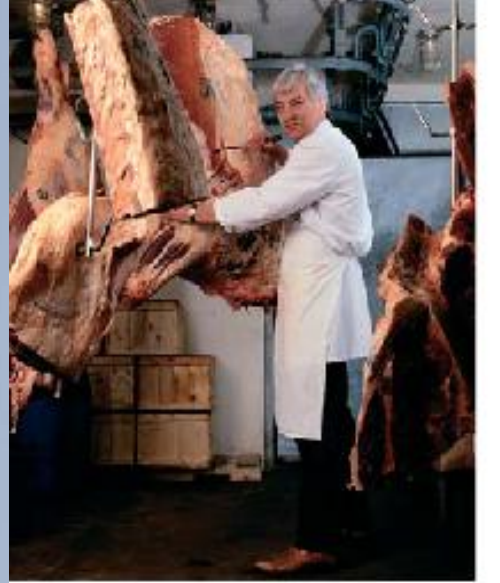


# **Requirements of ISO 22000 Food Safety Management System**





## ***Requirements for any organization In the food chain***



# Food Safety

**Assurance** that food will not cause **harm** to the **consumer** when it is prepared and/or eaten according to its **intended use**.



# Food Safety

- Protecting People
- Keeping the Employees and Customers
- Preventing Food Safety Errors



*For goodness sake*

## Tell us if you are ill



Many food poisoning incidents are caused by food handlers who have continued to handle food after falling ill themselves.

If you know you are suffering from, are a carrier, or have symptoms of a food-borne illness especially vomiting or diarrhoea you must:

- ▶ report this to your supervisor;
- ▶ not engage in food handling;
- ▶ if performing alternative duties, take all practicable measures to prevent food from being contaminated.

**FOOD SAFETY**  
*For goodness sake*

 DEPARTMENT OF HEALTH

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# Food Safety – Historical Background

- **First food law written in 2500 B.C.**
- **Egyptian food laws are dated back 1876.**
- **First HACCP system was developed between NASA and Pillsbury in 1971.**
- **Become a regulatory requirements in EU since 1998.**
- **US FDA also adopted the HACCP approach as part of control mechanism for food safety.**



# **ISO 22000:2005**

***A management system designed to enable organizations to control food safety hazards along the food chain in order to ensure that food is safe at the time of consumption.***



# ISO 22000:2005

## Features;

- First global food safety standard.
- Harmonizes the voluntary international standards.
- Employs proven management system principles.
- Enables a common understanding of what a food safety management system is.



# ISO 22000:2005

## Features;

- Requires legal compliance checking
- Integrates existing good practice
- Internal and external monitoring





# ISO2000:2005

## Benefits;

- Overcomes many of the limitations of traditional approaches to food safety control.
- Potential to identify all conceivable, reasonably expected hazards.
- Capable of accommodating the changes.

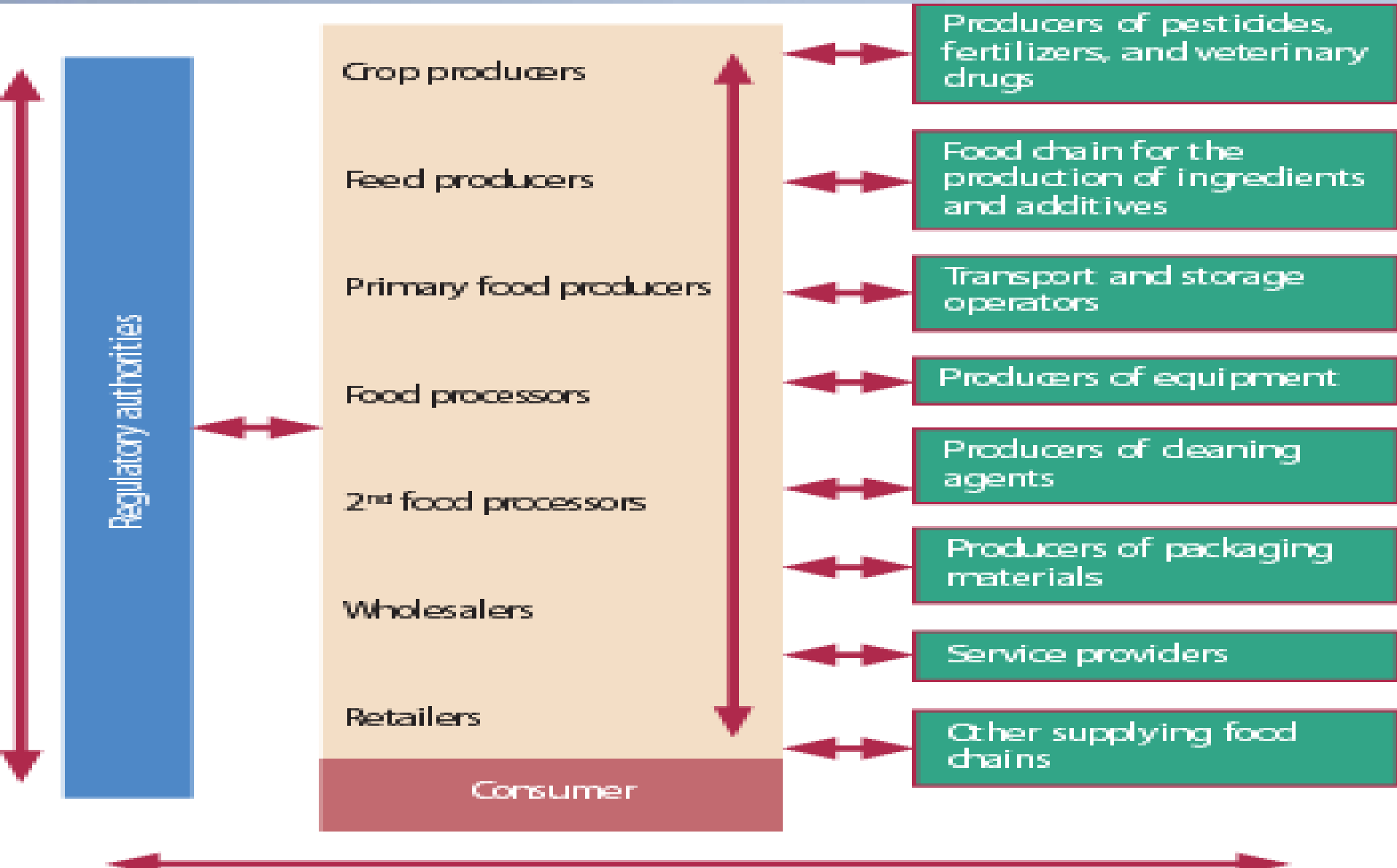


# ISO2000:2005

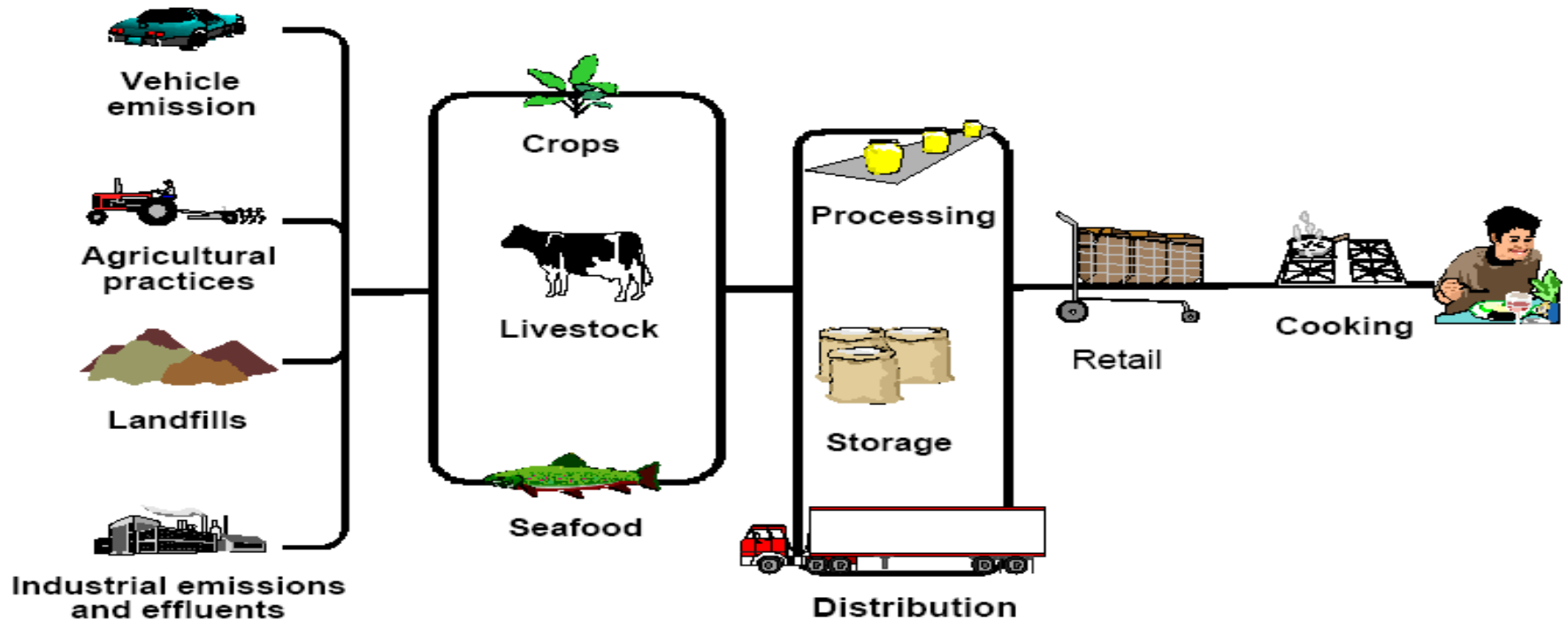
## Benefits;

- Help to target or manage resources to the most critical part of the food operation.
- Can promote international trade by equalizing food safety control and by increasing confidence in food safety.
- Applicable to whole food chain.

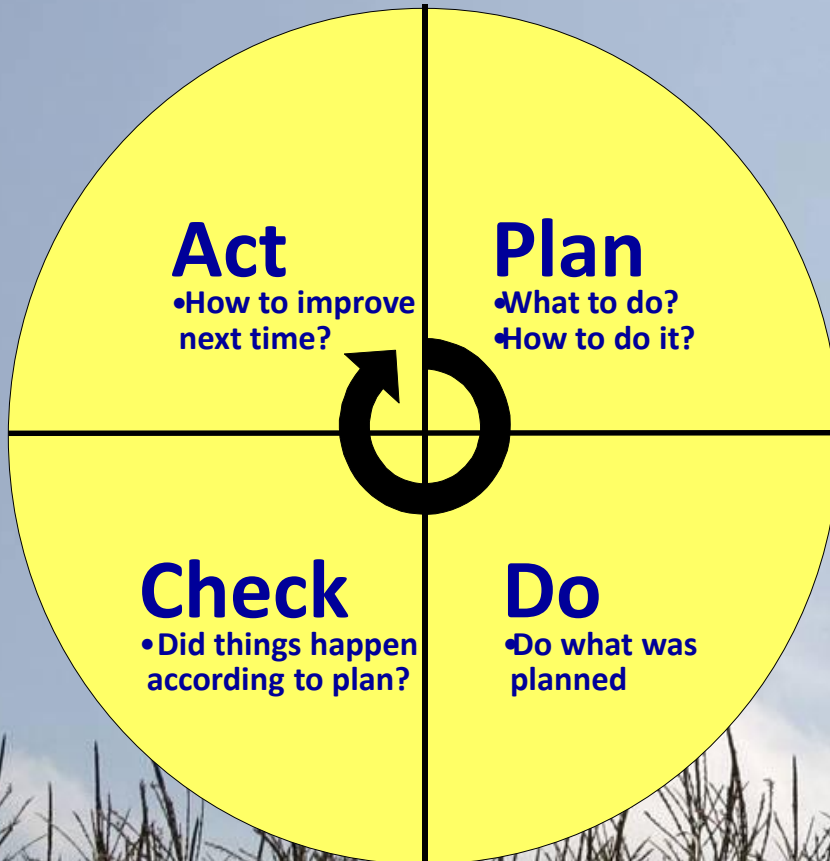
# Food chain



# Entry of Hazards in Food Chain

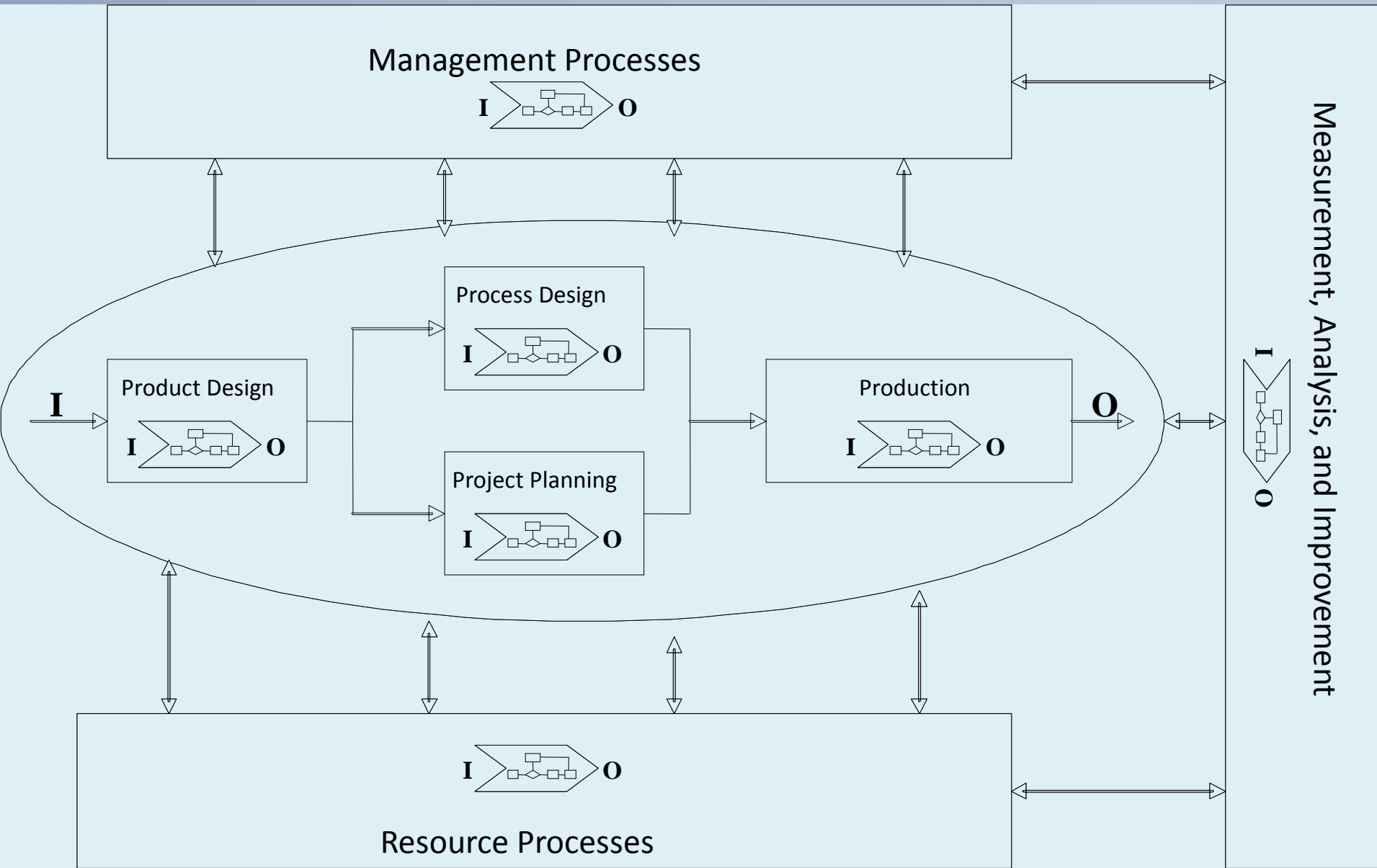


# Process Approach



A desired result is achieved more efficiently when related resources and activities are managed as a process

# Process Approach



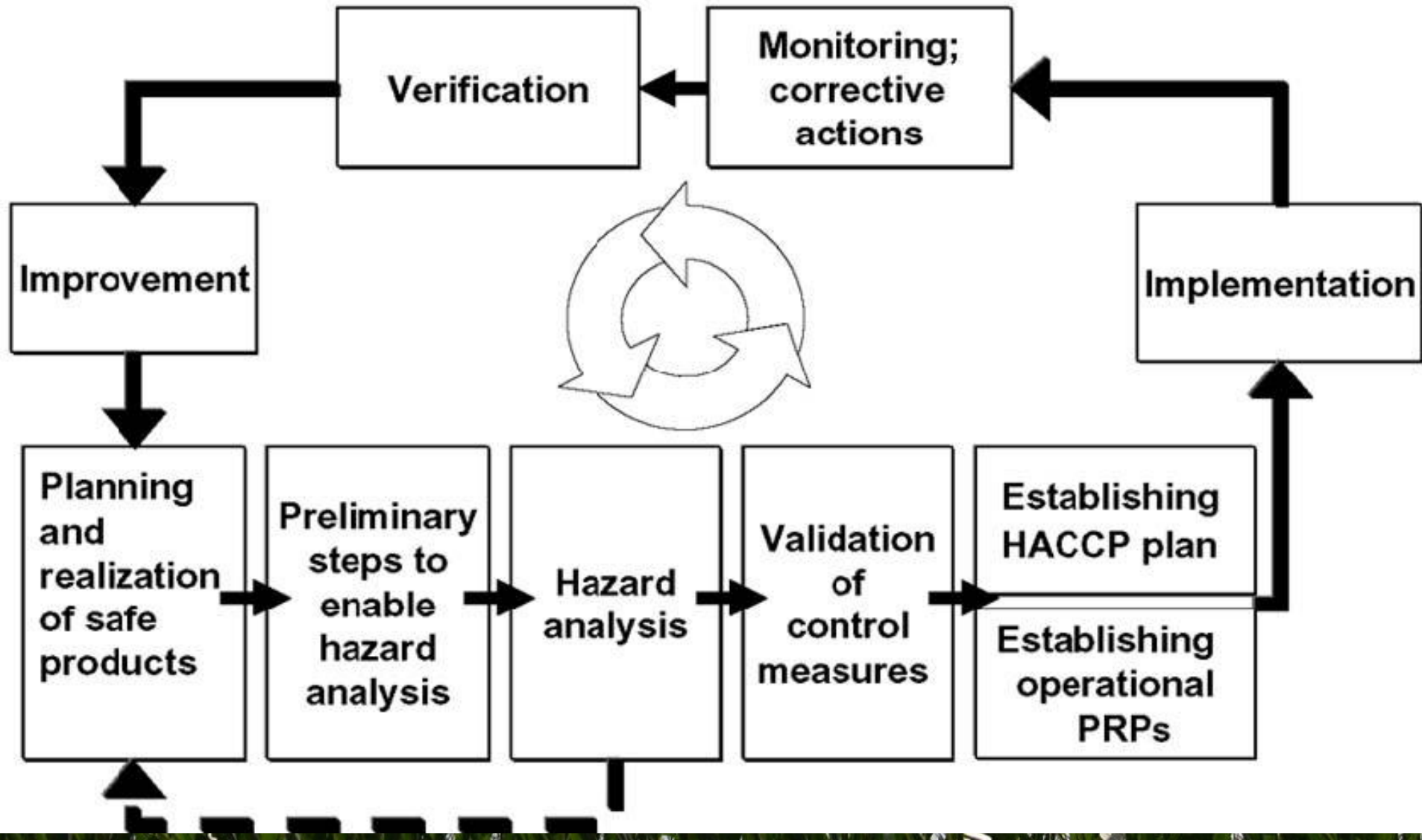
# Process Approach

## Benefits;

- Lower costs and shorter cycle times through effective use of resources
- Improved, consistent and predictable results
- Focused and prioritised improvement opportunities

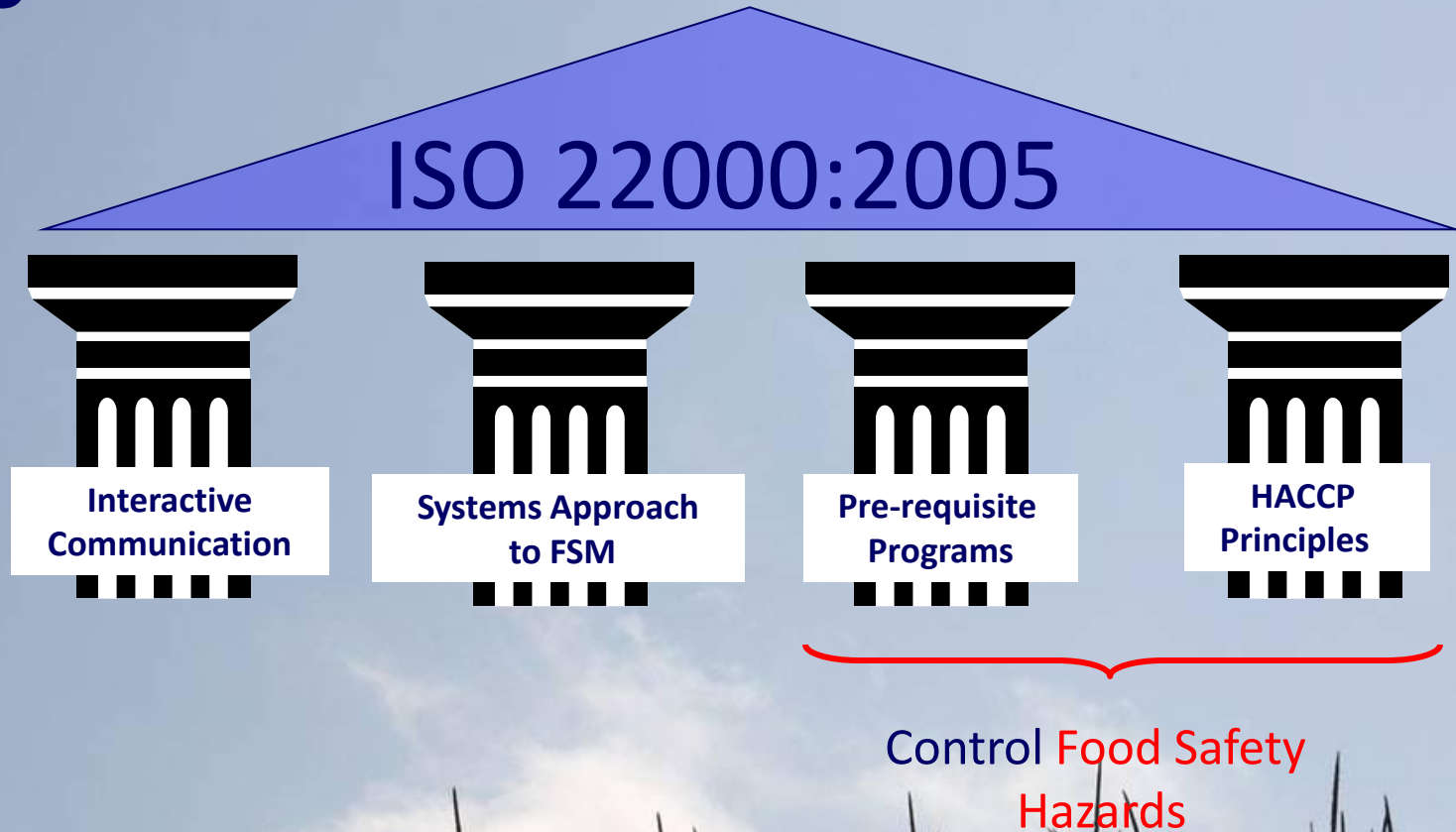


# FSMS Process model





# Key elements



# ISO 22000 standard

- Scope
- Normative references
- Terms and definitions
- **Requirements**
- Annex (s)



# Application

- **All requirements** of this International Standard are **generic** and are **intended** to be applicable to **all organisations in the food chain**, regardless of type, size and complexity.
- This includes organizations directly or indirectly involved in one or more steps of the food chain
- The standard allows small and/or less developed organization to **implement an externally developed** combination of control measures



# ISO 22000 standard - Requirements

- Section 4: Food Safety Management System (FSMS) – General Requirements
- Section 5: Management Responsibility
- Section 6: Resource Management
- Section 7: Planning and Realization of Safe Products
- Section 8: Validation, Verification and Improvement of the Food Safety Management System



# Section 4 – General Requirements

- Scope of the Food Safety Management System
- Documentation requirements
- More than twenty six types of documents required by ISO 22000:2005
- Twenty eight mandatory records required by ISO 22000:2005
- Documents needed by the organization to ensure effective development, implementation and updating of the FSMS

# **Section 4 – Documentation requirement**

- **Food safety policy & related objectives**
- **Documented procedures required by the standard**
- **Records required by the standard**
- **Documents needed to ensure effective development, implementation and updating of the Food SMS**



# Section 4 – Documentation requirement

- Mandatory documented procedures specified by ISO 22000:2005
  - Control of documents
  - Control of records
  - Corrections
  - Corrective actions
  - Handling potentially unsafe product
  - Withdrawals
  - Internal audits



## **4.2.2 Control of documents**

**Documented procedure defining controls for  
Food SMS required documents:**

- Approval for adequacy before use**
- Review/update & re-approval**
- Changes and current revision status clearly identified**





## **4.2.2 Control of documents**

- **Relevant version available at points of use**
- **Documents remain legible and readily identifiable**
- **Documents of external origin are identified and their distribution controlled**
- **Prevent use of obsolete documents, and identify if retained**



## 4.2.3 Control of records

- **Maintained to demonstrate conformance to requirements and the effective operation of the Food SMS**
- **System-level procedure for identifying, storage, retrieval, protection, retention times and disposal**



# 5. Management responsibility



# 5. Management responsibility

- Food safety team leader
- External communication
  - Suppliers and contractors
  - Customers/consumers
  - Statutory and regulatory authorities
  - Other organizations
- Internal communication



# 5. Management responsibility

- Emergency preparedness and response
  - Documented procedures to manage potential emergency situations and accidents
- Management Review
  - Review input: Food safety related requirements
  - Review output



# 5.1 General

**Top Management to provide evidence of its commitment to development & implementation of the Food SMS & continually improving its effectiveness**

**How???** (think first, then see next slide)



# 5.1 Cont.

## Top Management training school

- Showing food safety is supported by business objectives
- Communicating the importance of meeting customer/ statutory/ regulatory requirements
- Establishing the food safety policy
- Holding management reviews
- Ensuring availability of resources



*I'm out of here!*

# 5.2 Food safety policy

**Top management to ensure it:**

- **Is appropriate to the role of organization in food chain.**
- **Conforms with both statutory and regulatory and with agreed food safety requirements of customers**
- **Is communicated, implemented and maintained at all levels of organization**
- **Is reviewed for continuing suitability**
- **Adequately addresses communication**
- **Is supported by measurable objectives.**



# **5.3 Food safety management system planning**

**Top Management to ensure planning conducted to:**

- meet the overall requirements and food safety objectives**
- Ensure system integrity during changes**



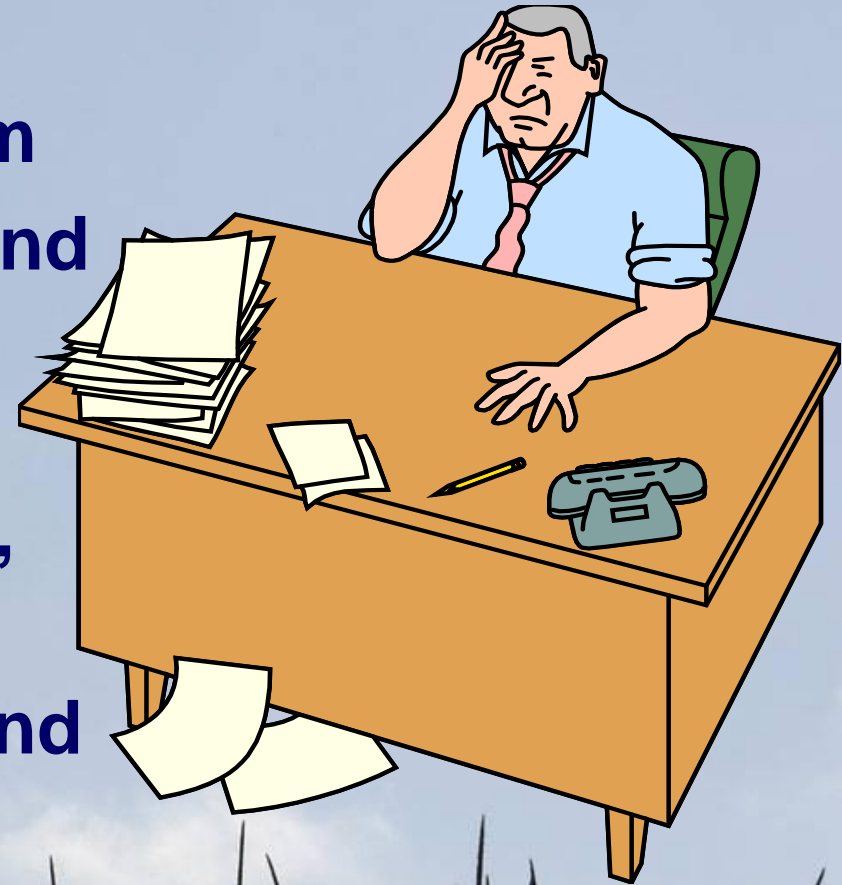
# 5.4 Responsibility and authority

- **Top Management to ensure that R&A are defined & communicated**
- **All personnel have the responsibility to report problems with the Food SMS to identified person (s).**
- **That designated personnel shall initiate and record action.**



# 5.5 Food Safety Team Leader

- **Manage a food safety team**
- **Ensure relevant training and education of team**
- **Ensure the Food SMS is established, implemented, maintained and updated**
- **Reporting effectiveness and suitability to top management**



# 5.6 Communication

- **External communication**
  - **Supplier and contractors**
  - **Customers or consumers**
  - **Statutory and regulatory authorities**
  - **Other impacted organization on food SMS**
- **Known food safety hazards, needed to be controlled by other organizations.**



# 5.6 Communication (Cont.)

- **Internal communication**
  - **Food safety team is informed of changes in food SMS.**
  - **Food safety team shall ensure the updating of the Food SMS.**



# **5.7 Emergency preparedness and response**

- **Procedure to manage potential emergency situation and accidents that can impact food safety**
- **Role of the organization in the food chain.**



# 5.8 Management review

- **Top management reviewing Food SMS to ensure suitability, adequacy & effectiveness**
- **Defined intervals**
- **Is there a need to amend the Food SMS, food safety policy.**



# 5.8 Management review (cont..)

**Review information to:**

- **Follow up issues from previous reviews**
- **Analysis results of verification activities**
- **Changing circumstances that affect to food safety.**
- **Emergency situation, accident and withdrawals**
- **Reviewing results of system updating activities.**
- **Review of communication activities, including customer feed back**
- **External audits or inspection**

**Data shall be presented in link to objectives**





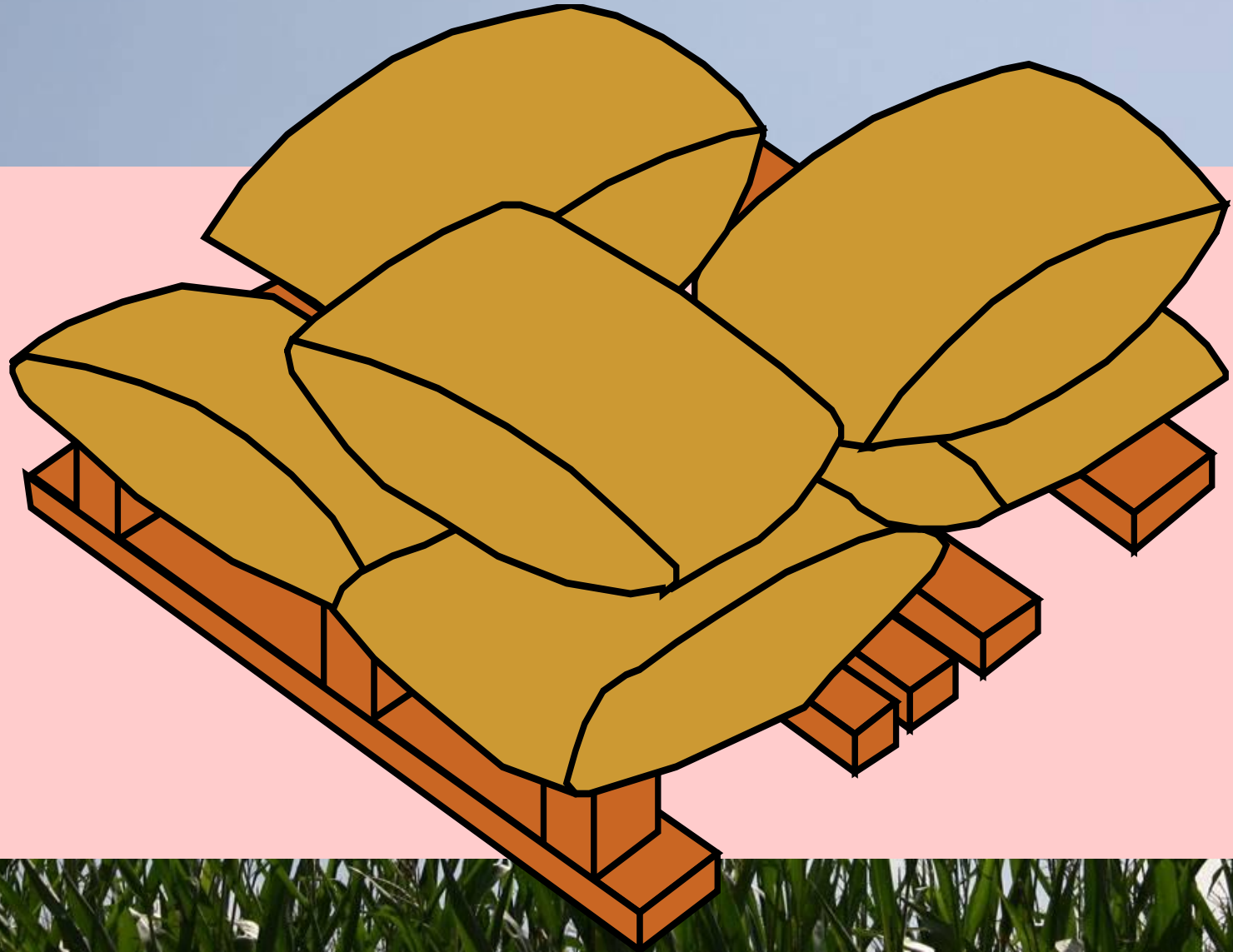
# 5.8 Management review (cont...)

Output shall include decisions and actions related to:

- Assurance of food safety
- Improvement of Food SMS
- Resource needs
- Revision of Food safety policy and objectives



# 6. Resource management



# 6. Resource management

The organization shall provide adequate resources for;

- Establishment
- Implementation
- Maintenance
- Updating



# 6. Resource management

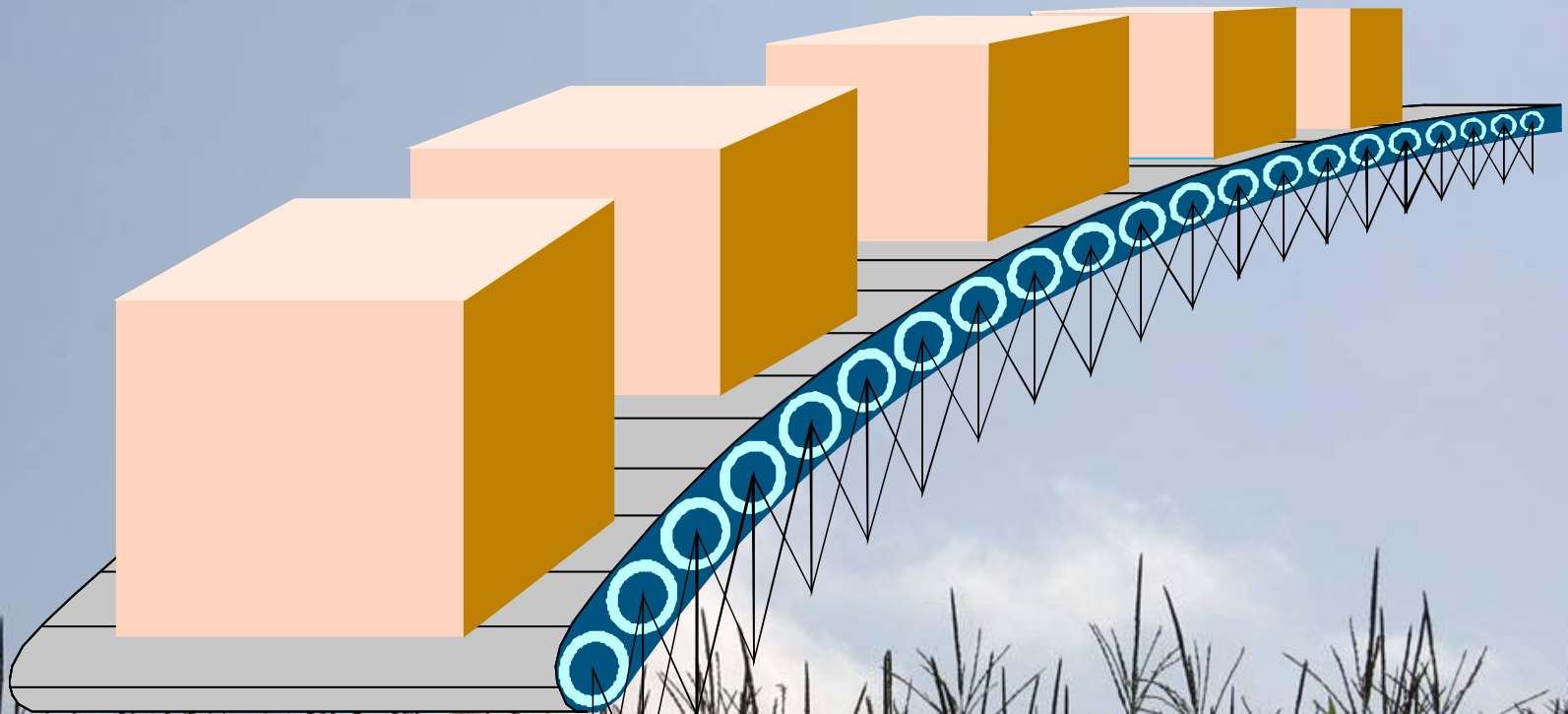
- **Human Resource**
  - Food safety team and personnel impacting food safety
  - External experts
- **Competence, Awareness and Training**
- **Infrastructure**
  - Buildings
  - Process equipment
  - Utilities
  - Surrounding areas
  - Supporting services

# 6. Resource management

- **Work Environment**

- Measures to prevent cross contamination
- Work space requirements
- Protective work wear requirements
- Availability and location of employee facilities

# 7. Planning and realization of Safe Products



# 7. Planning and realization of Safe Products

- The organization shall plan and develop the processes needed for the realization of safe products
- The organization shall implement, operate and ensure the effectiveness of the planned activities and any change to those activities including;
  - **Pre-requisite programmes ( PRPs)**
  - **Operational PRPs**
  - **HACCP plan**

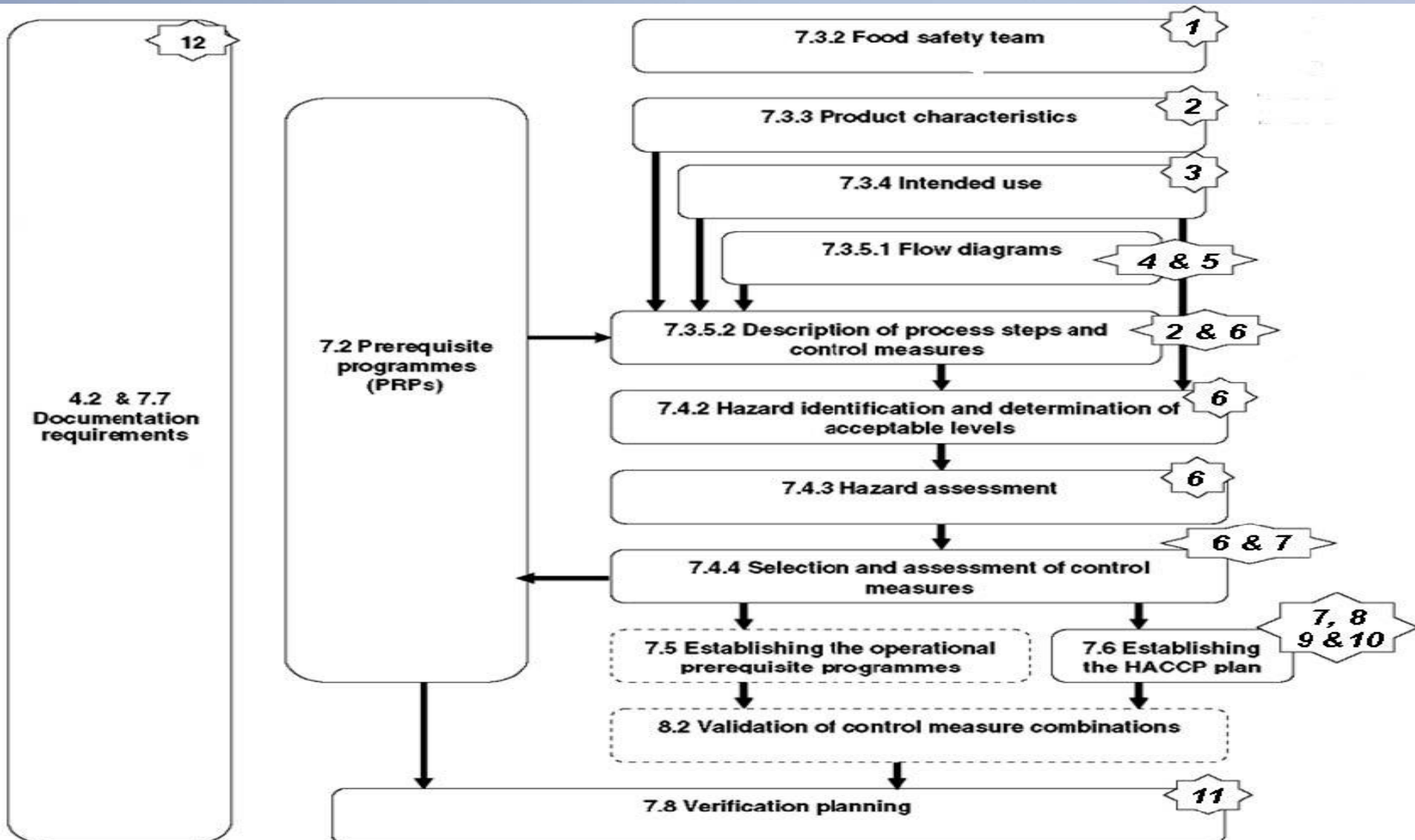
# 7. Planning and realization of Safe Products

- Prerequisite programmes (PRPs)
- Preliminary steps to enable hazard analysis
- Hazard analysis
- Establishing the operational prerequisite programmes (PRPs)
- Establishing the HACCP plan

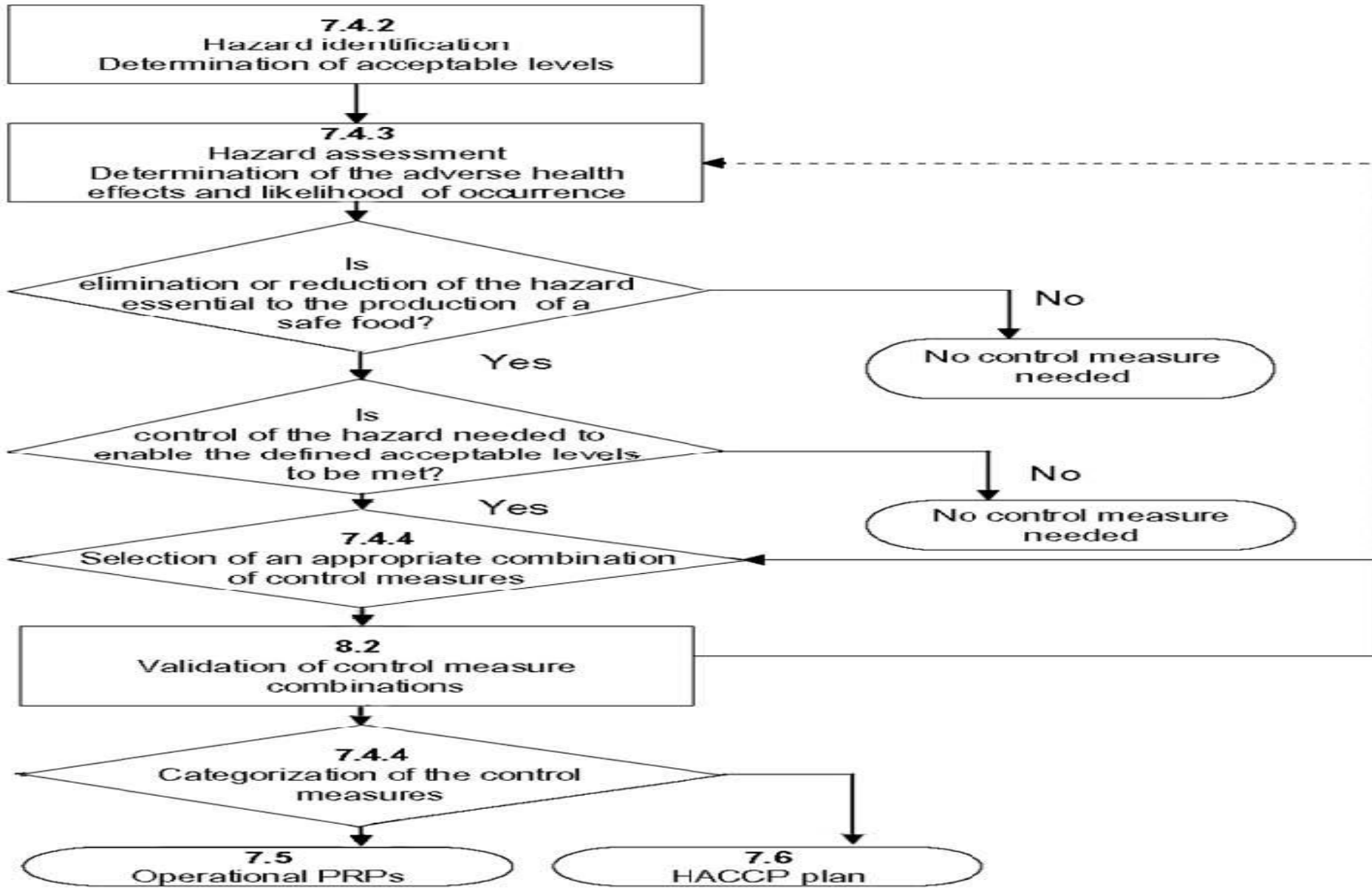




# Planning of safe food



# Decision tree



# **7.2 Prerequisite programmes (PRPs)**

## **7.2.1 Establish, implement and maintain PRP to assist in controlling**

- Likelihood Food safety hazards thru work environment**
- B / C / P contamination, cross contamination between product**
- Food safety hazard level in product and process environment**



# 7.2 Prerequisite programmes (PRPs)

- **Be appropriate to organization need**
- **Be appropriate to size, type and nature of products**
- **Be implemented across the entire production system**
- **Be approved by food safety team**
- **Shall identify related statutory and regulatory requirements**



# **7.2 Prerequisite programmes (PRPs)**

- **Construction and layout of building and utility**
- **Lay-out of premises, workspace & employee facilities**
- **Supplies of air, water, energy and other utilities**
- **Waste, sewage disposal**
- **Equipment, accessibility for cleaning, maintenance**
- **Management of purchased material, supplies, disposals and handling of products**

# **7.2 Prerequisite programmes (PRPs)**

- **Measures for prevention of cross contamination**
- **Cleaning and sanitizing**
- **Pest control**
- **Personnel hygiene**
- **Other aspects, as appropriate**

**PRP verification shall be planned and modified as necessary.**



# 7.3 Preliminary steps to enable hazard analysis

- **Collect information needed**
- **Appoint food safety team, multi-disciplinary knowledge & experienced**
- **Raw materials, ingredients, product-contact materials**
- **Characteristics of end products**
- **Intended use**
- **Flow diagrams, process step and control measure**



# 7.4 Hazard analysis

- **Determine which hazards need to be controlled, degree of control combination of control measures**
- **Hazard identification and determine acceptable levels, base on**
  - **Preliminary collected information & data**
  - **Experience**
  - **External information**
  - **Information from food chain**





## 7.4.2 Hazard identification

- **Consider to**
  - **Preceding and following step of specified operation**
  - **Process equipment, utilities and surrounding**
  - **Preceding and following links in food chain**
- **Determine acceptable level,**
- **Justification and result shall be recorded**



## 7.4.3 Hazard assessment

- **Conduct the hazard assessment to determine whether**
  - **Its elimination or reduction to acceptable levels**
  - **Its control is need to meet the defined acceptable level**
- **Describe the methodology used and record**



## **7.4.4 Selection and assessment of control measures**

- **Select appropriate combination of control measures**
- **Categorized selected control measures whether manage thru Operational PRP or HACCP plan**



# 7.5 Establishing the operational prerequisite programme

## Document operational PRP

- Food safety hazard(s) to be controlled
- Control measure
- Monitoring procedures
- Correction and corrective action to be taken
- Responsibilities and authorities
- Record of monitoring



# 7.6 Establishing the HACCP plan

- Document HACCP plan
- Identification of critical control points
- Determine critical limit for CCP
- System for monitoring of CCP
- Action when monitoring results exceed critical limit



# **7.7 Updating of preliminary information and document specifying the PRP and HACCP plan**

- **Updating the following information**
  - **Product char**
  - **Intended use**
  - **Flow diagram**
  - **Process step**
  - **Control measure**



# 7.8 Verification planning

- **Verification activities shall confirm that**
  - **PRP are implemented**
  - **Input to hazard analysis is updated**
  - **Effective of operational PRP and HACCP plan**
  - **Hazard levels are within acceptable level**
  - **Other procedure are implemented and effective**



# 7.9 Traceability system

- **Traceability system for product lot and their relation to batch of raw material, processing and delivery record**
- **Able to identify incoming material from immediate suppliers and initial distribution route of end product**





# 7.10 Control of nonconformity

- **Corrections**
  - Identify and assessment affected end product to determine proper handling
  - Review of the corrections carried out
- **Corrective actions**
  - Eliminate cause of detected N/C
  - Prevent recurrence
  - Bring the process or system back into control



# 7.10 Control of nonconformity

- **Handling of potentially unsafe product**
  - **To prevent the N/C product from entering the food chain**
  - **N/C product shall be held until they have been evaluated**
  - **Notify interested parties and initiate a withdrawal**



# 7.10 Control of nonconformity

- **Evaluation for release**
- **N/C product shall only be released as safe when**
  - **Evidence of effective control measure, other than monitoring system**
  - **Evidence of complies with performance intended**
  - **Result of sampling, analysis or other verification shows product complies acceptable level**



# 7.10 Control of nonconformity

- **Disposition of N/C products**
  - Reprocessing or further processing to acceptable levels
  - Destruction or disposal as waste
- **Withdrawals**
  - Appoint authority personnel to initiate and execute the withdrawal
  - Notify to interested parties
  - Handling of withdraw product
  - Procedure sequence of action to be taken

# **8. Validation, verification and improvement of the Food SMS**

## **8.1 General**

- Plan & implement**
  - Processes needed to validate control measures**
  - To verify and improve the Food SMS**



## **8.2 Validation of control measure combinations**

- **Validate the control measures are capable to control the Hazard**
- **Modify the control measures, as necessary.**



# 8.3 Control of measuring & monitoring

- To ensure valid results, devices are:
  - Calibrated/adjusted prior to use or at specified intervals against devices traceable to national/international stds. if not, define basis for calibration
  - identified & calibration status defined
  - Safeguarded from adjustments



## **8.3 Control of measuring & monitoring**

**Protected from damage & deterioration during handling, maintenance & storage**

- Assess & record previous results' validity & take action when device found not conforming to requirements**
- Record calibration & verification results**
- Software validated prior to use & when req.**





# 8.4 Food safety management system verification

## 8.4.1 Internal Audit

- **Verify Food SMS is complying & effectively implemented**
- **Planned based on status, importance and previous results**
- **Independent auditors**
- **Documented procedure**
- **Timely corrective action by relevant mgt.**
- **Follow-up**

## **8.4.2 Evaluation of individual verification results**

- **Systematic evaluate the individual results of planed verification**
- **Take action to achieve the require conformity**



## **8.4.3 Analysis of results of verification activities**

- **Analyse the results of verification activities, incl. Internal / External audit**
- **To confirm overall performance of system.**
- **To identify need for updating / improving the Food SMS**
- **To identify trends of potential unsafe products**
- **Information for internal audit**
- **To provide evidence the effectiveness of correction and corrective action**



# 8.5 Improvement

## 8.5.1 Continual improvement

- **Continually improve Food SMS effectiveness through use of various sources of information:**
  - **Communication, management review, internal audit, verification activities, validate result, corrective action, etc.**

## **8.5.2 Updating the Food SMS**

- **Continually update the food SMS**
- **Consider whether it is necessary to review hazard analysis, PRP and HACCP plan**
- **As the input for management review.**



# FSMS Overview

## Verification

- Confirm compliance (HACCP & Prerequis.)
- Review the study
- Review results
- Review records
- Review changes
- Review of validation data
- Gather Int. & Ext. Inf.

## Implementation

- Training
- Awareness
- Information
- Prerequisites
- Control Measures
- Monitoring
- Corrective actions
- Recording

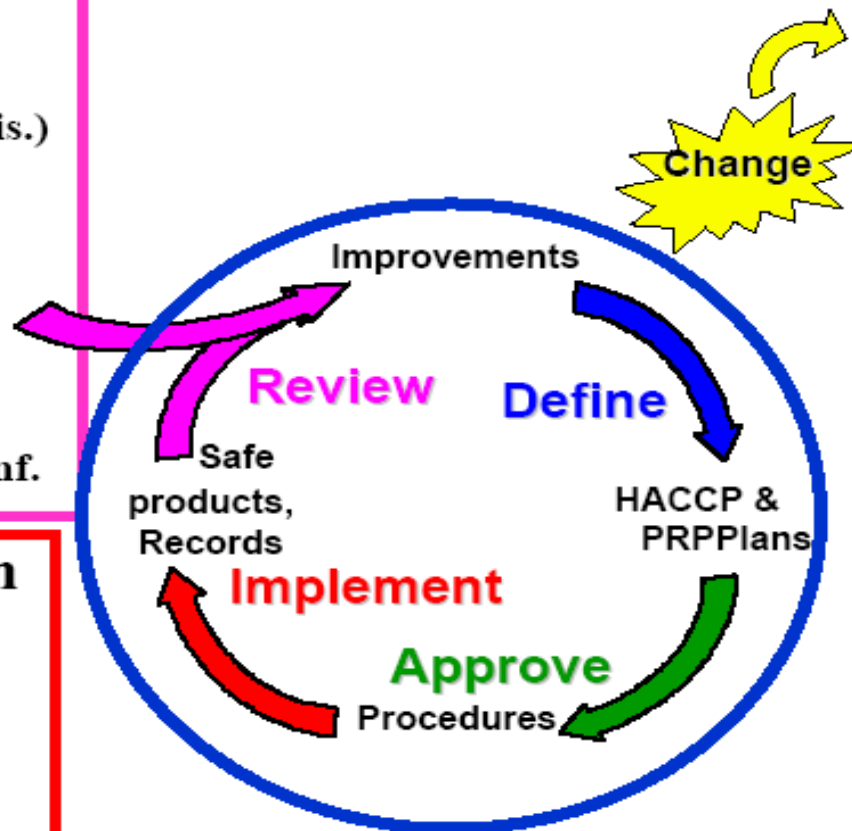
## Study

- List pot. hazards
- Hazard Analysis
- List significant haz.
- CCP (& CPs)
- Monitoring
- Critical Limits
- Corrective actions
- Validation
- List verification act.

## Approval:

(NOT VALIDATION)

- Monitoring (Prerequisites)
- Contr. meas.
- Modifications
- Corr. actions
- Verification



Continuous Improvement



*Thank you*

