SESSION 7B

ISO 22000:2005

Food safety management systems — Requirements for any organization in the food chain

Incorporating HACCP Principles
WHAT IS ISO 22000:2005?

- The standard developed within ISO by experts from the food industry, along with representatives of specialized international organizations and in close cooperation with the Codex Alimentarius Commission, the body jointly established by the United Nations’ Food and Agriculture Organization (FAO) and World Health Organization (WHO) to develop food standards.

- ISO 22000 will make it easier for organizations worldwide to implement the Codex HACCP (Hazard Analysis and Critical Control Point) system for food hygiene in a harmonized way, which does not vary with the country or food product concerned.

- ISO 22000 is designed to allow all types of organization within the food chain to implement a food safety management system. These range from feed producers, primary producers, food manufacturers, transport and storage operators and subcontractors to retail and food service outlets — together with related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients.
Users of ISO 22000:2005

ISO 22000 may apply to, and is not be limited to:

i) Primary food producers through to food manufacturers, including food processors

ii) Retail and food service outlets

iii) Feed producers

iv) Transport and storage operators

v) Producers of equipment and packaging material

vi) Producers of cleaning agents, additives and ingredients
Concept of continuous improvement

- Improvement
  - Planning and realization of safe products
  - Preliminary steps to enable hazard analysis
- Verification
- Monitoring; corrective actions
- Validation of control measures
- Establishing HACCP plan
- Establishing operational PRPs
- Implementation

Circular flow indicating continuous improvement and feedback loop.
Interactive communication

Statutory and regulatory authorities

Crop producers
Feed producers
Primary food producers
Food manufacturers
Secondary food manufacturers
Wholesalers
Retailers, food service operators and caterers

Consumers

Producers of pesticides, fertilizers, and veterinary drugs
Food chain for the production of ingredients and additives
Transport and storage operators
Producers of equipment
Producers of cleaning and sanitizing agents
Producers of packaging materials
Service providers
Benefits of ISO 22000:2005 Certification

- **Society** — Wide acceptance and predictable planning of suppliers

- **Consumers** — Conformity of products and services to international standards which provides assurance about quality, safety and reliability

- **Trade officials** — For trade officials negotiating the emergence of regional and global markets, ISO 22000 creates a “level playing field” for all competitors on those markets.

- **Developing countries** — For developing countries, ISO 22000 represents and international consensus and constitutes and important source of technological know-how.

- **Governments** — For governments, ISO 22000 provides technological and scientific know-how, bases for developing health, safety and environmental legislation, education of food regulatory personnel, certification or registration, international acceptance of standards used globally, economic benefits, social benefits, trade liberalization, food quality, food safety and food security.
Benefits for users

- Resource optimization — internally and along the food chain
- More efficient and dynamic food safety hazard control
- All control measures subjected to hazard analysis
- Better planning, less post process verification
- Improved documentation
- Systematic management of prerequisite programs
- Focuses on the most important issues for food safety; based on risk assessment results, resources can be maximised.
- Widely applicable because it is focused on end results
- Valid basis for taking decisions
- Increased due diligence
- Dynamic communication on food safety issues with suppliers, customers, government regulators, international traders, manufacturers, wholesalers, retailers and consumers and other interested parties
- A systematic and proactive approach to identification of food safety hazards and development and implementation of control measures.
- Saves resources by reducing overlapping system audits.
Benefits to other stakeholders

信心，即实施标准的组织具有识别和控制食品安全危害的能力

- 提供整个食品链的参考
- 有助于对Codex HACCP的更好理解和进一步发展
- 系统方法，而不是产品方法

- 提供第三方认证的框架
- 适合监管机构
- 提供潜在的国家标准的整合。

- 国际公认的能够整合不同客户或国家要求的标准。

- 提供可审计的标准，可以用于内部审计、自我认证或第三方认证。

- 系统方法，而不是产品方法。
ISO 22000:2005 elements

- Introduction
- 1. Scope
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- 3. Terms and definitions
- 4. Food safety management system
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  - 4.2 Documentation requirements
- 5. Management responsibility
  - 5.1 Management commitment
  - 5.2 Food safety policy
  - 5.3 Food safety management system planning
  - 5.4 Responsibility and authority
  - 5.5 Food safety team leader
  - 5.6 Communication
  - 5.7 Emergency preparedness and response
  - 5.8 Management review
- 6. Resource management
  - 6.1 Provision of resources
  - 6.2 Human resources
  - 6.3 Infrastructure
  - 6.4 Work environment
7  Planning and realization of safe products
   7.1 General
   7.2 Prerequisite programs (PRPs)
   7.3 Preliminary steps to enable hazard analysis
   7.4 Hazard analysis
   7.5 Establishing the operational prerequisite programs (PRPs)
   7.6 Establishing the HACCP plan
   7.7 Updating of preliminary information & documents specifying PRPs & HACCP plan
   7.8 Verification planning
   7.9 Traceability system
   7.10 Control of nonconformity

8  Validation, verification and improvement of the safety management system
   8.1 General
   8.2 Validation of control measure combinations
   8.3 Control of monitoring and measuring
   8.4 Food safety management system verification
   8.5 Improvement
Objectives of application of the HACCP system

- Prevention of foodborne illness
- More efficient quality assurance system
- Reduction of costs of food analyses
- Protection of reputation
- Reduction of losses due to product recall
HACCP principles

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limit(s)
4. Establish a monitoring system
5. Establish corrective actions
6. Establish verification procedures
7. Establish documentation
1 Scope

- This International Standard specifies generic requirements to enable an organization
to plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer,
to demonstrate compliance with applicable statutory and regulatory food safety requirements,
to evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction,
to effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain,
to ensure that the organization conforms to its stated food safety policy,
to demonstrate such conformity to relevant interested parties, and
to seek certification or registration of its food safety management system by an external organization.
4.1 General requirements

The organization shall

- ensure that food safety hazards that may be reasonably expected to occur in relation to products within the scope of the system are identified, evaluated and controlled in such a manner that the products of the organization do not, directly or indirectly, harm the consumer,

- communicate appropriate information throughout the food chain regarding safety issues related to its products,

- communicate information concerning development, implementation and updating of the food safety management system throughout the organization, to the extent necessary to ensure the food safety required by this International Standard, and

- evaluate periodically, and update when necessary, the food safety management system to ensure that the system reflects the organization's activities and incorporates the most recent information on the food safety hazards subject to control.
4.2 Documentation requirements

The organization shall establish the necessary food safety management system documentation, define the necessary controls for them and establish a system for controlling its records.
5 Management responsibility

Top management shall provide evidence of its commitment to the development and implementation of the food safety management system and to continually improving its effectiveness by

- Showing food safety is supported by the business objectives of the organization,
- Communicating to the organization the importance of meeting the requirements of this International Standard, any statutory and regulatory requirements, as well as customer requirements relating to food safety,
- Establishing the food safety policy,
- Planning the food safety management system,
- Ensuring that responsibilities are defined and communicated,
- Appointing a competent food safety team leader,
- Establishing, implementing and maintaining emergency procedures,
- Conducting management reviews, and
- Ensuring the availability of resources.
6 Resource management

• The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system.

• The food safety team and the other personnel [internal or contracted] carrying out activities having an impact on food safety shall be competent and shall have appropriate education, training, skills and experience.

• The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement the requirements of this International Standard.

• The organization shall provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of this International Standard.
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 changes to those activities. This includes PRP(s) as well as operational PRP(s) and/or the HACCP plan.
Planning of safe foods

4.2 & 7.7 Documentation requirements

7.2 Prerequisite programmes (PRPs)

7.3.2 Food safety team

7.3.3 Product characteristics

7.3.4 Intended use

7.3.5.1 Flow diagrams

7.3.5.2 Description of process steps and control measures

7.4.2 Hazard identification and determination of acceptable levels

7.4.3 Hazard assessment

7.4.4 Selection and assessment of control measures

7.5 Establishing the operational prerequisite programmes

7.6 Establishing the HACCP plan

7.8 Verification planning

Steps addressed by the Codex Alimentarius HACCP Guidelines

Steps specific to ISO 22000
7.2 Prerequisite programs (PRPs)

- Assemble a HACCP team
- Identify the product involved and its characteristics
- Determine and state the intended use of the product
- Establish an operational flow chart
- Confirm the operational flow chart on-site
Key considerations for PRPs

a) construction and lay-out of buildings and associated utilities;
b) lay-out of premises, including workspace and employee facilities;
c) supplies of air, water, energy and other utilities;
d) supporting services, including waste and sewage disposal;
e) the suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance;
f) management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation);
g) measures for the prevention of cross contamination;
h) cleaning and sanitizing;
i) pest control;
j) personnel hygiene;
k) other aspects as appropriate.
7.4 Hazard analysis

- The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

- All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded.

- The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

- For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible.

- A hazard assessment shall be conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met.

- Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence.

- Based on the hazard assessment, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels.

- In this selection, each of the control measures shall be reviewed with respect to its effectiveness against the identified food safety hazards.

- The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan.

- The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.
Where hazards arise in the food chain

- Vehicle emission
- Agricultural practices
- Landfills
- Industrial emissions and effluents
- Crops
- Livestock
- Seafood
- Processing
- Storage
- Distribution
- Retail
- Cooking
- Eating
Hazard determination

Questions to be answered for each potential hazard for each step

- Presence of agent in raw material probable?
  - NO
  - YES

- Presence of agent in line or environment probable?
  - NO
  - YES

- Unaccept. survival, persistence or increase at this step probable?
  - NO
  - YES

- Reduction, if any, at a further step adequate?
  - NO
  - YES

* Not a hazard to be controlled at this step

** Reduction step becomes thus a CCP
Urbanization and food contamination

- A longer and more complex food chain;
- Thus greater opportunities for food contamination.
Microbial ecology

- *Microbes are everywhere:*
  - Air
  - Water
  - Food
  - Soil
  - Humans (e.g. gut, nose, skin)
  - Surfaces
The *Salmonella* (non typhi) cycle

1. **Wildlife reservoirs**
2. **Animal importation**
3. **Effluent, slurry and sludge**
4. **Slaughterhouses**
5. **Human food**
6. **Man**
7. **Pets**
8. **Imported food**

**Imported animal / vegetable protein**

**Animal feeds**
- Meat / bone meal, dried poultry waste, etc.
- Offal
Transmission of *Campylobacter*
Potential hazards in meat and meat products

- *Salmonella*
- *Staphylococcus aureus*
- *Yersinia enterocolitica*
- *Clostridium perfringens*
- *Clostridium botulinum*
- Pathogenic *Escherichia coli*
- *Listeria monocytogenes*
- *Parasites*
The contamination chain for meat

- **Infected portion**
- **Cross contamination**
- **Jointed meat**
- **Blood and tissue drip**
- **Slaughter**
- **Butcher**
- **Pass**
- **Fail**
- **Diseased or contaminated**

Cross contamination links between different stages of meat processing.
### Mycotoxins

<table>
<thead>
<tr>
<th>Mycotoxin</th>
<th>Source</th>
<th>Associated Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aflatoxins</td>
<td>Aspergillus flavus and A. parasiticus</td>
<td>Corn, peanuts, tree nuts, milk</td>
</tr>
<tr>
<td>Trichotheccenes</td>
<td>Mainly Fusarium</td>
<td>Cereals and other foods</td>
</tr>
<tr>
<td>Ochratoxin A</td>
<td>Penicillium verrucosum A. ochraceus</td>
<td>Wheat, barley, corn</td>
</tr>
<tr>
<td>Ergot alkaloids</td>
<td>Claviceps purpurea</td>
<td>Rye, barley, wheat</td>
</tr>
<tr>
<td>Fumonisins</td>
<td>Fusarium moniliforme</td>
<td>Corn</td>
</tr>
<tr>
<td>Patulin</td>
<td>P. expansum</td>
<td>Apples, pears</td>
</tr>
<tr>
<td>Zearalenone</td>
<td>Fusarium spp.</td>
<td>Cereals, oil, starch</td>
</tr>
</tbody>
</table>
## Inherent plant food toxicants

<table>
<thead>
<tr>
<th>Toxicant</th>
<th>Associated Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxalates</td>
<td>Rhubarb, tea, cocoa, spinach, beet</td>
</tr>
<tr>
<td>Glycoalkaloids</td>
<td>Green potato</td>
</tr>
<tr>
<td>Cyanoglycosides</td>
<td>Lima bean, cassava</td>
</tr>
<tr>
<td>Phytohaemagglutinin</td>
<td>Red kidney beans and other beans</td>
</tr>
<tr>
<td>Various carcinogens</td>
<td>Spices and herbs</td>
</tr>
</tbody>
</table>
Physical hazards in foods

- Bone particles
- Stones
- Insect fragments
- Metal
- Meat, Poultry, Fish
- Dried fruits
- Cereals
- Mechanically harvested materials
7.6 Establishing the HACCP plan

- The HACCP plan shall be documented and shall include the following information for each identified critical control point (CCP):
  - food safety hazard(s) to be controlled at the CCP;
  - control measure(s);
  - critical limit(s);
  - monitoring procedure(s);
  - corrections and corrective action(s) to be taken if critical limits are exceeded;
  - responsibilities and authorities;
  - record(s) of monitoring.

- Critical limits shall be determined for the monitoring established for each CCP.

- A monitoring system shall be established for each CCP to demonstrate that the CCP is in control.

- Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.
7.7 Updating of preliminary information and documents specifying the PRPs and the HACCP plan

Following the establishment of operational PRP(s) and/or the HACCP plan, the organization shall update the following information, if necessary:

- a) product characteristics;
- b) intended use;
- c) flow diagrams;
- d) process steps;
- e) control measures.

If necessary, the HACCP plan and the procedures and instructions specifying the PRP(s) shall be amended.
7.8 & 7.9 Verification planning and traceability system

- Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities.
- Verification results shall be recorded and shall be communicated to the food safety team. Verification results shall be provided to enable the analysis of the results of the verification activities.
- The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.
- The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product.
- Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.
7.10 Control of nonconformity

- The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of operational PRP(s), the products affected are identified and controlled with regard to their use and release and that necessary corrective actions are effected and their effectiveness verified.

- The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to carry out corrective actions, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered.

- The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain.

- The controls and related responses and authorization for dealing with potentially unsafe products including withdrawal/recall, reprocessing or destruction shall be documented.
Validation, verification and improvement of the food safety management system

- The food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system.
- The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures.
- The organization shall conduct internal audits at planned intervals to determine whether the food safety management system a) conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this International Standard, and b) is effectively implemented and updated.
- The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.
- The food safety team shall analyze the results of verification activities, including the results of the internal audits and external audits.
- Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, corrective actions and food safety management system updating.
- Top management shall ensure that the food safety management system is continually updated.
HACCP Plan

1. Define
   - QMS, Procedures
   - HACCP Plan

2. Implement
   - Safe products, Records
   - Monitoring
   - Corrective actions
   - Recording

3. Review
   - Improvements
   - Verification
     - Confirm compliance
     - List pot. hazards
     - Hazard Analysis
     - List significant haz.
     - CCP (& CPs)
     - Critical Limits
     - Corrective actions
     - Validation
     - List verification act.

4. Approve
   - Approval
     - (NOT VALIDATION)
     - Monitoring (Prerequisites)
     - Contr. meas.
     - Modifications
     - Corr. actions
     - Verification, Validation

Continuous Improvement

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

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

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

Change
Responsibility of industry

- To ensure proper application of HACCP principles and implementation of the HACCP plan

- To provide evidence of this to government authorities when required
Roles

- Shared responsibility:

Farmers
Manufacturers
Consumers

Government
Your Role.!? 

What is your role in the food chain?

Hopefully, you can see why hawking food anywhere, everywhere, wherever, anyhowly by anybody and everybody is to be avoided!