a detailed review of the different elements of your business. This will help potential investors to correctly understand your business goal and the uniqueness of your offering.

Your Business Description should include:

- A description of the nature of your business
- The market needs that you are aiming to satisfy
- The ways in which your products and services meet these needs
- The specific consumers and organizations that you intend to serve
- Your specific competitive advantages

Market Analysis

The market analysis section usually follows the business description. The aim of this section is to showcase your industry and market knowledge. This is also the section where you should lay down your research findings and conclusions.

Your Market Analysis should include:

- Your industry description and outlook
- Information on your target market
- The needs and demographics of your target audience
- The size of your target market
- The amount of market share you want to capture
- Your pricing structure
- Your competitive analysis
- Any regulatory requirements

Organization & Management

This section should come immediately after the Market Analysis. Your Organization & Management section should include:

- Your company's organizational structure
- Details of your company's ownership
- Details of your management team

- Qualifications of your board of directors
- Detailed descriptions of each division/department and its function
- The salary and benefits package that you offer your people
- The incentives that you offer

Service or Product Line

The next section is the service or product line section. This is where you describe your service or product, and stress on their benefits to potential and current customers. Explain in detail why your product of choice will fulfill the needs of your target audience.

Your Service or Product Line section should include:

- A description of your product/service
- A description of your product or service's life cycle
- A list of any copyright or patent filings
- A description of any R&D activities that you are involved in or planning

Marketing & Sales

Once the Service or Product Line section of your plan has been completed, you should start on the description of the marketing and sales management strategy for your business.

Your Marketing section should include the following strategies:

- **Market penetration strategy:** This strategy focuses on selling your existing products or services in existing markets, in order to increase your market share.
- **Growth strategy:** This strategy focuses on increasing the amount of market share, even if it reduces earnings in the short-term.
- **Channels of distribution strategy:** These can be wholesalers, retailers, distributers and even the internet.
- **Communication strategy:** These can be written strategies (e-mail, text, chat), oral strategies (phone calls, video chats, face-to-face conversations), non-verbal strategies (body language, facial expressions, tone of voice) and visual strategies (signs, webpages, illustrations).

Your Sales section should include the following information:

- **A salesforce strategy:** This strategy focuses on increasing the revenue of the enterprise.
- **A breakdown of your sales activities:** This means detailing out how you intend to sell your products or services – will you sell it offline or online, how many units do you intend to sell, what price do you plan to sell each unit at, etc.

Funding Request

This section is specifically for those who require funding for their venture. The Funding Request section should include the following information:

- How much funding you currently require.
- How much funding you will require over the next five years. This will depend on your long-term goals.
- The type of funding you want and how you plan to use it. Do you want funding that can be used only for a specific purpose, or funding that can be used for any kind of requirement?
- Strategic plans for the future. This will involve detailing out your long-term plans – what these plans are and how much money you will require to put these plans in motions.

- Historical and prospective financial information. This can be done by creating and maintaining all your financial records, right from the moment your enterprise started, to the present day. Documents required for this are your balance sheet which contains details of your company's assets and liabilities, your income statement which lists your company's revenues, expenses and net income for the year, your tax returns (usually for the last three years) and your cash flow budget which lists the cash that came in, the cash that went out and states whether you had a cash deficit (negative balance) or surplus (positive balance) at the end of each month.

Financial Planning

Before you begin building your enterprise, you need to plan your finances. Take a look at the steps for financial planning:

- **Step 1:** Create a financial plan. This should include your goals, strategies and timelines for accomplishing these goals.
- **Step 2:** Organize all your important financial documents. Maintain a file to hold your investment details, bank statements, tax papers, credit card bills, insurance papers and any other financial records.
- **Step 3:** Calculate your net worth. This means figure out what you own (assets like your house, bank accounts, investments etc.), and then subtract what you owe (liabilities like loans, pending credit card amounts etc.) the amount you are left with is your net worth.
- **Step 4:** Make a spending plan. This means write down in detail where your money will come from, and where it will go.
- **Step 5:** Build an emergency fund. A good emergency fund contains enough money to cover at least 6 months' worth of expenses.
- **Step 6:** Set up your insurance. Insurance provides long term financial security and protects you against risk.

Risk Management

As an entrepreneur, it is critical that you evaluate the risks involved with the type of enterprise that you want to start, before you begin setting up your company. Once you have identified potential risks, you can take steps to reduce them. Some ways to manage risks are:

- Research similar business and find out about their risks and how they were minimized.
- Evaluate current market trends and find out if similar products or services that launched a while ago are still being well received by the public.
- Think about whether you really have the required expertise to launch your product or service.
- Examine your finances and see if you have enough income to start your enterprise.
- Be aware of the current state of the economy, consider how the economy may change over time, and think about how your enterprise will be affected by any of those changes.
- Create a detailed business plan.

12.6.5.2 Tips

1. Ensure all the important elements are covered in your plan.
2. Scrutinize the numbers thoroughly.
3. Be concise and realistic.
4. Be conservative in your approach and your projections.
5. Use visuals like charts, graphs and images wherever possible.

12.6.6 Procedure and Formalities for Bank Finance

The Need for Bank Finance

For entrepreneurs, one of the most difficult challenges faced involves securing funds for start-ups. With numerous funding options available, entrepreneurs need to take a close look at which funding methodology works best for them. In India, banks are one of the largest funders of start-ups, offering funding to thousands of start-ups every year.

12.6.6.1 What Information Should Entrepreneurs Offer Banks for Funding

When approaching a bank, entrepreneurs must have a clear idea of the different criteria that banks use to screen, rate and process loan applications. Entrepreneurs must also be aware of the importance of providing banks with accurate and correct information. It is now easier than ever for financial institutions to track any default behaviour of loan applicants. Entrepreneurs looking for funding from banks must provide banks with information relating to their general credentials, financial situation and guarantees or collaterals that can be offered.

General Credentials

This is where you, as an entrepreneur, provide the bank with background information on yourself. Such information includes:

- **Letter(s) of Introduction:** This letter should be written by a respected business person who knows you well enough to introduce you. The aim of this letter is set across your achievements and vouch for your character and integrity.
- **Your Profile:** This is basically your resume. You need to give the bank a good idea of your educational achievements, professional training, qualifications, employment record and achievements.
- **Business Brochure:** A business brochure typically provides information on company products, clients, how long the business has been running for etc.
- **Bank and Other References:** If you have an account with another bank, providing those bank references is a good idea.
- **Proof of Company Ownership or Registration:** In some cases, you may need to provide the bank with proof of company ownership and registration. A list of assets and liabilities may also be required.

Financial Situation

Banks will expect current financial information on your enterprise. The standard financial reports you should be prepared with are:

- Balance Sheet
- Profit-and-Loss Account
- Cash-Flow Statement
- Projected Sales and Revenues
- Business Plan
- Feasibility Study

Guarantees or Collaterals

Usually banks will refuse to grant you a loan without security. You can offer assets which the bank can seize and sell off if you do not repay the loan. Fixed assets like machinery, equipment, vehicles etc. are also considered to be security for loans.

12.6.6.2 The Lending Criteria of Banks

Your request for funding will have a higher chance of success if you can satisfy the following lending criteria:

- Good cash flow
- Adequate shareholders' funds
- Adequate security
- Experience in business
- Good reputation

The Procedure

To apply for funding the following procedure will need to be followed.

- Submit your application form and all other required documents to the bank.
- The bank will carefully assess your credit worthiness and assign ratings by analyzing your business information with respect to parameters like management, financial, operational and industry information as well as past loan performance.
- The bank will make a decision as to whether or not you should be given funding.

12.6.6.3 Tips 

1. Get advice on funding options from experienced bankers.
2. Be cautious and avoid borrowing more than you need, for longer than you need, at an interest rate that is higher than you are comfortable with.

12.6.7 Enterprise Management - An Overview

To manage your enterprise effectively you need to look at many different aspects, right from managing the day-to-day activities to figuring out how to handle a large scale event. Let's take a look at some simple steps to manage your company effectively.

Step 1: Use your leadership skills and ask for advice when required: Let's take the example of Ramu, an entrepreneur who has recently started his own enterprise. Ramu has good leadership skills – he is honest, communicates well, knows how to delegate work etc. These leadership skills definitely help Ramu in the management of his enterprise. However, sometimes Ramu comes across situations that he is unsure how to handle. What should Ramu do in this case? One solution is for him to find a more experienced manager who is willing to mentor him. Another solution is for Ramu to use his networking skills so that he can connect with managers from other organizations, who can give him advice on how to handle such situations.

Step 2: Divide your work amongst others – realize that you cannot handle everything yourself: Even the most skilled manager in the world will not be able to manage every single task that an enterprise will demand of him. A smart manager needs to realize that the key to managing his enterprise lies in his dividing all his work between those around him. This is known as delegation. However, delegating is not enough. A manager must delegate effectively if he wants to see results. This is important because delegating, when done incorrectly, can result in you creating even more work for yourself. To delegate effectively, you can start by making two lists. One list should contain the things that you know you need to handle yourself. The second list should contain the things that you are confident can be given to others to manage and handle. Besides incorrect delegation, another issue that may arise is over-delegation. This means giving away too many of your tasks to others. The problem with this is, the more tasks you delegate, the more time you will spend tracking and monitoring the work progress of those you have handed the tasks to. This

will leave you with very little time to finish your own work.

Step 3: Hire the right people for the job: Hiring the right people goes a long way towards effectively managing your enterprise. To hire the best people suited for the job, you need to be very careful with your interview process. You should ask potential candidates the right questions and evaluate their answers carefully. Carrying out background checks is always a good practice. Running a credit check is also a good idea, especially if the people you are planning to hire will be handling your money. Create a detailed job description for each role that you want filled and ensure that all candidates have a clear and correct understanding of the job description. You should also have an employee manual in place, where you put down every expectation that you have from your employees. All these actions will help ensure that the right people are approached for running your enterprise.

Step 4: Motivate your employees and train them well: Your enterprise can only be managed effectively if your employees are motivated to work hard for your enterprise. Part of being motivated involves your employees believing in the vision and mission of your enterprise and genuinely wanting to make efforts towards pursuing the same. You can motivate your employees with recognition, bonuses and rewards for achievements. You can also motivate them by telling them about how their efforts have led to the company's success. This will help them feel pride and give them a sense of responsibility that will increase their motivation.

Besides motivating your people, your employees should be constantly trained in new practices and technologies. Remember, training is not a one-time effort. It is a consistent effort that needs to be carried out regularly.

Step 5: Train your people to handle your customers well: Your employees need to be well-versed in the art of customer management. This means they should be able to understand what their customers want, and also know how to satisfy their needs. For them to truly understand this, they need to see how you deal effectively with customers. This is called leading by example. Show them how you sincerely listen to your clients and the efforts that you put into understand their requirements. Let them listen to the type of questions that you ask your clients so they understand which questions are appropriate.

Step 6: Market your enterprise effectively: Use all your skills and the skills of your employees to market your enterprise in an effective manner. You can also hire a marketing agency if you feel you need help in this area.

Now that you know what is required to run your enterprise effectively, put these steps into play, and see how much easier managing your enterprise becomes!

12.6.7.1 Tips

1. Get advice on funding options from experienced bankers.
2. Be cautious and avoid borrowing more than you need, for longer than you need, at an interest rate that is higher than you are comfortable with.

12.6.7.2 Considering Entrepreneurship

Questions to Ask Yourself Before Considering Entrepreneurship

- Why am I starting a business?
- What problem am I solving?
- Have others attempted to solve this problem before? Did they succeed or fail?
- Do I have a mentor1 or industry expert that I can call on?

- Who is my ideal customer2?
- Who are my competitors3?
- What makes my business idea different from other business ideas?
- What are the key features of my product or service?
- Have I done a SWOT4 analysis?
- What is the size of the market that will buy my product or service?
- What would it take to build a minimum viable product5 to test the market?
- How much money do I need to get started?
- Will I need to get a loan?
- How soon will my products or services be available?
- When will I break even6 or make a profit?
- How will those who invest in my idea make a profit?
- How should I set up the legal structure7 of my business?
- What taxes8 will I need to pay?
- What kind of insurance9 will I need?
- Have I reached out to potential customers for feedback

12.6.7.3 Tips

1. It is very important to validate your business ideas before you invest significant time, money and resources into it.
2. The more questions you ask yourself, the more prepared you will be to handle to highs and lows of starting an enterprise.

Footnotes:

1. A mentor is a trusted and experienced person who is willing to coach and guide you.
2. A customer is someone who buys goods and/or services.
3. A competitor is a person or company that sells products and/or services similar to your products and/or services.
4. SWOT stands for Strengths, Weaknesses, Opportunities and Threats. To conduct a SWOT analysis of your company, you need to list down all the strengths and weaknesses of your company, the opportunities that are present for your company and the threats faced by your company.
5. A minimum viable product is a product that has the fewest possible features, that can be sold to customers, for the purpose of getting feedback from customers on the product.
6. A company is said to break even when the profits of the company are equal to the costs.
7. The legal structure could be a sole proprietorship, partnership or limited liability partnership.
8. There are two types of taxes – direct taxes payable by a person or a company, or indirect taxes charged on goods and/or services.
9. There are two types of insurance – life insurance and general insurance. Life insurance covers human life while general insurance covers assets like animals, goods, cars etc.

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