# **TRAINING ON ISO 22000 :2005**

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

## ISO 22000 key elements

#### • Involvement of the management team

Food safety is not just something to be handled by the quality department. It is a topmanagement issue. ISO 22000 focuses on the involvement of the management team, which has to develop overall policy.

#### Communication

As food safety hazards may be introduced at any stage of the food chain, interactive communication both upstream and downstream is essential. In addition, internal communication is a key element to avoiding misunderstandings and minimizing risks. A common vocabulary is a great help in this connection.

#### • The HACCP (Hazard Analysis & Critical Control Point) principles

ISO 22000 combines the recognized HACCP principles with prerequisite programmes The hazard analysis determines a strategy and the prerequisite programmes set up an action plan.

#### System management

ISO 22000 relies on a structured management system based on relevant parts of ISO 9001. It is possible to integrate them into one management system together with ISO 14001.

## **ISO 22000**

Introduction

•Objectives

•Background to ISO 22000

•Requirements of the standard

- 1.0 Scope
- 2.0 References
- 3.0 Terms and definitions
- 4.0 FSMS
- 5.0 Management responsibility
- 6.0 Resource management
- 7.0 Planning and realization of safe products
- 8.0 Validation, verification and improvement of the food safety management system

# **Requirements of the standard**

1.0 Scope of the ISO 22000

All the requirements of this standard are kept generic and are intended to be :

Applicable to all organizations in the food chain, regardless of size and complexity

# Coverage of ISO 22000:2005



1.0 Scope of the ISO 22000

All the requirements of this standard are kept generic and are intended to be :

Applicable to all organizations in the food chain, regardless of size and complexity

2.0 References

ISO 9000 (normative)

**ISO TS 22003** 

**ISO/IEC 17000** 

**ISO/IEC 17021** 

ISO/TS 22004 (interim until 6<sup>th</sup> june 2008)

#### 3.0 Terms and definitions

## 3.1 food safety

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

NOTE 2 Food safety is related to the occurrence of food safety hazards (3.3) and does not include other human health aspects related to, for example, malnutrition.

#### 3.2 food chain

sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption

NOTE 1 This includes the production of feed for food-producing animals and for animals intended for food production.

NOTE 2 The food chain also includes the production of materials intended to come into contact with food or raw materials.

#### 3.3 food safety hazard

biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect

NOTE 2 The term "hazard" is not to be confused with the term "risk" which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization, absence from work, etc.) when exposed to a specified hazard.

Risk is defined in ISO/IEC Guide 51 as the combination of the probability of occurrence of harm and the severity of that harm.

**NOTE 3 Food safety hazards include allergens.** 

NOTE 4 In the context of feed and feed ingredients, relevant food safety hazards are those that may be present in and/or on feed and feed ingredients and that may subsequently be transferred to food through animal consumption of feed and may thus have the potential to cause an adverse human health effect. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, cleaning agents, etc.), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food because of the intended use of the provided products and/or services and thus can have the potential to cause an adverse human health effect.

#### 3.4 food safety policy

overall intentions and direction of an organization related to food safety (3.1) as formally expressed by top management

3.5 end product

product that will undergo no further processing or transformation by the organization

NOTE A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.7 control measure

(food safety) action or activity that can be used to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level

### 3.8 prerequisite programme

(food safety) basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption

NOTE The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization (see Annex C). Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

#### 3.9 operational prerequisite programme

PRP (3.8) identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

#### **3.10** CCP critical control point

(food safety) step at which control can be applied and is essential to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level

3.11 critical limit

criterion which separates acceptability from unacceptability

NOTE 2 Critical limits are established to determine whether a CCP (3.10) remains in control. If a critical limit is exceeded or violated, the products affected are deemed to be potentially unsafe.

3.15 validation

(food safety) obtaining evidence that the control measures (3.7) managed by the HACCP plan and by the operational PRPs (3.9) are capable of being effective

NOTE This definition is based on Reference [11] and is more suitable for the field of food safety (3.1) than the definition given in ISO 9000.

3.16 verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

# 4.0 **FSMS**

- 4.1 General requirements
  - organizations shall establish, document, implement and maintain an effective FSMS
  - scope of the FSMS defined



- 4.2 **Documentation requirements** 
  - Food safety policy
  - Documented procedures & records
  - control of documents and records

## 5.0 Management responsibility

- 5.1 Management commitment
  - -business objectives
  - communication on the importance of meeting ISO 22000, statutory/legal, Customer rqts related to food safety
  - Establishing food safety policy
  - conducting management review
  - availability of resources
- 5.2 Food safety policy

Top mgt shall define, document and communicate its FSP

- is appropriate to the role of the organization in the food chain
- conforms with both statutory and regulatory rqts with mutually agreed food safety rqts of customers
- is communicated, implemented and maintained at all levels of the organization
- is reviewed for continual suitability
- adequately addresses communication
- is supported by measurable objectives

## 5.3 FSMS Planning

- planning meets the rqts of 4.1
- integrity of the FSMS maintained when changes are planned and implemented
- 5.4 Responsibility and authority
  - Top mgt shall ensure all responsibilities and authorities are defined and communicated
- 5.5 Food safety Team leader
  - Top management shall appoint a FS Team Leader
  - The FS Team leader is responsible for:
    - managing the FS team
    - ensure relevant training and education in the FS team members
    - ensure FSMS is established, implemented, maintained, updated
    - report to Tops mgt on effectiveness and suitability of the FSMS
    - responsibilities may include liasing externally

## 5.6 Communication

## 5.6.1 **EXTERNAL** communication

organization shall establish, implement and maintain effective arrangements for EXTERNAL communication with:

- supplies & contractors
- Customers or consumers
- Statutory & regulatory authorities
- any other relevant organizations

## 5.6.2 INTERNAL communication

organization shall establish, implement and maintain effective arrangements for INTERNAL communication with:

- personnel on issues having an impact of food safety
- specifically when any changes occur in the system that makes impact on food safety

- 5.7 Emergency Preparedness & response
  - establish , implement and maintain procedures
  - must be documented

- 5.8 Management review
- 5.8.1 General
  - Top mgt involvement
  - Review FSMS effectiveness

#### 5.8 Management review

#### - Review Inputs:

previous MR follow up actions analysis of verification activity results Changes affecting food safety emergency situations review of system updating activities communication including complaints external audits

## - Review Outputs:

decisions and actions related to food safety

assurance of food safety

Improvements

**Resource needs** 

Revision of policy and objectives

### 6.0 Resource mgt

#### 6.1 Provision of resources

adequate resources must be provided to ensure the establishment, implementation, maintenance and updating of the FSMS

- 6.2 Human Resources
- 6.2.1 Human resources (General)

FS team and other relevant personnel shall be competent

Appropriate education, training, skills and experience

6.2.2 Competence, awareness and training

a) identify the necessary competencies for personnel whose activities have an impact on food safety,

b) provide training or take other action to ensure personnel have the necessary competencies,

c) ensure that personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained,

d) evaluate the implementation and the effectiveness of a), b) and c),

e) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety,

f) ensure that the requirement for effective communication (see 5.6) is understood by all personnel whose activities have an impact on food safety, and

g) maintain appropriate records of training and actions described in b) and c).

# 6.3 Infrastructure

-includes buildings, process equipment, utilities, surrounding areas, supporting services

## 6.4 Work environment

-Can include: measures to prevent costs- contamination, work space rqts, protective work wear rqts, availability & location of employee facilities 7.0 Planning & realization of safe products

7.1 General

- implement, operate and ensure the effectiveness of the planned activities and any changes

- control measures – 3 key groups:

-PRE REQUISITE PROGRAMMES (PRPs)

-OPERATIONAL PRPs

-HACCP PLAN

- validation, monitoring, verification

7.2 Prerequisite programmes (PRPs)

7.2.1 The organization shall establish, implement and maintain PRP(s) to assist in controlling

a) the likelihood of introducing food safety hazards to the product through the work environment,

b) biological, chemical and physical contamination of the product(s), including cross contamination between products, and

c) food safety hazard levels in the product and product processing environment

7.2.2 The PRP(s) shall

a)be appropriate to the organizational needs with regard to food safety,

b) be appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled,

c) be implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line, and

d) be approved by the food safety team.

The organization shall identify statutory and regulatory requirements related to the above

7.2.3 When selecting and/or establishing PRP(s), the organization shall consider and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards].

NOTE Annex C gives a list of relevant Codex publications.

The organization shall consider the following when establishing these programmes:

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.

Verification of PRP(s) shall be planned (see 7.8) and PRP(s) shall be modified as necessary (see 7.7). Records of verifications and modifications shall be maintained.

Documents should specify how activities included in the PRP(s) are managed.

### Pre Requisite Programmes

Manage basic conditions and activities

Not selected for the purpose of controlling specific identified hazards but for maintaining a hygienic production, process and/or handling Environment eg GMP- pest control, approved supplier programme, sanitation, personnel hygiene

**Operational Pre Requisite Programmes** 

Manage those control measures that the hazard analysis identifies as Necessary to control identified hazards to acceptable levels- not managed by the HACCP Plan Eg sieve condition program, Entoletor, different uniforms, raw material processing & cooked meat, glass jar rinser 7.3 Preliminary steps to enable hazard analysis

- 7.3.1 General
- 7.3.2 Food safety team

A food safety team shall be appointed.

The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system.

Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience (see 6.2.2).

#### 7.3 Preliminary steps to enable hazard analysis

#### 7.3.3 Product characteristics

consider raw materials, ingredients, product contact materials biologiocal, chemical and physical characteristics origin, production control, packaging, storage, preparation consider end product – name, composition, biological.. shelf life/storage, packaging, labelling distribution

#### 7.3.4 Intended use

- -expected handling of end product
- expected misuse of product
- groups of users/consumers for each product
- identify any vulnerable user groups eg children, elderly

7.3.5 Flow diagrams, process steps & control measures

7.3.5.1 Flow diagrams for products or process categories

Flow diagrams must show: all steps, outsourced work, raw materials, ingredients, intermediate products, rework and by products

7.3.5.2 Description of process steps and control measures

to include description of external rqts eg regulatory authorities or customers

## 7.4.1 General

Food safety team must conduct , maintain, update & document hazard analysis . Records shall be maintained.

## 7.4.2 Hazard identification and determination of acceptable levels

The identification shall be based on

a) the preliminary information and data collected according to 7.3,

b) experience,

c) external information including, to the extent possible, epidemiological and other historical data, and

d) information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption.

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

#### 7.4 Hazard analysis

7.4.2.2 When identifying the hazards, consideration shall be given to a) the steps preceding and following the specified operation,

b) the process equipment, utilities/services and surroundings, andc) the preceding and following links in the food chain.

7.4.2.3 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. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data.

The justification for, and the result of, the determination shall be recorded.
#### 7.4.3 Hazard assessment

A hazard assessment shall be conducted for each FS hazard identified – aim to eliminate or reduce hazard to acceptable levels for a safe product and whether controls needed to enable the defined acceptable levels to be met

Each food safety hazard –evaluate for severity of hazard and likelihood of occurrence

Methodology used shall be described and the results recorded

more than one control measures may be required

prevent, eliminate, reduce food safety hazards to acceptable levels categorise control measures as to whether they are managed through operational PRPs or by the HACCP Plan

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following:

a)its effect on identified food safety hazards relative to the strictness applied;
b) its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections);

c) its place within the system relative to other control measures;

d) the likelihood of failure in the functioning of a control measure or significant processing variability;

e) the severity of the consequence(s) in the case of failure in its functioning;

f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s);

g) synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

# 7.5 Establishing the operational PRPs

**Document the following:** 

- Food safety hazard to be controlled
- Control measures
- Monitoring procedures
- corrections/corrective actions if PRP is not in control
- responsibilities and authorities
- records of monitoring

7.6 Establishing the HACCP Plan

7.6.1 HACCP Plan – for each critical control point include same as for 7.5

The HACCP plan shall be documented and shall include the following information for each identified critical control point (CCP):

a) food safety hazard(s) to be controlled at the CCP (see 7.4.4);b) control measure(s) (see 7.4.4)

- c) critical limit(s) (see 7.6.3);
- d) monitoring procedure(s) (see 7.6.4);

e) corrections and corrective action(s) to be taken if critical limits are exceeded (see 7.6.5);

- f) responsibilities and authorities;
- g) record(s) of monitoring.

7.6.2 Identification of critical control points (CCPs)

For each hazard that is to be controlled by the HACCP plan, CCP(s) shall be identified for the control measures identified (see 7.4.4).

7.6.3 Determination of critical limits for critical control points

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

Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product (see 7.4.2) is not exceeded.

Critical limits shall be measurable.

The rationale for the chosen critical limits shall be documented. Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and/or education and training.

## 7.6.4 System for the monitoring of CCPs

-monitoring /measurement must provide results within a time frame that allows for timely adjustments to ensure critical limits are not exceeded

- Monitoring devices are used
- -- applicable calibration methods
- --monitoring frequency

-- responsibility and authority related to monitoring and evaluation of non conforming results

-- record requirements and methods

7.6.5 Actions when monitoring results exceed critical limits

- need to be specified in the HACCP Plan

-Procedures documented for handling potentially unsafe products to ensure no release until evaluated

-Operational limits (industry term)

- 7.7 Updating of preliminary information & documents specifying the PRPs and the HACCP Plan
- product characteristics
- Intended use
- --flow diagrams
- -- process steps
- -- control measures

#### 7.8 Verification planning

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities shall confirm that

- a) the PRP(s) are implemented (see 7.2),
- b) input to the hazard analysis (see 7.3) is continually updated,
- c) the operational PRP(s) (see 7.5) and the elements within the HACCP plan (see 7.6.1) are implemented and effective,
- d) hazard levels are within identified acceptable levels (see 7.4.2), and e) other procedures required by the organization are implemented and effective.

The output of this planning shall be in a form suitable for the organization's method of operations.

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 (see 8.4.3).

If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard (see 7.4.2), the affected lots of product shall be handled as potentially unsafe in accordance with 7.10.3. 7.9 Traceability system

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

#### 7.10.1 Corrections

The organization shall ensure that when critical limits for CCP(s) are exceeded (see 7.6.5), 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.

A documented procedure shall be established and maintained defining

a) the identification and assessment of affected end products to determine their proper handling (see 7.10.3), and

b) a review of the corrections carried out.

#### 7.10.1 Corrections

Products manufactured under conditions where critical limits have been exceeded are potentially unsafe products and shall be handled in accordance with 7.10.3.

Products manufactured under conditions where operational PRP(s) have not been conformed with shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall, where necessary, be handled in accordance with 7.10.3. The evaluation shall be recorded.

All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

#### 7.10.2 Corrective actions

Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge (see 6.2) and authority (see 5.4) to initiate corrective actions.

Corrective actions shall be initiated when critical limits are exceeded (see 7.6.5) or when there is a lack of conformity with operational PRP(s).

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

These actions include

a) reviewing nonconformities (including customer complaints),

b) reviewing trends in monitoring results that may indicate development towards loss of control,

- c) determining the cause(s) of nonconformities,
- d) evaluating the need for action to ensure that nonconformities do not recur,
- e) determining and implementing the actions needed,
- f) recording the results of corrective actions taken, and
- g) reviewing corrective actions taken to ensure that they are effective.

Corrective actions shall be recorded.

7.10.3 Handling of potentially unsafe products

#### 7.10.3.1 General

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that

a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels,
b) the food safety hazard(s) of concern will be reduced to identified acceptable levels (see 7.4.2) prior to entering into the food chain, or
c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal (see 7.10.4).

NOTE The term "withdrawal" includes recall. The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

#### 7.10.3.2 Evaluation for release

Each lot of product affected by the nonconformity shall only be released as safe when any of the following conditions apply:

a)evidence other than the monitoring system demonstrates that the control measures have been effective;

b) evidence shows that the combined effect of the control measures for that particular product complies with

the performance intended (i.e. identified acceptable levels as identified in accordance with 7.4.2);

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

# 7.10.3.3 Disposition of non conforming products

- reprocess or further process
- destruction & for disposal as waste

## 7.10.3.4 Withdrawals

- removal of unsafe product from eg market place, storage
- product to be held under supervision until destroyed, used for other purposes, determined to be safe or reprocessed
- Top mgt involvement include in management review

# 7.10.4 Withdrawals

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe

a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and
b) the organization shall establish and maintain a documented procedure for
1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),

2) handling of withdrawn products as well as affected lots of the products still in stock, and

3) the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review (see 5.8.2). The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).

## 8.0 Validation, verification and improvement of the FSMS

# 8.1 General

- Information for the FSMS design can come from:
  - academic institutions
  - regulatory agencies
  - consultants
  - any party with educated expertise in the food process & product

## 8.2 Validation of control measure combinations

-Validation of CCp critical limts must occur prior to the implementation of control measures

-- usually include:

- reference to validations carried out by others, scientific lierature
- experiments trials to simulate process conditions
- biological, chemical, physical hazard data collected during normal operating conditions
- statistically designed surveys
- mathematical modelling
- guide approved by competent authorities

8.3 Control of monitoring & measuring

-measuring equipment and methods shall be:

-Calibrated or verified at specific intervals against measurement standards traceable to international or national measurement standards

- identified to enable calibration status
- safeguarded from adjustments
- protected from damage & deterioration
- non conforming measuring equipment action must be taken & documented

8.4 Food safety management system verification

# 8.4.1 Internal audit

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.

An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits (see 8.5.2 and 5.8.2).

The audit criteria, scope, frequency and methods shall be defined.

Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

8.4.2 Evaluation of individual verification results

The food safety team shall systematically evaluate the individual results of planned verification (see 7.8).

If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity.

Such action shall include, but is not limited to, review of

a) existing procedures and communication channels (see 5.6 and 7.7),
b) the conclusions of the hazard analysis (see 7.4), the established operational PRP(s) (see 7.5) and the HACCP plan (see 7.6.1),
c) the PRP(s) (see 7.2), and
d) the effectiveness of human resource management and of training activities (see 6.2).

8.4.3 Analysis of results of verification activities

The food safety team shall analyse the results of verification activities, including the results of the internal audits (see 8.4.1) and external audits. The analysis shall be carried out in order

a) to confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization,

b) to identify the need for updating or improving the food safety management system,

c) to identify trends which indicate a higher incidence of potentially unsafe products,

d) to establish information for planning of the internal audit programme concerning the status and importance of areas to be audited, and

e) to provide evidence that any corrections and corrective actions that have been taken are effective.

The results of the analysis and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review (see 5.8.2).

It shall also be used as an input for updating the food safety management system (see 8.5.2).

#### 8.5 Improvement

#### **8.5.1 Continual improvement**

Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication (see 5.6), management review (see 5.8), internal audit (see 8.4.1), evaluation of individual verification results (see 8.4.2), analysis of results of verification activities (see 8.4.3), validation of control measure combinations (see 8.2), corrective actions (see 7.10.2) and food safety management system updating (see 8.5.2).

NOTE ISO 9001 addresses continual improvement of the effectiveness of quality management systems. ISO 9004 provides guidance on continual improvement of the effectiveness and efficiency of quality management systems beyond what is addressed in ISO 9001. Top management shall ensure that the food safety management system is continually updated.

In order to achieve this, the food safety team shall evaluate the food safety management system at planned intervals.

The team shall then consider whether it is necessary to review the hazard analysis (see 7.4), the established operational PRP(s) (see 7.5) and the HACCP plan (see 7.6.1).

The evaluation and updating activities shall be based on

a) input from communication, external as well as internal, as stated in 5.6,
b) input from other information concerning the suitability, adequacy and effectiveness of the food safety management system,
c) output from the analysis of results of verification activities (see 8.4.3), and
d) output from management review (see 5.8.3).
System updating activities shall be recorded and reported, in an appropriate manner, as input to the management review (see 5.8.2).

# END OF ISO 22000 TRAINING