unit-9: quality assurance

Although industry and national regulators strive for production and processing systems which ensure that all food is 'safe and wholesome', complete freedom from risks is an unattainable goal. Safety and wholesomeness are related to a level of risk that society regards as reasonable in the context, and in comparison with other risks in everyday life.

The microbiological safety of foods is principally assured by:

➢ Control at the source

➢ Product design and process control

➢ The application of good hygienic practices during production, processing (including labelling), handling, distribution, storage, sale, preparation and use.

➢ The above in conjunction with the application of the Hazard Analysis Critical Control Point (HACCP) system. This preventative system offers more control than end-product testing, because the effectiveness of microbiological examination in assessing the safety of food is limited.

Consideration of safety needs to be applied to the complete food chain, from food production on the farm, or equivalent, through to the consumer. To achieve this an integration of following food safety tools is required. (refer Fig. 9.1)

➢ Good Manufacturing Practice (GMP)
➢ Good Hygienic Practice (GHP)
➢ Hazard Analysis Critical Control Point (HACCP)

➢ Microbiological Risk Assessment (MRA)

➢ Quality management: ISO series

➢ Total Quality Management (TQM)

These tools can be implemented worldwide, which can ease communication with food distributors and regulatory authorities especially at port of entry.

9.1 Relevance of Microbiological Standards for Food Safety

It is important to understand that the ratification of the World Trade Organisation Agreement is a major factor in developing new hygiene measures for the international trade in food. There has been a noted requirement for quantitative data on the microbial risks associated with different classes of foods, and traditional Good Manufacturing Practice-based food hygiene requirements (i.e. end-product testing) are being challenged. Subsequently risk assessment as a decision-making criterion for risk management will '
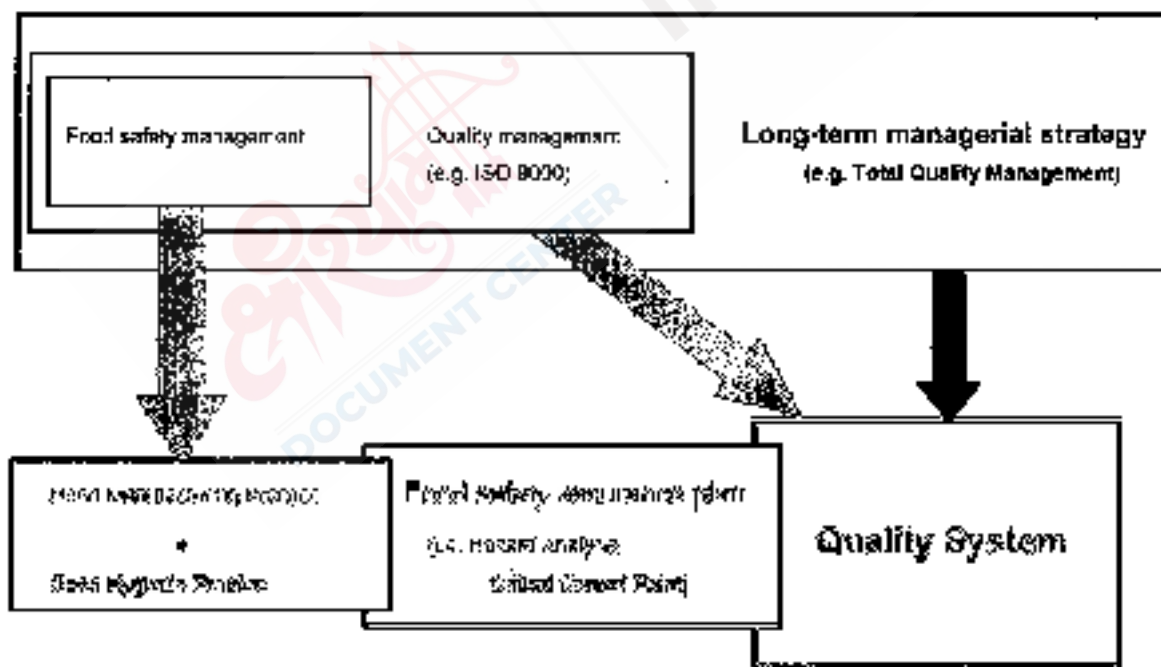
Fig. 9.1 Food safety management tools (adapted from Jouve et. Al 1998)

put more emphasis on predictive microbiology for the generation of exposure data and establishing Critical Limits for HACCP schemes.

The Final Act of the Uruguary Round of multilateral trade negotiations established the World Trade Organisation (WTO) to succeed the General Agreement on Tariffs and Trade (GATT). The Final Act led to the 'Agreement on the Application of Sanitary and Phytosanitary Measures' (SPS Agreement), and the 'Agreement to Technical Barriers to Trade' (TBT Agreement). These are intended to facilitate the free movement of foods across borders, by ensuring that means established by countries to protect human health are scientifically justified and are not used as non-tariff barriers to trade in foodstuffs. The Agreement states that SPS measures based on appropriate standards, codes and guidelines developed by the Codex Alimentarius Commission are deemed to be necessary to protect human health and consistent with the relevant GATT provisions.

The SPS Agreement is of particular relevance to food safety. It provides a framework for the formulation and harmonisation of sanitary and phytosanitary measures. These measures must be based on science and implemented in an equivalent and transparent manner. They cannot be used as an unjustifiable barrier to trade by discriminating among foreign sources of supply or providing an unfair advantage to domestic producers. To facilitate .safe food production for domestic and international markets, the SPS Agreement encourages governments to harmonise their national measures or base them on international standards, guidelines and recommendations developed by international standard setting bodies.

The purpose of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers all types of standards including quality requirements for food (except requirements related to sanitary and phytosanitary measures), and it includes numerous measures designed to protect the consumer against deception and economic fraud. The TBT Agreement also places emphasis on international standards. WTO members are obliged to use international standards or parts of them, except where the international standard would be ineffective or inappropriate in the national situation.

The WTO Agreement also states that risk assessment, should be used to provide the scientific basis for national food regulations on food safety and SPS measures, by taking into account risk-assessment techniques developed by international organisations. Because of SPS and WHO, the standards, guidelines and other recommendations have become the baseline for safe production of food as well as consumption.

9.2 THE MANAGEMENT OF HAZARDS IN FOOD WHICH IS IN INTERNATIONAL TRADE

The management of microbiological hazards for foods in international trade can he divided into five steps (ICMSF 1997):

(1) *Conduct a risk assessment.* The risk assessment and consequential risk management decisions provide a basis for determining the need to establish microbiological safety objectives.

(2) *Establish food safety objectives.* A microbiological food safety objective is a statement of the maximum level of a microbiological hazard considered acceptable for consumer protection. These should be developed by

governmental bodies with a view to obtaining consensus with respect to a food in international trade.

(3)   *Achievable food safety objectives*. The food safety objectives should lie achievable throughout the food chain. They can be applied through the general principles of food hygiene and any product specific codes and HACCP systems. The HACCP requirements must be developed by the food industry.

(4)   *Establish microbiological criteria*, when appropriate. This must be performed by an expert group of food microbiologists.

(5)   *Establish acceptance procedures for the food at port of entry*. A list of approved suppliers as determined by inspection of facilities and operations, certification, microbiological testing and/or other testing such as pH and water activity measurements.

Therefore, an understanding of HACCP, Microbiological Risk Assessment, Food Safety Objectives and Microbiological Criteria is required.

9.3   QUALITY MANAGEMENT SYSTEM

9.3.1 Quality – Its Meaning and Importance

`Quality' has much a broader perspective today. Quality today is anticipating, conforming to, and exceeding customer requirements. The earlier version of **ISO 9000** defined Quality as `*the totality of characteristics of a product or service that bears on its ability to satisfy stated or implied needs*. **ISO 9000:2000** now defines Quality as the `*degree to which a set of inherent characteristics fulfils requirement'*.

The Food Processing, Hospitality and Food Catering Industry in India has for long tried to built Quality into its food products through `**inspection'** and `**quality control'**, both of which are `**Detection and Firefighting'** methodologies.

In a `Detection and Firefighting environment', the emphasis is more on the products and not on the processes. Further, considerable effort is expended on inspecting, checking, screening and testing the food products after production and reactive `quick fixes' in a bid to ensure that only conforming food products are available or catered to the customers. With this approach, non-conforming products are sorted, graded and decisions made on reprocessing, if possible, downgrading or disposal. Therefore, a `Detection and Firefighting system' may prevent non-conforming food products from reaching the customer but it does not stop them being made.

A lasting and continuous improvement in quality can be achieved only by directing organizational efforts towards preventing problems occurring at source. This concept led to the next stage of development in Quality Management i.e. **Quality Assurance.**

Quality Assurance is a prevention based system which improves product and service quality and increases productivity by placing the emphasis on product and process design and process control. By concentrating on source activities, it prevents the emergence of non-conforming products or services. Further, quality is created in the design stage (product and processes) and not in the control stage.

Changing from `**Detection to Prevention'** requires not just the use of a set of quality management tools and techniques but the development of a new operating philosophy, which is what TQM entails. Fig 9.2 shows the evolution of Total Quality Management.
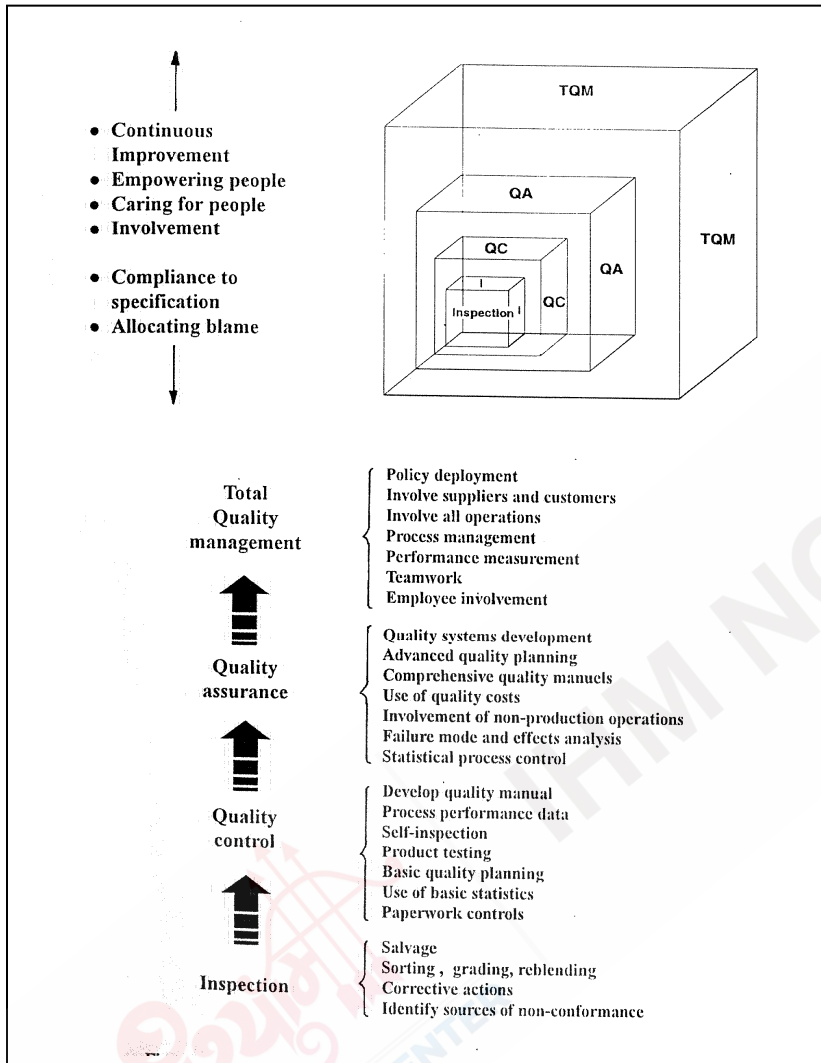
- Continuous
  Improvement
- Empowering people
- Caring for people
- Involvement

- Compliance to
  specification
- Allocating blame

TQM

QA

QC

Inspection

QA

QC

TQM

Total Quality management
{
Policy deployment
Involve suppliers and customers
Involve all operations
Process management
Performance measurement
Teamwork
Employee involvement
}

Quality assurance
{
Quality systems development
Advanced quality planning
Comprehensive quality manuels
Use of quality costs
Involvement of non-production operations
Failure mode and effects analysis
Statistical process control
}

Quality control
{
Develop quality manual
Process performance data
Self-inspection
Product testing
Basic quality planning
Use of basic statistics
Paperwork controls
}

Inspection
{
Salvage
Sorting , grading, reblending
Corrective actions
Identify sources of non-conformance
}

Fig. 9.2 : The four levels in the evolution of Total Quality Management

9.3.2 Total Quality Management (TQM)

TQM is the application of quantitative methods and human resources to improve the material and services supplied, all the processes within an organization, and the degree to which the needs of the customers are met now and in the future.

TQM is a process and a journey, not a destination. It is a philosophy, culture and way of doing business. It is a comprehensive and integrated way of managing any organization in order to:

- meet the needs of the customer consistently
- achieve continuous improvement in every aspect of the organization's activities.

The basic tenets of TQM are:

- Customer Satisfaction
    - o Internal Customers
    - o External Customers
- Continuous Improvement
- Employee involvement and empowerment
- Measurement and recording the work
- Doing it right the first time
- Effective communication and education

The paths to TQM are :

(a) KAIZEN

KAIZEN is primarily incremental improvements carried out by the person doing the job himself in his/her day- to-day work. It is generally subtle and undramatic. Results are not immediately visible. It is a never ending journey centered on the concept of starting anew each day with the principle that methods can always be improved.

(b) JUST-IN-TIME (JIT)

A Structural approach in a manufacturing organization focused on improving Timeliness, Quality, Productivity and Flexibility utilizing various methods of Work Simplification and Waste Reduction. In this approach waste includes any thing other than the absolute minimum amount of equipment, material, parts and working time absolutely essential for production.

9.3.3 RISK ANALYSIS

Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. Risk Analysis is a process comprising three components, namely risk assessment, risk management and risk communication.

(a) Risk Assessment

Risk Assessment is a scientifically based process consisting of the following steps:

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

i) **Hazard identification** comprises the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods

ii) **Hazard characterization** entails the qualitative and / or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

iii) **Exposure assessment** comprises the qualitative and / or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

iv) **Risk characterization** involves the qualitative and / or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain, i.e., from farm to table, including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects. The results of the risk assessment should be conveyed in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so they can review the assessment.

(b) Risk Management

Risk Management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. Risk Management decisions should be determined primarily by human health considerations, and unjustified differences in the level of consumer health protection should be avoided.

_____

(c) Risk Communication

Risk Communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
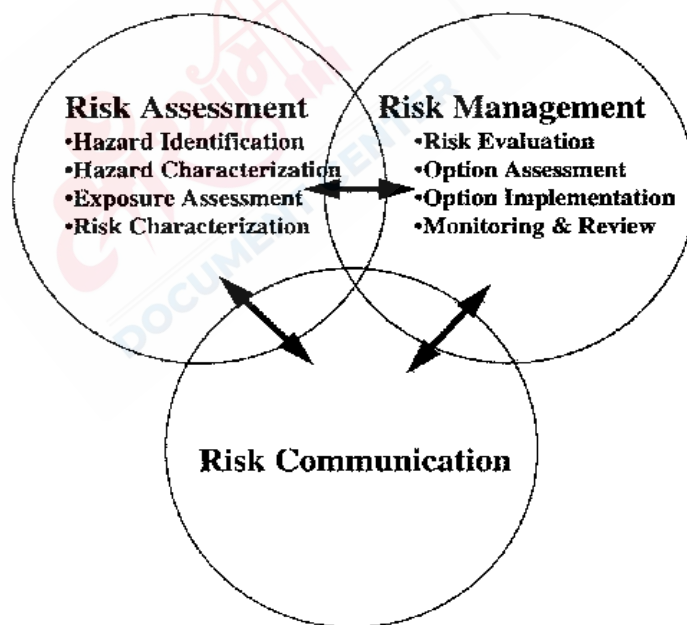
Fig. 9.3 : Diagramatic Representation Of Risk Analysis Process

9.3.4 Hazard Analysis Critical Control Point (HACCP) System

HACCP is a system which **identifies, evaluates and controls hazards** which are significant for food safety. Hazard is a **physical, chemical or biological agent** in, or condition of food, with the potential to cause an adverse health effect.

HACCP was originally developed as a microbiological safety system in the early days of the US manned space programme, as it was vital to ensure the safety of food for the astronauts. At this time most food safety and quality systems were based on end product testing, but it was realized that this could only fully assure safe products through testing 100%of the product – a method which obviously could not have worked as all the products would have been used up. Instead it became clear that a preventative system was required which would give a high level of food safety assurance and the HACCP system was born.

The original system was drawn up by the Pillsbury Company working alongside NASA and the US Army laboratories at Natick. HACCP is based on an engineering system viz. Failure, Mode and Effect Analysis (FMEA), which looks at what could potentially go wrong at each stage in an operation along with possible causes and the likely effect before deploying effective control mechanisms. Like FMEA, HACCP looks for hazards, or what could go wrong, but in the product safety sense. Control and management systems are then implemented to ensure that the product is safe and cannot cause harm to the consumer.

(a) Explanation of HACCP Terminology

i) Critical Control Point (CCP) : CCP is an operation (practice, process, procedure or location) at which a preventive or control measure can be exercised that will eliminate, prevent or minimize a hazard or several hazards.

ii) Critical Limit: The value of a monitored action which separates the acceptable from unacceptable.

iii) Control Point: It is an operation at which preventive and/or control actions are taken because of good manufacturing practices, regulations, product reputation, corporate/company policies or aesthetics. Such distinction between control points and critical control points are one of the unique aspects of the HACCP concept that sets priorities on risk & emphasizes operations that offer the greatest potential for control.

iv) Corrective Action: It is a specified prompt action to be taken when the criteria are not met or when the results of monitoring the CCP indicates a trend towards loss of control.

v) Verification: Review of monitoring records to determine whether the HACCP system is in place and functioning as planned and to ensure that monitoring is carried out effectively and efficiently. Verification is different than monitoring and it does not always call for immediate corrective action. It may necessitate modification of some components of the HACCP system or holding or reworking a finished product.

vi) Decision Tree: A sequence of questions applied to each process step with a potential hazard to identify which process steps are critical to food safety.

(b)   Seven HACCP Principles

(i)   Conduct Hazard Analysis

Principle 1 describes where the HACCP team should start. A process flow diagram is put together, detailing all the steps in the process, from incoming raw materials to finished product. When complete, the HACCP team identify all the hazards which could occur at each stage and describe preventative measures for their control.

(ii)   Determine the Critical Control Points (CCP's) in the process

When all the hazards and preventative measures have been described, the HACCP team establish the points where control is critical to managing the safety of the product.

(iii)   Establish Critical Limits for preventative measures associated with each identified CCP

The critical limits describe the difference between safe and unsafe product at the CCP's. These must involve a measurable parameter and may also be known as the absolute tolerance for the CCP.

(iv)   Establish a system to monitor control of the CCP

The HACCP team should specify monitoring requirements for management of the CCP within its critical limits. This will involve specifying monitoring actions along with frequency and responsibility.

(v)   Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
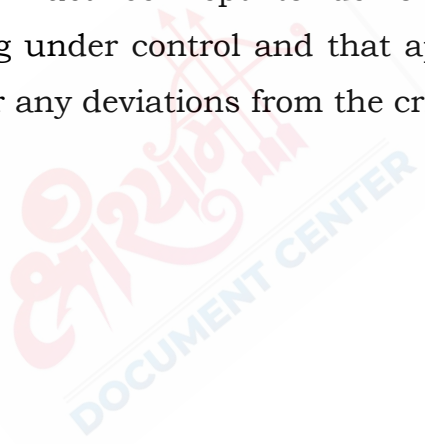
Corrective action procedures and responsibilities for their implementation need to be specified. This will include action to bring the process back under control and action to deal with product manufactured while the process was out of control.

(vi)   Establish procedures for verification to confirm that the HACCP system is working effectively

Verification procedure must be developed to maintain the HACCP system and ensure that it continues to work effectively.

(vii)   Establish documentation concerning all procedures and records appropriate to these principles and their application

Records must be kept to demonstrate that the HACCP system is operating under control and that appropriate corrective action has been taken for any deviations from the critical limits.

(c)   Application Stages of HACCP

Define the terms of reference

$\downarrow$

Assemble and train the HACCP Team

$\downarrow$

Describe the products / processes

$\downarrow$

Identify intended use

$\downarrow$

Construct Flow Diagram

$\downarrow$

On-site verification of Flow Diagram

$\downarrow$

List all Potential Hazards
Conduct a Hazard Analysis
Determine Control Measures

$\downarrow$

Determine CCP's

$\downarrow$

Establish Critical Limit for each CCP

$\downarrow$

Establish a Monitoring System for each CCP

↓

Establish Corrective Action for Deviations that may occur

↓

Establish Verification Procedures

↓

Establish Record Keeping and Documentation

↓

Review the HACCP Plan

(d)   Need for HACCP

a) Ensuring Food Safety

It is now well known that the end product inspection and testing does not provide safety of food. It has inherent limitation of mapping the potential hazards that could be present in a lot of raw material or food product. It has been proved that a 100 percent inspection is not reliable control technique for this purpose. Further, for inspection and testing, a sampling plan is used and it is imperative to note that no sampling plan can reflect the lot characteristics or ensure absence of a particular organism.

Accordingly, there is a need for development of a comprehensive and effective food system which functions in such a way that food safety

considerations are built into the food chain from production to consumption.

b) **Preventing Food Borne Disease Outbreaks**

WORLDWIDE IT IS RECOGNIZED THAT THE APPLICATION OF HACCP SYSTEM TO FOOD PRODUCTION AND PREPARATION HAS CLEAR BENEFITS AND THE POTENTIAL OF ENHANCING FOOD SAFETY AND PREVENTING FOOD BORNE DISEASE OUTBREAKS. AS PER A WHO STUDY, THE FOOD BORNE DISEASES CONSTITUTE A MAJOR PUBLIC HEALTH PROBLEM OF THE CONTEMPORARY WORLD AND IT IS ESTIMATED TO ANNUALLY EFFECT UPTO 10% OR MORE OF THE POPULATION IN INDUSTRIALIZED NATIONS AND THOUGH THERE ARE NO ESTIMATIONS FOR DEVELOPING COUNTRIES, IT IS BELIEVED THAT THE PREVALENCE OF FOOD BORNE DISEASES IN THESE COUNTRIES IS EVEN GREATER.

Worldwide, the incidence of diarrhoeal diseases alone has been estimated at 4000 million cases per year, which per se indicates a serious underlying food safety problem. Epidemiological investigations have indicated that a large proportion of food borne diseases result from poor hygienic handling of food in small businesses.

c) **International Obligations – Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT)**

The SPS Agreement, to which India is a signatory, makes it obligatory for us as a nation to maintain measures to ensure that food is safe for consumers and to prevent the spread of pests or diseases among animals and plants. The TBT agreement encourages the development of international standards

and conformity assessment systems that facilitate trade and that the technical regulations do not form non-tariff barriers to trade.

Both these agreements have wider implications in the International Trade and in this background the various Codex Standards / Guidelines, including those on HACCP, GHP and GMP, take an unprecedented importance with respect to consumer protection and international food trade.

(e)   *Benefits Of Implementing HACCP*

i) Benefits To Consumers

- Reduced risk of food borne diseases;
- Increased confidence in food supply;
- Increased awareness of basic hygiene;
- Increased quality of life (health & socio-economic)

ii) Benefits To Industry

- Increased market access;
- Reduction in production costs through reduced wastage and recall of food;
- Increased consumer and government confidence;
- Mitigating the business risk

iii) Benefits To Governments

- Improved Public Health;
- Reduced Public Health costs;
- Enhanced facilitation of International Trade;
- Increased confidence of the community in the food supply.