ISO 22000:2005 Standard

Food Safety Management System

INTERNATIONAL STANDARDS REGISTRATIONS

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 1 Adapted from Reference [11].
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 1 Adapted from Reference [11].
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.

3.6 FLOW DIAGRAM
schematic and systematic presentation of the sequence and interactions of steps

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 NOTE Adapted from Reference [11].

3.8 - PRP - 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 PRP

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 NOTE Adapted from Reference [11].

3.11 - CRITICAL LIMIT
criterion which separates acceptability from unacceptability
NOTE 1 Adapted from Reference [11].

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.

3.12 MONITORING
conducting a planned sequence of observations or measurements to assess whether **control measures** (3.7) are operating as intended

3.13 CORRECTION
action to eliminate a detected nonconformity [ISO 9000:2000, definition 3.6.6] NOTE 1 For the purposes of this International Standard, a correction relates to the handling of potentially unsafe products, and can therefore be made in conjunction with a **corrective action** (3.14).

NOTE 2 A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labeling).

3.14 CORRECTIVE ACTION
action to eliminate the cause of a detected nonconformity or other undesirable situation
NOTE 1 There can be more than one cause for a nonconformity. [ISO 9000:2000, definition 3.6.5]
NOTE 2 Corrective action includes cause analysis and is taken to prevent recurrence.

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**

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

3.17 - UPDATING
immediate and/or planned activity to ensure application of the most recent information

4 FOOD SAFETY MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENTS
The organization shall establish, document, implement and maintain an effective food safety management system and update it when necessary in accordance with the requirements of this International Standard.

The organization shall define the scope of the food safety management system. The scope shall specify the products or product categories, processes and production sites that are addressed by the food safety management system.

The organization shall
a) 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,
b) communicate appropriate information throughout the food chain regarding safety issues related to its products,
c) 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
d) 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.

Where an organization chooses to outsource any process that may affect end product conformity, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety management system.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

The food safety management system documentation shall include
a) documented statements of a food safety policy and related objectives (see 5.2),
b) documented procedures and records required by this International Standard, and
c) documents needed by the organization to ensure the effective development, implementation and updating of the food safety management system.

4.2.2 CONTROL OF DOCUMENTS

Documents required by the food safety management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.3.

The controls shall ensure that all proposed changes are reviewed prior to implementation to determine their effects on food safety and their impact on the food safety management system.

A documented procedure shall be established to define the controls needed
a) to approve documents for adequacy prior to issue,
b) to review and update documents as necessary, and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,

f) to ensure that relevant documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to ensure that they are suitably identified as such if they are retained for any purpose.

4.2.3 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and evidence of the effective operation of the food safety management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

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
a) showing food safety is supported by the business objectives of the organization,
b) 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,
c) establishing the food safety policy,
d) conducting management reviews, and
e) ensuring the availability of resources.

5.2 FOOD SAFETY POLICY

Top management shall define, document and communicate its food safety policy.

Top management shall ensure that the food safety policy
a) is appropriate to the role of the organization in the food chain,
b) conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers,
c) is communicated, implemented and maintained at all levels of the organization,
d) is reviewed for continued suitability (see 5.8),
e) adequately addresses communication (see 5.6), and
f) is supported by measurable objectives.

5.3 FOOD SAFETY MANAGEMENT SYSTEM PLANNING

Top management shall ensure that
a) planning of the food safety management system is carried out to meet requirements given in 4.1 as well as the objectives of the organization that support food safety, and

b) the integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented.

5.4 RESPONSIBILITY AND AUTHORITY

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety management system. All personnel shall have responsibility to report problems with the food safety management system to identified person(s). Designated personnel shall have defined responsibility and authority to initiate and record actions.

5.5 FOOD SAFETY TEAM LEADER

Top management shall appoint a food safety team leader who, irrespective of other responsibilities, shall have the responsibility and authority

a) to manage a food safety team (see 7.3.2) and organize its work,

b) to ensure relevant training and education of the food safety team members (see 6.2.1),

c) to ensure that the food safety management system is established, implemented, maintained and updated, and

d) to report to the organization's top management on the effectiveness and suitability of the food safety management system.

NOTE The responsibility of the food safety team leader may include liaison with external parties on matters relating to the food safety management system.

5.6 COMMUNICATION

5.6.1 EXTERNAL COMMUNICATION

To ensure that sufficient information on issues concerning food safety is available throughout the food chain, the organization shall establish, implement and maintain effective arrangements for communicating with

a) suppliers and contractors,

b) customers or consumers, in particular in relation to product information (including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life), enquiries, contracts or order handling including amendments, and customer feedback including customer complaints,

c) statutory and regulatory authorities, and

d) other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system. Such communication shall provide information on food safety aspects of the organization's products that may be relevant to other organizations in the food chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the food chain. Records of communications shall be maintained. Food safety requirements from statutory and regulatory authorities and customers shall be available. Designated personnel shall have defined responsibility and authority to communicate externally any information

concerning food safety. Information obtained through external communication shall be included as input to system updating (see 8.5.2) and management review (see 5.8.2).

5.6.2 INTERNAL COMMUNICATION

The organization shall establish, implement and maintain effective arrangements for communicating with personnel on issues having an impact on food safety. In order to maintain the effectiveness of the food safety management system, the organization shall ensure that the food safety team is informed in a timely manner of changes, including but not limited to the following:

a) products or new products;
b) raw materials, ingredients and services;
c) production systems and equipment;
d) production premises, location of equipment, surrounding environment;
e) cleaning and sanitation programmes;
f) packaging, storage and distribution systems;
g) personnel qualification levels and/or allocation of responsibilities and authorizations;
h) statutory and regulatory requirements;
i) knowledge regarding food safety hazards and control measures;
j) customer, sector and other requirements that the organization observes;
k) relevant enquiries from external interested parties;
l) complaints indicating food safety hazards associated with the product;
m) other conditions that have an impact on food safety. The food safety team shall ensure that this information is included in the updating of the food safety management system (see 8.5.2). Top management shall ensure that relevant information is included as input to the management review (see 5.8.2).

5.7 EMERGENCY PREPAREDNESS AND RESPONSE

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain.

5.8 MANAGEMENT REVIEW

5.8.1 GENERAL

Top management shall review the organization's food safety management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the food safety management system, including the food safety policy. Records of management reviews shall be maintained (see 4.2.3).

5.8.2 REVIEW INPUT

The input to management review shall include, but is not limited to, information on

a) follow-up actions from previous management reviews,
b) analysis of results of verification activities (see 8.4.3),

c) changing circumstances that can affect food safety (see 5.6.2),
d) emergency situations, accidents (see 5.7) and withdrawals (see 7.10.4),
e) reviewing results of system-updating activities (see 8.5.2),
f) review of communication activities, including customer feed-back (see 5.6.1), and
g) external audits or inspections.
NOTE The term “withdrawal” includes recall.
The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety management system.

5.8.3 REVIEW OUTPUT

The output from the management review shall include decisions and actions related to
a) assurance of food safety (see 4.1),
b) improvement of the effectiveness of the food safety management system (see 8.5),
c) resource needs (see 6.1), and
d) revisions of the organization's food safety policy and related objectives (see 5.2).

6 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

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

6.2 HUMAN RESOURCES

6.2.1 GENERAL

The food safety team and the other personnel carrying out activities having an impact on food safety shall be competent and shall have appropriate education, training, skills and experience. Where the assistance of external experts is required for the development, implementation, operation or assessment of the food safety management system, records of agreement or contracts defining the responsibility and authority of external experts shall be available.

6.2.2 COMPETENCE, AWARENESS AND TRAINING

The organization shall
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

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

6.4 WORK ENVIRONMENT

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.

7 PLANNING AND REALIZATION OF SAFE PRODUCTS

7.1 GENERAL

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.

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.

7.3 PRELIMINARY STEPS TO ENABLE HAZARD ANALYSIS

7.3.1 GENERAL

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

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).

7.3.3 PRODUCT CHARACTERISTICS

7.3.3.1 RAW MATERIALS, INGREDIENTS AND PRODUCT-CONTACT MATERIALS

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis (see 7.4), including the following, as appropriate:

a) biological, chemical and physical characteristics;
b) composition of formulated ingredients, including additives and processing aids;
c) origin;
d) method of production;
e) packaging and delivery methods;
f) storage conditions and shelf life;

g) preparation and/or handling before use or processing;
h) food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.

The organization shall identify statutory and regulatory food safety requirements related to the above.The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.3.2 CHARACTERISTICS OF END PRODUCTS

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard
analysis (see 7.4), including information on the following, as appropriate:
a) product name or similar identification;
b) composition;
c) biological, chemical and physical characteristics relevant for food safety;
d) intended shelf life and storage conditions;
e) packaging;
f) labelling relating to food safety and/or instructions for handling, preparation and usage;
g) method(s) of distribution.
The organization shall identify statutory and regulatory food safety requirements related to the above. The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.4 INTENDED USE

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis (see 7.4). Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered. The descriptions shall be kept up-to-date including, when required, in accordance with 7.7.

7.3.5 FLOW DIAGRAMS, PROCESS STEPS AND CONTROL MEASURES

7.3.5.1 FLOW DIAGRAMS

Flow diagrams shall be prepared for the products or process categories covered by the food safety management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following:
a) the sequence and interaction of all steps in the operation;
b) any outsourced processes and subcontracted work;
c) where raw materials, ingredients and intermediate products enter the flow;

d) where reworking and recycling take place;
e) where end products, intermediate products, by-products and waste are released or removed. In accordance with 7.8, the food safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

7.3.5.2 DESCRIPTION OF PROCESS STEPS AND CONTROL MEASURES

The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis (see 7.4).
External requirements (e.g. from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.
The descriptions shall be updated in accordance with 7.7.

7.4 HAZARD ANALYSIS

7.4.1 GENERAL

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.

7.4.2 HAZARD IDENTIFICATION AND DETERMINATION OF ACCEPTABLE LEVELS

7.4.2.1 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 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.

7.4.2.2 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, and
c) 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 to determine, for each food safety hazard identified (see 7.4.2), 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. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

7.4.4 SELECTION AND ASSESSMENT OF CONTROL MEASURES

Based on the hazard assessment of 7.4.3, 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 as described in 7.3.5.2 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 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).

Control measures categorized as belonging to the HACCP plan shall be implemented in accordance with 7.6.

Other control measures shall be implemented as operational PRPs according to 7.5.

The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.

7.5 ESTABLISHING THE OPERATIONAL PREREQUISITE PROGRAMMES (PRPS)

The operational PRPs shall be documented and shall include the following information for each programme:

a) food safety hazard(s) to be controlled by the programme (see 7.4.4);

b) control measure(s) (see 7.4.4);

b) monitoring procedures that demonstrate that the operational PRPs are implemented;

c) corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control (see 7.10.1 and 7.10.2, respectively);

e) responsibilities and authorities;

f) record(s) of monitoring.

7.6 ESTABLISHING THE HACCP PLAN

7.6.1 HACCP plan

The HACCP plan shall be documented and shall include the following information for each identified criticalcontrol 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 CRITICAL CONTROL POINTS

A monitoring system shall be established for each CCP to demonstrate that the CCP is in control. The system shall include all scheduled measurements or observations relative to the critical limit(s).

The monitoring system shall consist of relevant procedures, instructions and records that cover the following:

a) measurements or observations that provide results within an adequate time frame;

b) monitoring devices used;

c) applicable calibration methods (see 8.3);

d) monitoring frequency;

e) responsibility and authority related to monitoring and evaluation of monitoring results;

f) record requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

7.6.5 ACTIONS WHEN MONITORING RESULTS EXCEED CRITICAL LIMITS

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented (see 7.10.2).
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 (see 7.10.3).

7.7 UPDATING OF PRELIMINARY INFORMATION AND DOCUMENTS SPECIFYING THE PRPS AND THE HACCP PLAN

Following the establishment of operational PRP(s) (see 7.5) and/or the HACCP plan (see 7.6), the organization shall update the following information, if necessary:
a) product characteristics (see 7.3.3);
b) intended use (see 7.3.4);
c) flow diagrams (see 7.3.5.1);
d) process steps (see 7.3.5.2);
e) control measures (see 7.3.5.2).
If necessary, the HACCP plan (see 7.6.1) and the procedures and instructions specifying the PRP(s) (see 7.2) shall be amended.

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. 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 NONCONFORMING PRODUCTS
Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:
a) reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels;
b) destruction and/or disposal as waste.

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 VALIDATION, VERIFICATION AND IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM

8.1 GENERAL

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.

8.2 VALIDATION OF CONTROL MEASURE COMBINATIONS

Prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein (see 8.5.2), the organization shall validate (see 3.15) that a) the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and

b) the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels. If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed (see 7.4.4). Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.

8.3 CONTROL OF MONITORING AND MEASURING

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. Where necessary to ensure valid results, the measuring equipment and methods used

a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,
b) shall be adjusted or re-adjusted as necessary,
c) shall be identified to enable the calibration status to be determined,
d) shall be safeguarded from adjustments that would invalidate the measurement results, and
e) shall be protected from damage and deterioration.
Records of the results of calibration and verification shall be maintained. In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting actions shall be maintained. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

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. he 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).

8.5.2 UPDATING THE FOOD SAFETY MANAGEMENT SYSTEM

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).

THANK YOU……

INTERNATIONAL STANDARDS REGISTRATIONS

www.isoregistrations.com