

CONCEPTS OF FOOD SAFETY AND QUALITY MANAGEMENT SYSTEMS

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JUNE-2010 – FSSAI
REGULATORS TRAINING

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Brief background

- **1963** - The Codex Alimentarius Commission was created by FAO and WHO to develop food standards, guidelines and related texts.
- **1969** - The Codex Alimentarius Commission brought out the Recommended International Code of Practice-General Principles of Food Hygiene GHP which has undergone four revisions . Ver 4.
- **2005**- The ISO (International Organization for Standardization) stepped in and brought out ISO 22000:2005 . Harmonize on a global level, Food safety management systems - Requirements for any organization in the food chain.

Food safety standards : CODEX

- Primary objective - food is safe and suitable for human consumption.
- Ensuring fair trade practices in the food trade.
- Follows the food chain - farm to fork.
- Takes into account the wide diversity of activities and varying degrees of risk involved in food production.
- Lays a firm foundation for ensuring food hygiene with each specific code of hygiene practice applicable to each sector.

CODEX ALIMENTARIUS

- Codex recommends a HACCP based approach wherever possible to enhance food safety as desired.
- HACCP (Hazard **Analysis** And Critical **Control** Point).
- Codex guidelines and HACCP approach forms the core of the entire food safety program .

Food safety standards : ISO 22000

- Since ISO 22000 is a generic food safety management standard.
- It can be used by any organization directly or indirectly involved in the food chain.
- It applies to all organizations in the food chain.
- It doesn't matter how complex the organization is or what size it is, ISO 22000 can help ensure the safety of its food products.

Food safety standards : ISO 22000

An ideal food safety management system:

- Meets the food safety policy and achieve the measurable objectives related to the policy
- Meets performance of "effectiveness" (extent to which planned activities are realized and planned results achieved) and "efficiency" (relationship between the results achieved and the resources needed).
- Applies proven management principles aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stakeholders.

An effective FSMS should be one that:

- Is well-established, documented, implemented, maintained and continually improved / updated.
- Has its products / services that actually meet its intended usage and are safe .
- Is proactive and innovative, scientific, risk-avoiding and prevention-oriented

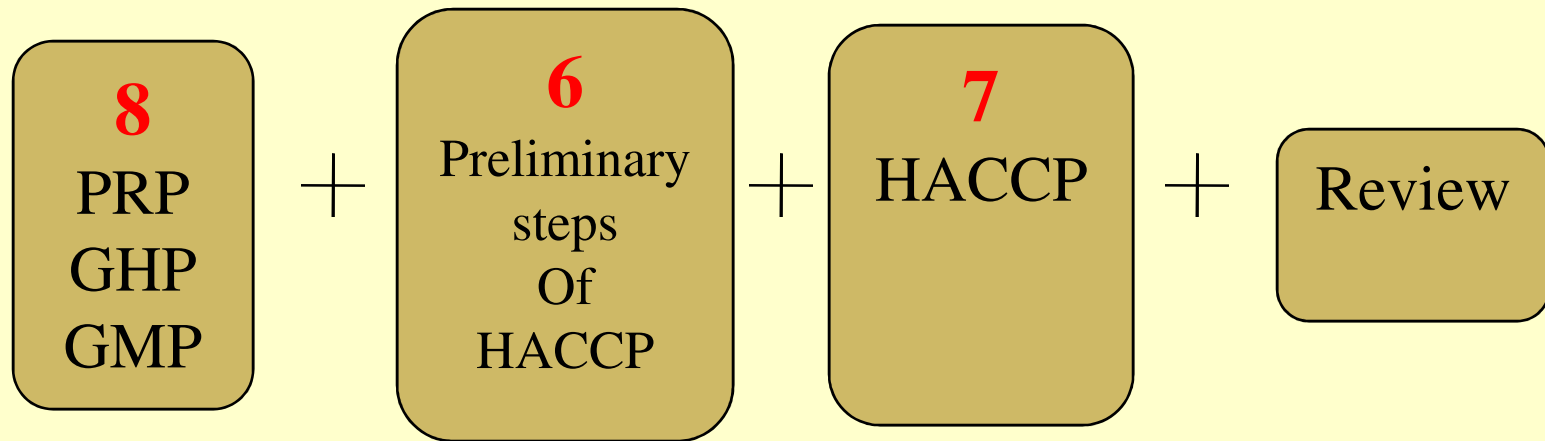
Food safety standards : ISO 22000

- ISO 22000 integrates the Codex Alimentarius Commission's 7 principles of HACCP and dynamically combine it with PRPs necessary to control and reduce any food safety hazards.
- PRPs (PRE-REQUISITE PROGRAM) are also referred to as good hygienic practices(GHP), good agricultural practices, good production practices, good manufacturing practices(GMP), good distribution practices, and good trading practices.

CODEX ALIMENTARIUS & ISO 22000

- **EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE.**
 - Pre-requisite program with specific hygiene standards.
 - 41 codes of hygienic and technological practices. (product specific and process specific)
- **SEVEN PRINCIPLES OF HACCP SYSTEM**

ISO 22000



Requires Management to commit & communicate

PRP –GHP/GMP

1. Primary production

2. Establishment Design and facilities

8. Training

Eight Principals of Hygiene GHP Throughout the food chain

3. Control of operations

7. Product information and consumer awareness

4. Maintenance and sanitation

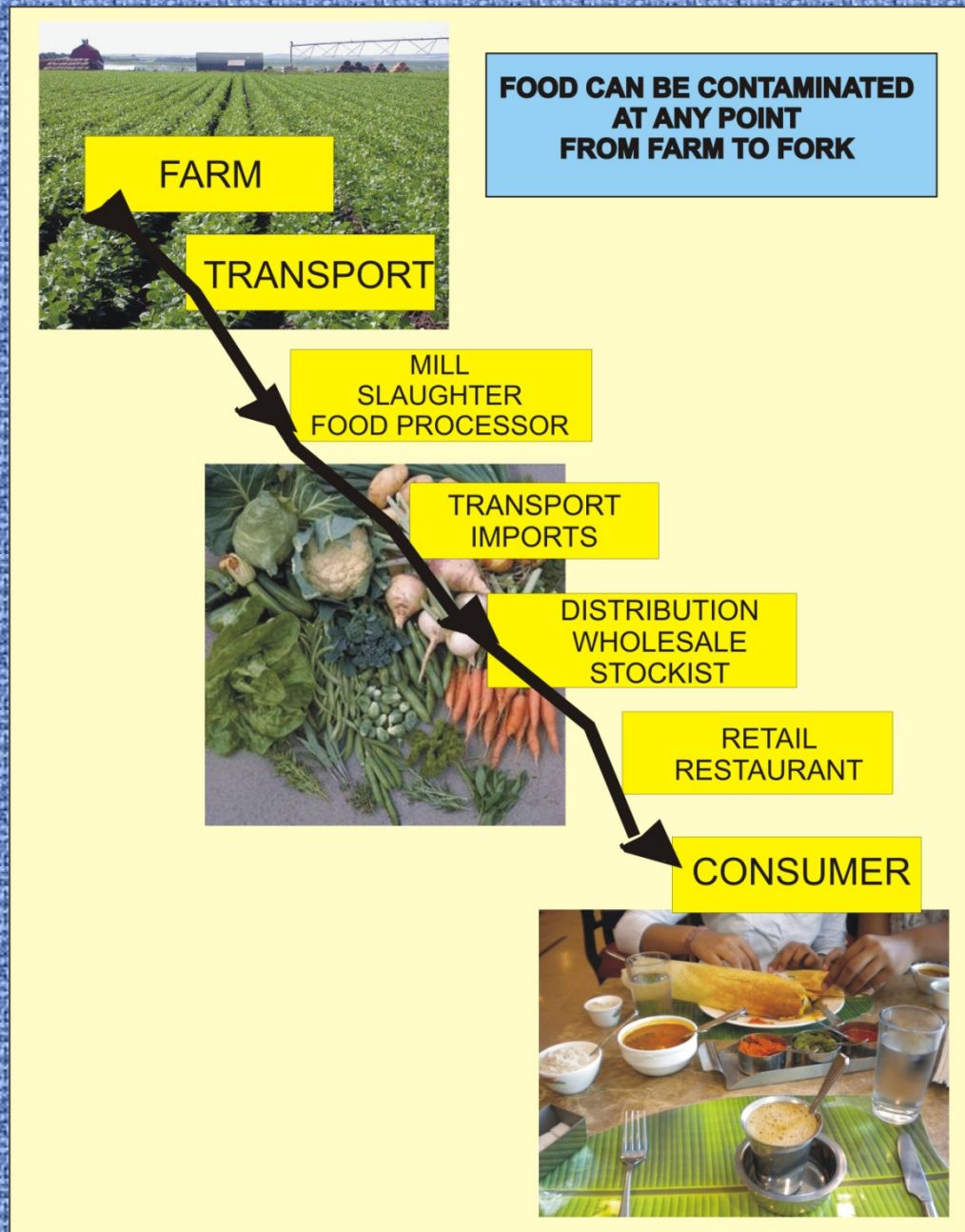
6. Transportation

5. Personnel Hygiene

Definition of Food Chain

Sequence of stages and operations involved in production, processing, distribution, storage & handling of a food & food ingredients from primary production to consumption.

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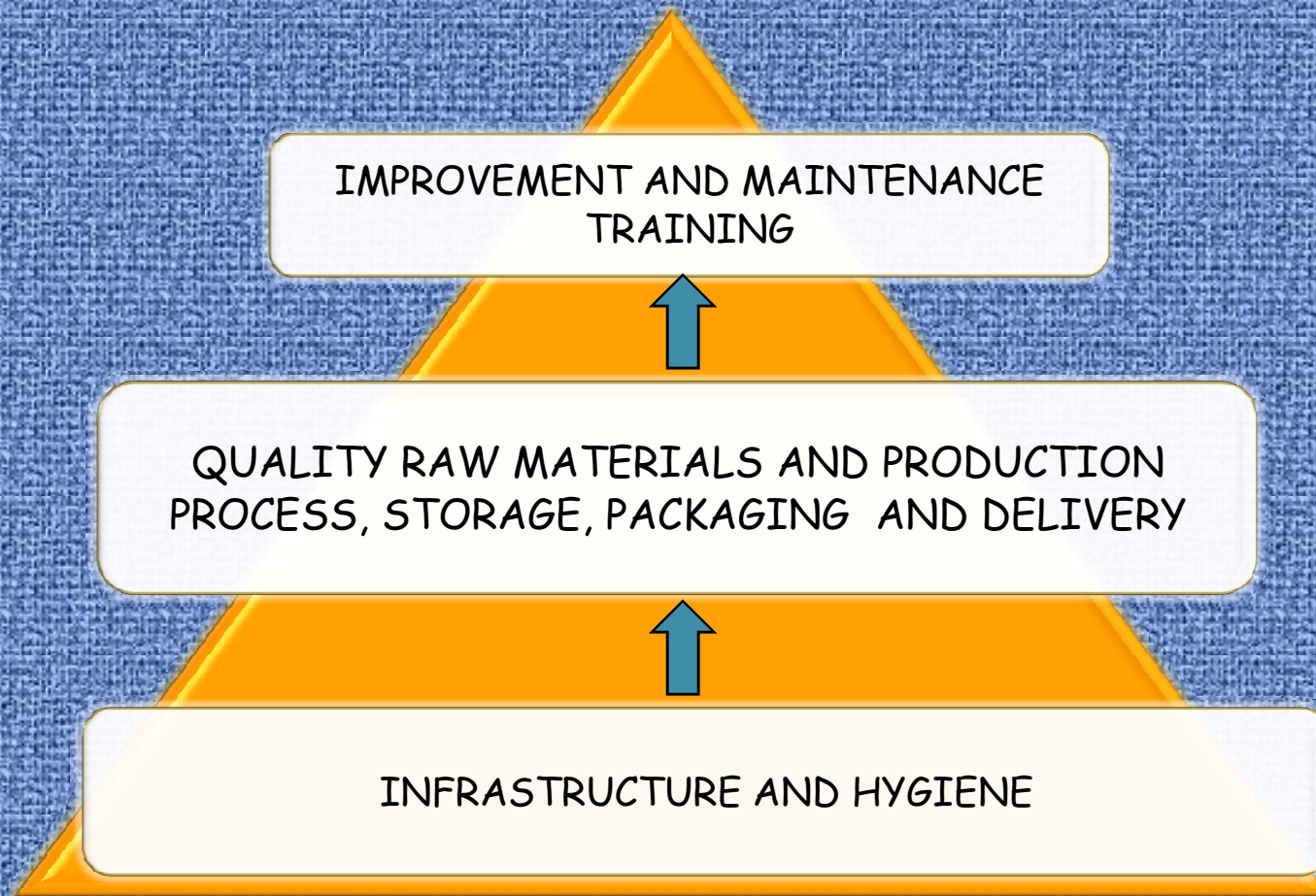


PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE- GHP

1. Primary production
2. Establishment Design and Facilities
3. Control of operations
4. Maintenance and sanitation
5. Personal Hygiene
6. Transportation
7. Product information and consumer awareness
8. Training

Foundation of Food safety



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PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE-GHP

1. Primary production

- Environmental hygiene (where the environment/ surrounding poses a threat to food safety)
- Hygienic production of Food Sources
(Control contamination from air, soil, water, feed-stock, pesticides, veterinary drugs or any other agent used in primary production. Protect food sources from fecal and other contaminant)
- Handling storage and transport
(Use appropriate storage materials and equipment. Protect food and food ingredients from contamination by pests, chemicals, microbiological or physical or other objectionable substances during handling storage and transportation. Cross contamination.)
- Cleaning maintenance and personal hygiene.

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE-GHP

2. Establishment Design and Facilities

Nature of operations, associated risks –
Premises and equipment and facilities to
minimize risk and ensure food safety

- Location (Potential sources of contamination from surroundings)
- Internal design, structures and layout of the premises rooms and equipment (Should facilitate MEASURES THAT PREVENT CONTAMINATION, durable, movable and capable of being disassembled to allow for maintenance, cleaning, disinfecting and monitoring)
- Facilities (Directly or indirectly impact food safety : water quality, air quality, drainage and waste disposal, temperature control, personal hygiene, lighting, storage-ensure effective protection from contamination during storage.)

Especially temporary or mobile facilities

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE- GHP

3. Control of Operations:

- Control of food hazards through the use of HACCP system (Potential sources of contamination from surroundings, Time and Temperature).
- Key aspects of hygiene control systems (Specific process steps, Microbiological and other specifications, microbial cross contamination, physical and chemical contamination).
- Incoming material requirements(specification to be identified and applied, where possible inspected and sorted before processing).

– *cont ...*

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE-GHP

3. Control of Operations *(cont.)* :

- Packaging (Design and materials used).
- Water - (in contact with food and used as an ingredient Special care for Ice and steam).
- Management and supervision (Size of the business, nature of activity and type of food).
- Documentation and records (period that exceeds shelf life).
- Recall procedures. (complete recall, handling and communication).

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE-GHP

4. Maintenance and Sanitation

- Cleaning methods and procedures. (Appropriate for the type of product and type of machine. Hidden residual food/pest infestation).
- Cleaning Programs (Method, frequency and monitored for their suitability and effectiveness).
- Pest Control Systems (Preventing access, preventing harborage and infestation, monitoring and detection, eradication measures).
- Waste Management (Method, frequency and effectiveness).
- Monitoring Effectiveness (Periodic Audit, microbial sampling).

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE- GHP

5. Personal Hygiene

- Health Status of Employees.
- Illness and injuries (Communicable diseases and surface injuries to hands or parts that come in contact with food items.)
- Personal cleanliness-Clothing
- Personal Behavior (smoking, spitting, chewing and eating, sneezing , personal effects.)
- Visitors (Rules and guidelines for entry and access and safety or protective covering).

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE-GHP

6. Transportation

- Design of conveyances and bulk containers. (Proper segregation to prevent cross contamination, Time, temperature and humidity controls available and monitored, Appropriate for type of packaging)
- Use and maintenance. (Mixed and prior usage, appropriate scheduling and corrective measures)

7. Product information and consumer awareness

- Lot identification (Codex standard & FSSA rules)
- Product information (Bear adequate information to enable the next person in the food chain to handle, display, store prepare and use the product safely and correctly.)
- Labelling (Codex standards and FSSA rules)
- Consumer education. (hygiene, nutrition, label instructions)

PRP – PRE-REQUISITE PROGRAM

EIGHT GENERAL PRINCIPLES OF FOOD HYGIENE- GHP

8. Training (most important) Cause of most food safety Hazards and incidents.

- Awareness and responsibility
- Training Programs
 - nature of food and its ability to sustain growth of harmful micro-organisms.
 - manner in which food is handled/packed .
 - extent/nature of processing or further preparation before final consumption.
 - conditions under which the food will be stored.
 - expected length of time before consumption.
- Instructions and supervisions
- Refresher Training

PRP – PRE-REQUISITE PROGRAM

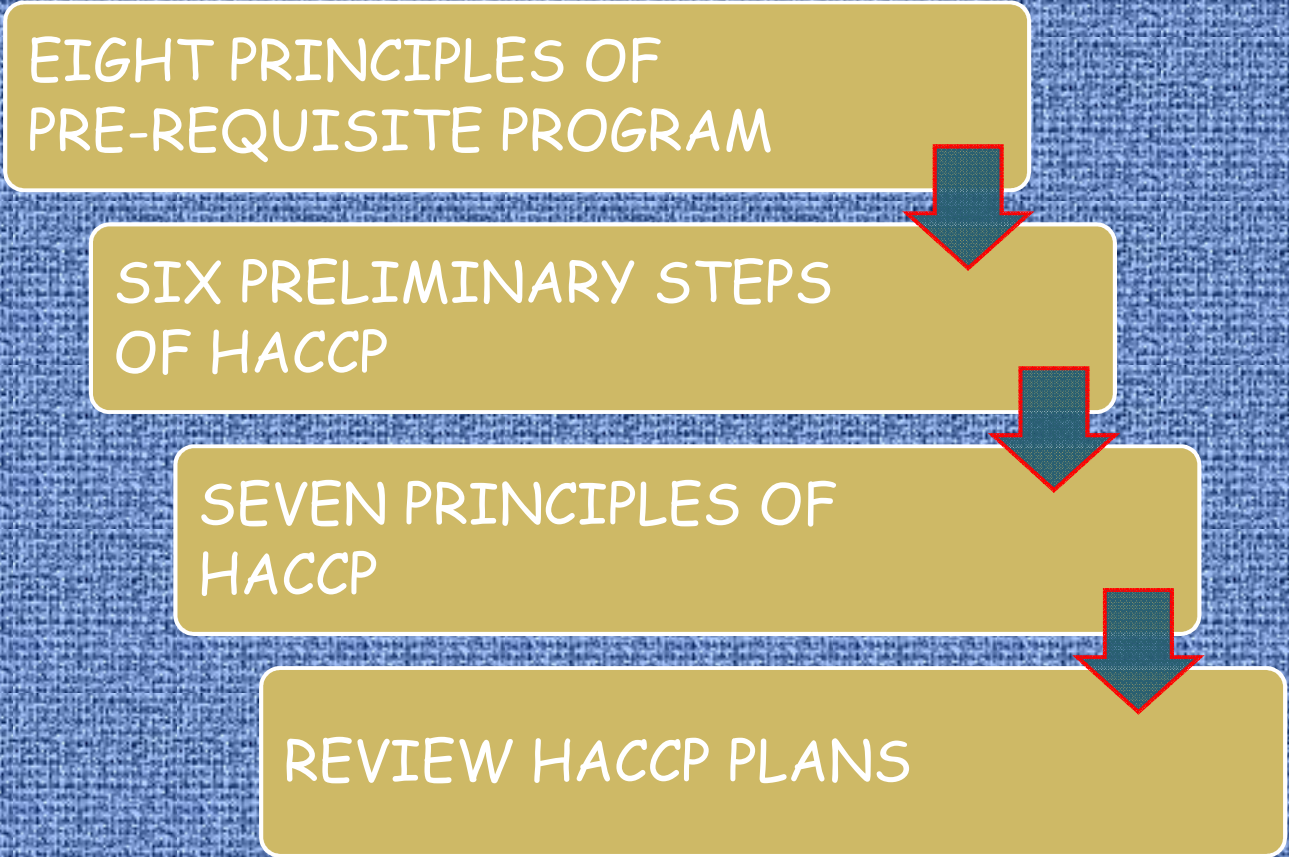
GMP- GOOD MANUFACTURING PRACTICES

- GMP requires a **quality approach** to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
- It addresses issues including:
 - recordkeeping,
 - personnel qualifications,
 - sanitation,
 - cleanliness,
 - equipment verification,
 - process validation,
 - and complaint handling.
- Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls.
- This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

STAGES IN A HACCP STUDY

1. Ensure all PRPs and CODEX standards are met and not critical risk factors.
2. Carry out the six preliminary steps before commencing a HACCP study.
3. Carry out the activities required for the seven principles of HACCP
4. Review the HACCP Plans.

IMPLEMENTING A FOOD SAFETY PROGRAM



THE SIX PRELIMINARY STEPS

1. Define terms of reference (clearly spells out scope, extent, resources committed, terms of appointment of outside consultants, third party auditors, levels of authority and accountability for implementation).
2. Select the HACCP team (include product and process team members).
3. Describe the product and process
4. Identify intended use
5. Construct a flow diagram (schematic flow that describes the process).
6. On-site confirmation of flow diagram (walk through).

SEVEN PRINCIPLES OF HACCP SYSTEM

1. Conduct a Hazard analysis(for both PRP's and for stages in the flow diagram of the selected product or process).
2. Determine critical control points (CCP's)
3. Establish Critical Limits.
4. Establish a system to monitor & control CCP's.
5. Establish corrective action to be taken when monitoring indicated that a particular CCP is not under control.
6. Establish procedures for verification to confirm that HACCP system is working effectively.
7. Establish Documentation concerning all procedures and records appropriate to these principles and their applications.

SEVEN PRINCIPLES OF HACCP SYSTEM

1. Conduct a Hazard analysis (for both PRP's and for stages in the flow diagram of the selected product or process)

- This is a risk assessment of Biological, Chemical and Physical.
 - Risk value : 1-3 scale with 1 being lowest and 3 being highest.
 - Severity : 1-3 scale with 1 being lowest and 3 being highest.
 - Risk assessment : $R \times S$ value .
 - Likely to be a CCP if value greater than 4

Final assessment also determined by lead questions:

- Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable limit.
- Could contamination with the identified hazard occur in excess of acceptable levels or could it increase to an unacceptable level?
- Do control measures exist for the identified hazard.

SEVEN PRINCIPLES OF HACCP SYSTEM

2. Determine Critical Control Points (CCPs)

- This is a step at which controls can be applied and is essential to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.
- Complete and accurate identification of a CCP is fundamental to food safety hazards.
 - Thermal Process
 - Retention or holding time
 - Environmental conditions e.g.: humidity.
 - Chilling
 - Testing ingredients
 - Product formulation control
 - End product testing

SEVEN PRINCIPLES OF HACCP SYSTEM

2. Determine Critical Control Points (CCPs)

Uses a management tool called the CCP decision Tree- Asking lead questions like:

1. Does this step involve a hazard of sufficient likelihood of occurrence and severity to warrant its control.
2. Does a control measure of hazard exist at this step.
3. Is the control at this step essential to prevent , eliminate or reduce the risk of the hazard to consumers.
4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence.

'Yes' or 'No' answers determine the decisions taken.

SEVEN PRINCIPLES OF HACCP SYSTEM

3. Establish Critical Limits

- The decision tree instructs your team to establish a critical limit. The critical limit must be met.
- A critical limit is usually a reading or an observation like :
 1. temperature,
 2. time,
 3. humidity,
 4. moisture content,
 5. concentration levels,
 6. component rations,
 7. quantity of preservative,
 8. additives pH,
 9. chemical or physical properties etc.

SEVEN PRINCIPLES OF HACCP SYSTEM

3. Establish Critical Limits

The critical limit is specific and exact and not ranges.

- There are two types :
 - an upper limit beyond which set amounts or levels cannot be exceeded.
 - Or
 - a lower limit where a minimum amount is required to produce safe effect.
- When setting the limits several sources are to be considered - first are regulatory requirements which apply to your process or product.
- These have to be strictly met.

SEVEN PRINCIPLES OF HACCP SYSTEM

3. Establish Critical Limits- Definition

A critical limit is a maximum or minimum value to which biological, chemical and physical parameters must be controlled at a CCP to prevent, eliminate or reduce to acceptable levels the occurrence of a food safety hazard.

A critical limit is used to differentiate between safe and unsafe operating conditions at a CCP.

Critical limits should not be confused with operational limits that are established for reasons other than food safety.

SEVEN PRINCIPLES OF HACCP SYSTEM

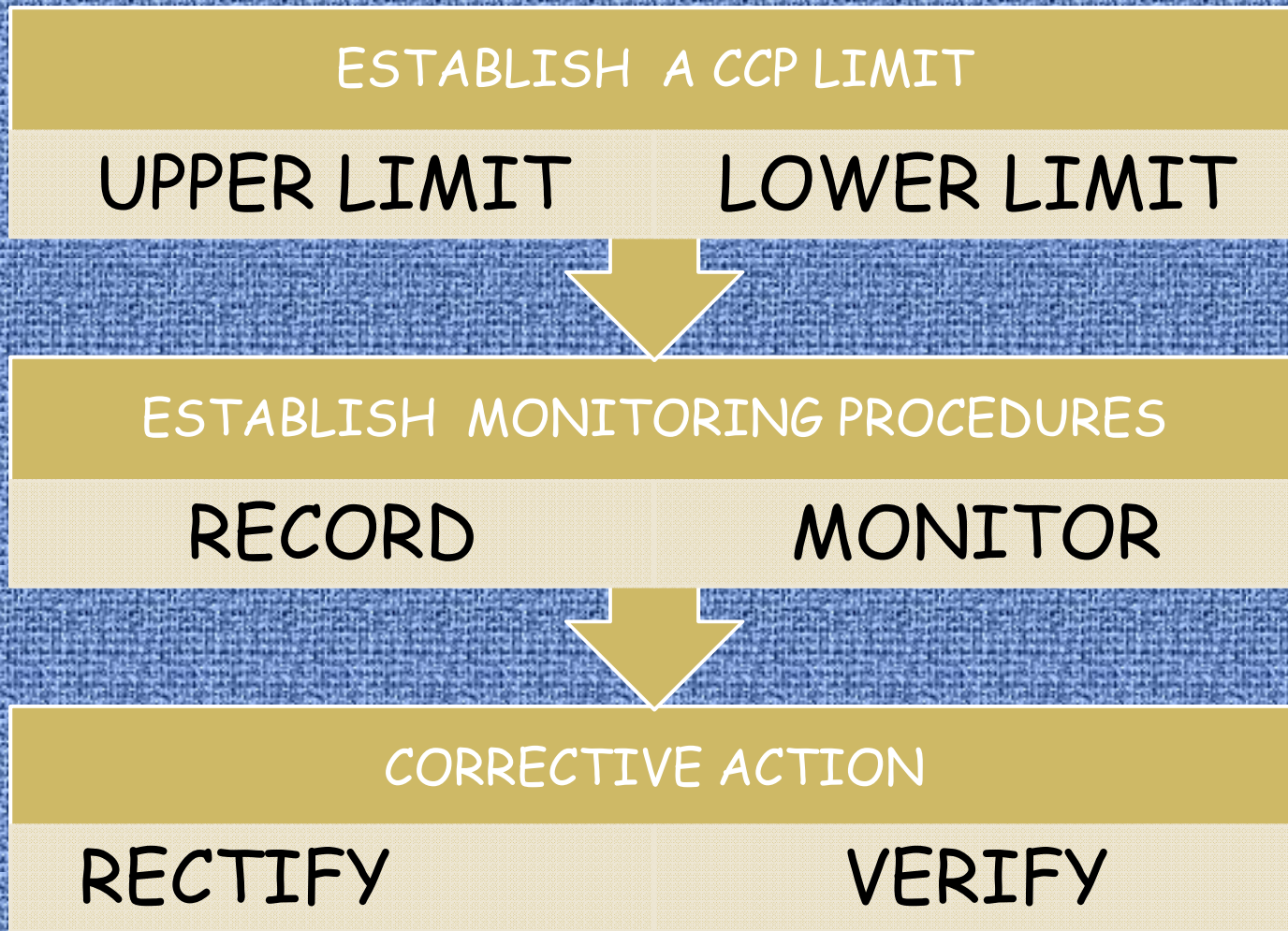
4. Establish Monitoring Procedures

- A planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
- These are done routinely by a person or mechanical means.
- It is done for every established CCP and serves three main purposes:
 - It facilitates tracking of the operations. And to bring the operations back on track before a deviation from a Critical limit occurs.
 - **Caution** : teams must consider the capacity of the unit to take corrective actions when monitoring procedures reveal that there is deviation.
 - Determines when there is a loss of control and a deviation occurs at a CCP. And a corrective action must be taken.
 - Provide written documentation for use in verification.

SEVEN PRINCIPLES OF HACCP SYSTEM

4. Establish Monitoring Procedures

- Monitoring persons must record exact values **and not Yes/No.**
- Responsibilities must be specifically assigned.
- Need to be rapid because they relate to online "real time" processes.
- Establish proper frequency when it is not possible for a continuous monitoring.
- Monitoring processes need to be well planned and effective because of the potentially serious consequences of loss of control.
- Employees monitoring CCPs should be trained in technique to be used to monitor each preventive measure or control.
- They should fully understand the purpose and importance of what they are monitoring and importance of accurate reporting.



SEVEN PRINCIPLES OF HACCP SYSTEM

5. Establish Corrective Actions

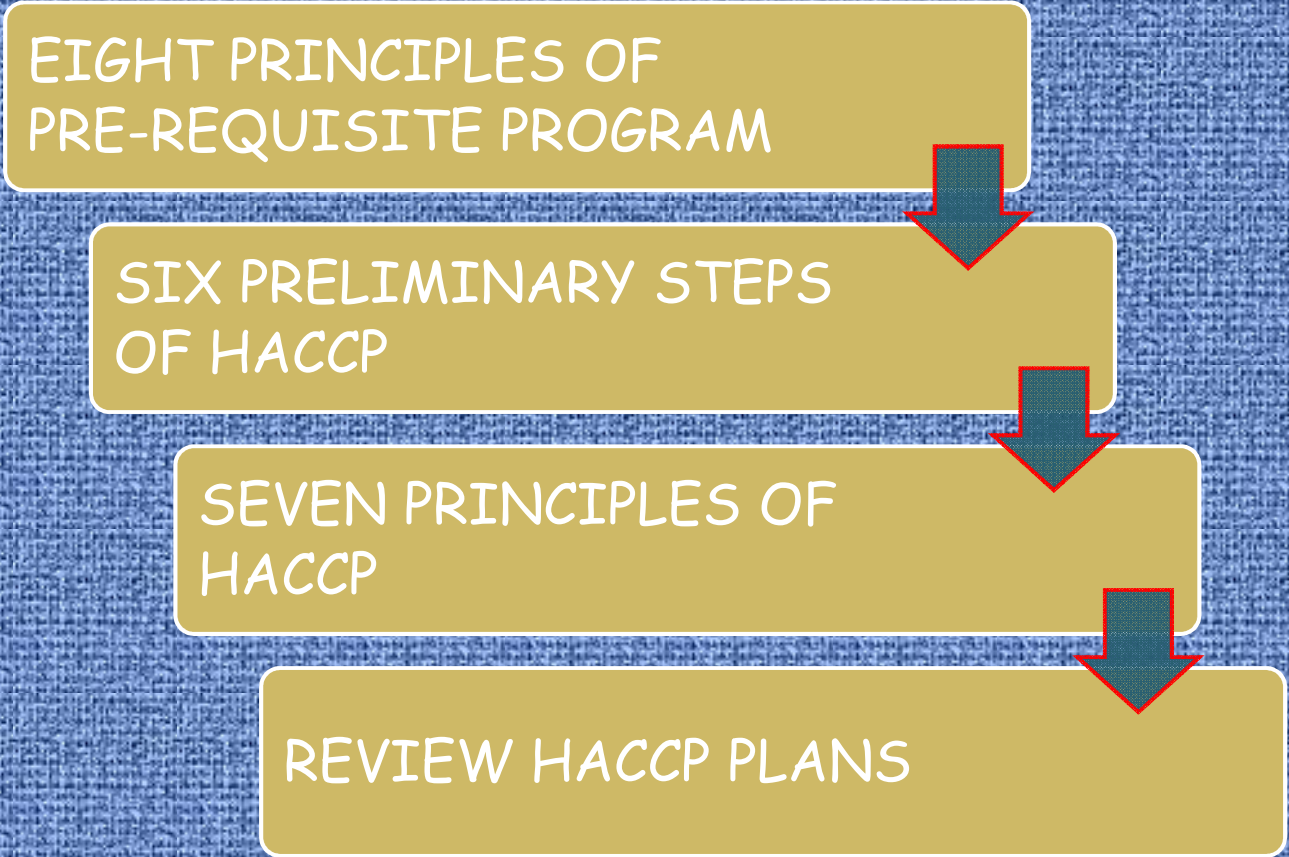
- Determine and correct the cause of noncompliance.
- Determine the disposition of non-compliant product.
- Record the corrective actions that have been taken.
- Devise a standardised set of actions that company employees will follow when there is a deviations from a critical limit.
- Assign specific responsibilities for implementing the corrective actions and the records that will be maintained.

SEVEN PRINCIPLES OF HACCP SYSTEM

5. Establish Corrective Actions

- Has the cause of the deviations been identified and eliminated ?
- Will the CCP be under control after the corrective action has been taken ?
- Have Measures to prevent recurrence of the deviation been established ?
- Do the corrective action procedures make sure that no product , which is injurious to health or otherwise adulterated because of the deviation enter commerce?
- Remember as regulators and auditors you will be checking this aspect

IMPLEMENTING A FOOD SAFETY PROGRAM



SEVEN PRINCIPLES OF HACCP SYSTEM

6. Establish Verification Procedures

- Verification procedures make sure the plan is working correctly. It is those set of activities other than monitoring that determine the validity of the HACCP Plan.
- It also determines that the plan is scientifically and technically sound.
- Three types of verifications:
 - Validation (Based on scientific expertise and knowledge)
 - Ongoing Verification (Activity, frequency, responsibility)
 - Reassessment (Procedures, records and reporting systems)

SEVEN PRINCIPLES OF HACCP SYSTEM

7. Establish Record Keeping and Documentation procedures

Typical records of a HACCP System:

- Ingredients for which critical limits have been established.
 - Monitored CCPs,
 - Supplier documentation,
 - storage temperature & humidity records,
 - Shelf life of ingredients records etc
- Preparation, processing storage and distribution records
(Monitoring and verification records)

SEVEN PRINCIPLES OF HACCP SYSTEM

7. Establish Record Keeping and Documentation procedures

- Packaging records (indicating compliance with specifications of packaging materials , labeling requirements and sealing requirements)
- Finished products - storage, delivery, sale.
- Deviation and corrective action records
- Employee training records.
- Documentation of the adequacy of the HACCP procedure from an authority (certification).

Benefits of HACCP System

- Correctly applied a HACCP study should identify all currently conceivable hazards including those which can realistically be predicted to occur.
- A cost effective control for food borne hazards.
- Focuses technical resources into critical parts of the process.
- Leads to reduced product losses.
- It is complementary to other management systems.
- It ensures compliances with legal requirements.

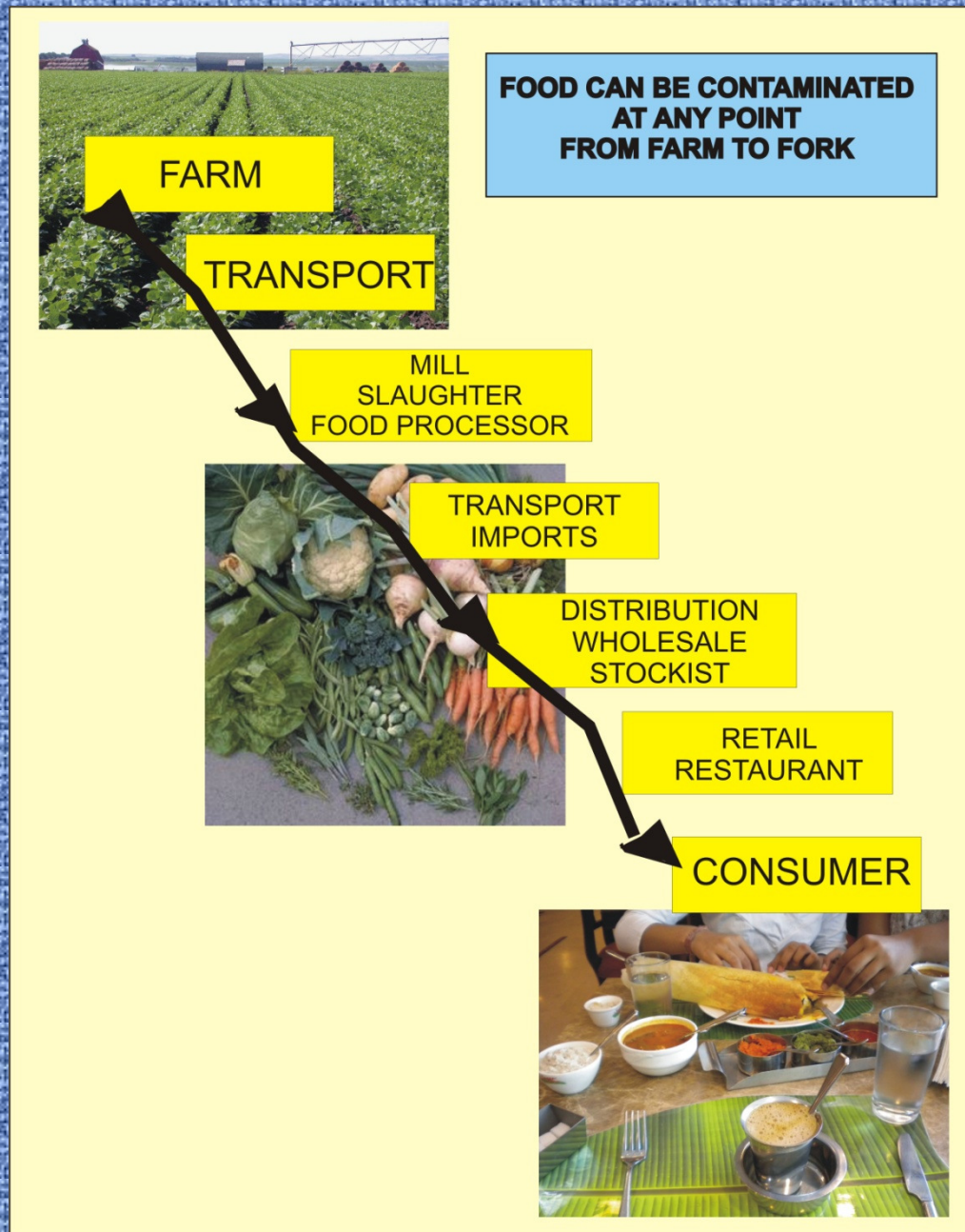
Benefits of HACCP System

- Management tool that provides a more structured approach to the control of identified hazards in comparison to traditional inspection and quality control procedures.
- It moves a company from a retrospective end product testing approach towards a preventive quality assurance approach.
- It is a systematic approach covering all aspects of food safety from raw material to final product.
- Under the FSSA 2006, essential to ensure license and consent to operate.
- International authorities such as the joint FAO/WHO Codex Alimentarius commission promote HACCP as the system of Choice for ensuring food safety.

Definition of Food Chain

Sequence of stages and operations involved in production, processing, distribution, storage & handling of a food & food ingredients from primary production to consumption.

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There is no such thing as
"ZERO RISK"

Therefore
Risk Analysis
is needed to determine
what the hazards are and to identify
their immediate, interim and
long-term effects on human health.

Thank you

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