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

Systèmes de management de la sécurité des denrées alimentaires — Exigences pour tout organisme appartenant à la chaîne alimentaire

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management system for food safety*.

This second edition cancels and replaces the first edition (ISO 22000:2005), which has been technically revised through the adoption of a revised clause sequence.

The following Annexes are included to provide the users of this document further information:

- Annex A Cross references between the CODEX HACCP principles and this document;
- Annex B Comparison of clauses between this draft standard (ISO/DIS 22000:2017) and the – at present – existing version (ISO 22000:2005).

Introduction

0.1 General

The adoption of a food safety management system is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a food safety management system based on this document are:

a) the ability to consistently provide safe foods and relevant products and services that meet customer and applicable statutory and regulatory requirements;

b) addressing risks associated with its objectives;

c) the ability to demonstrate conformity to specified food safety management system requirements.

This document employs the process approach (see 0.3), which incorporates the Plan-Do-Check-Act (PDCA) (0.3.2) cycle and risk-based thinking (0.3.3).

This process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its food safety management system to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;

- “should” indicates a recommendation;

- “may” indicates a permission;

- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.2 Food safety management system principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a food safety management system that combines the following generally recognized key elements:

- interactive communication;

- system management;

- prerequisite programmes;

- hazard analysis and critical control points (HACCP) principles.

In addition, this document is based on the principles that are common to all other ISO management system standards. The management principles are:

- customer focus;

- leadership;

- engagement of people;

- process approach;

- improvement;

- evidence-based decision making;

- relationship management.

0.3 Process approach

0.3.1 General

This document promotes the adoption of a process approach when developing and implementing a food safety management system and improving its effectiveness in order to enhance production of safe products and services and meet applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be described briefly as follows:

Plan: establish the objectives of the system and its processes and provide the resources needed to deliver the results and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

Act: take actions to improve performance, as necessary.

In this document and as illustrated in Figure 1, the process approach embraces two PDCA cycles. One cycle covers the overall frame of the food safety management system (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other cycle covers the operational processes within the food safety system as described in Clause 8. This means that communication between the two cycles is essential.

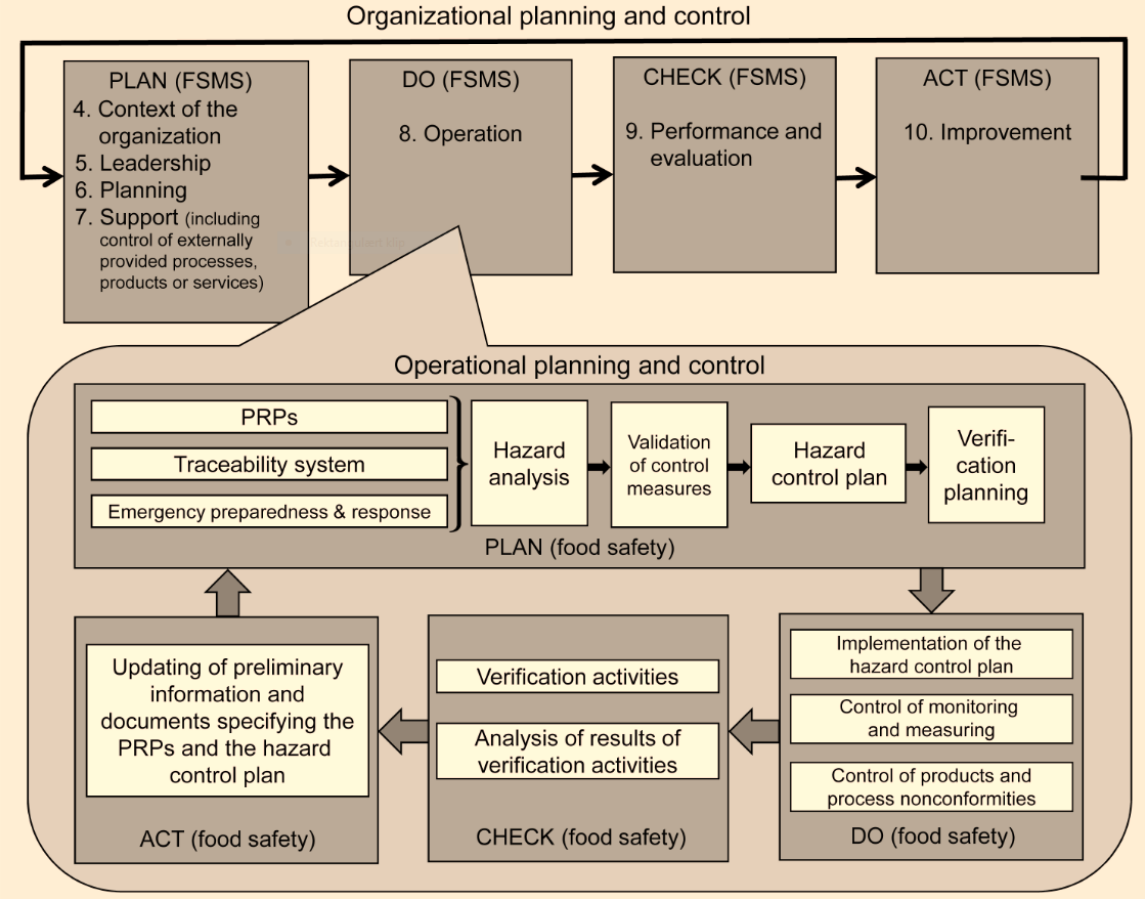

Figure 1 – Illustration of the two Plan-Do-Check-Act cycles

0.3.3 Risk-based thinking

Risk-based thinking is essential for achieving an effective food safety management system. In this document risk-based thinking is also addressed in two levels like the ones described in 0.3.2.

0.3.3.1 Organizational risk management

Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

To conform to the requirements of this document, an organization plans and implements actions to address organizational risks (see Clause 6). Addressing risks establishes a basis for increasing the effectiveness of the food safety management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity.

0.3.3.2 Hazard analysis – operational processes

The concept of risk-based thinking at the operational level has been implicit in ISO 22000 based on HACCP principles.

The subsequent steps in the HACCP process can be considered as the necessary measures to prevent or reduce hazards to acceptable levels to ensure food is safe at the time of consumption (see Clause 8).

Decisions taken in the application of the HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision making process.

0.4 Relationship with other management system standards

This document is developed within the ISO High Level Structure (HLS). The objective of the HLS is to improve alignment between the ISO management system standards. This document enables an organization to use the process approach, coupled with the PDCA cycle and risk based thinking, to align or integrate its food safety management system approach with the requirements of other management systems and supporting standards.

This document is the core principle and framework for food safety management systems. It sets out the specific food safety management system requirements for organizations throughout the food chain. Other food safety related guidance, specifications and/or requirements specific to food sectors can be used together with this framework.

The ISO/TS 22002 series specifies requirements and guidance for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling food safety hazards.

These Technical Specifications are:

- ISO/TS 22002-1 Prerequisite programmes on food safety - Part 1: Food manufacturing

- ISO/TS 22002-2 Prerequisite programmes on food safety - Part 2: Catering

- ISO/TS 22002-3 Prerequisite programmes on food safety - Part 3: Farming

- ISO/TS 22002-4 Prerequisite programmes on food safety - Part 4: Food packaging manufacturing

- ISO/TS 22002-6 Prerequisite programmes on food safety - Part6: Feed and animal food production.

Furthermore, the ISO 22000 family includes the following publications:

- ISO/TS 22003 Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems

- ISO 22004 Food safety management systems – Guidance on the application of ISO 22000

- ISO 22005 Traceability in the feed and food chain – General principles and basic requirements for system design and implementation.

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

1 Scope

This document specifies requirements for a food safety management system to enable an organization:

a) 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 consumers;

b) to demonstrate compliance with applicable statutory/regulatory food safety requirements;

c) to evaluate and assess food safety customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety;

d) to effectively communicate food safety issues to interested parties within the food chain;

e) to ensure that the organization conforms to its stated food safety policy;

f) to demonstrate conformity to relevant interested parties; and

g) to seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to this document.

All requirements of this document are generic and are intended to be applicable to all organizations in the food chain regardless of size and complexity. This includes organizations directly or indirectly involved in one or more steps of the food chain. Organizations that are directly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services, transportation, storage and distribution services. Other organizations that are indirectly involved include, but are not limited to, suppliers of equipment, cleaning and disinfectants, packaging materials, and other food contact materials.

This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer-distributor, a small retail or food service outlet) to implement externally developed elements in the food management system.

The means of meeting any requirements of this document can be accomplished through the use of internal and/or external resources.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
acceptable level
level of a *food safety hazard* (3.22) not to be exceeded in the *end product* (3.15) provided by the *organization (3.32)*

3.2
action criterion
measurable or observable specification for the *monitoring* (3.28) of an *OPRP* (3.31)

Note 1 to entry: An action criterion is established to determine whether an *OPRP* (3.31) remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

3.3
audit
systematic, independent and documented *process* (3.35) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines such as food safety management, quality management or environmental management).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: The terms "audit evidence" and "audit criteria" are defined in ISO 19011.

3.4
competence
ability to apply knowledge and skills to achieve intended results

3.5
conformity
fulfilment of a *requirement* (3.38)

3.6
contamination
introduction or occurrence of a contaminant including *food safety hazard* (3.22) in *product* (3.37) or processing environment

3.7
continual improvement
recurring activity to enhance *performance* (3.34) of the food safety management system

3.8
control measure
⟨food safety⟩ action or activity that is essential to prevent a significant *food safety hazard* (3.22) or reduce it to an *acceptable level* (3.1) (see definition on *significant food safety hazards* (3.40))

Note 1 to entry: Control measure(s) is (are) identified by the hazard analysis.

3.9
correction
action to eliminate a detected *nonconformity* (3.29)

Note 1 to entry: A correction includes the handling of potentially unsafe products, and can therefore be made in conjunction with a *corrective action* (3.10).

Note 2 to entry: A correction may be, e.g. reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.10
corrective action
action to eliminate the cause of a *nonconformity* (3.29) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

3.11
critical control point
CCP
step in the process at which *control measure(s)* (3.8) is (are) applied, *critical limit(s)* (3.12) is (are) defined, and where *measurement* (3.27) enables effective control of the *product* (3.36)

3.12
critical limit
measurable value which separates acceptability from unacceptability

Note 1 to entry: Critical limits are established to determine whether a *CCP* (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products.

[SOURCE: CAC/RCP 1-1969]

3.13
documented information
information required to be controlled and maintained by an *organization* (3.32) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any defined source.

Note 2 to entry: Documented information can refer to:

- the *food safety management system* (3.23), including related *processes* (3.36);

- information created in order for the organization to operate (documentation);

- evidence of results achieved (records).

3.14
effectiveness
extent to which planned activities are realized and planned results achieved

3.15
end product
product (3.37) that will undergo no further processing or transformation by the *organization* (3.32)

Note 1 to entry: 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.

3.16
feed
any single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to food producing animals

Note 1 to entry:

- *Food* (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food**;**
- *Feed* (3.16) is intended to be fed to food producing animals;
- *Animal food* (3.19) is intended to be fed to non-food producing animals, like pets.

[SOURCE: CAC/GL 81-2013, modified – The word "materials" changed to "products" and "directly" deleted]

3.17
flow diagram
schematic and systematic presentation of the sequence and interactions of steps

3.18
food
any substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which have been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

Note 1 to entry:
- *Food* (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food**;**
- *Feed* (3.16) is intended to be fed to food producing animals;
- *Animal food* (3.19) is intended to be fed to non-food producing animals, like pets.

[SOURCE: Codex procedural manual, modified – The word "human" has been deleted]

3.19
food, animal
any single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to non-food producing animals

Note 1 to entry:
- *Food* (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food**;**
- *Feed* (3.16) is intended to be fed to food producing animals;
- *Animal food* (3.19) is intended to be fed to non-food producing animals, like pets.

[SOURCE: CAC/GL 81-2013, modified - The word "materials" changed to "products", "non" added and "directly" deleted]

3.20
food chain
sequence of the stages in the production, processing, distribution, storage and handling of a *food* (3.18) and its ingredients, from primary production to consumption

Note 1 to entry: This includes the production of *feed* (3.16) and *animal food* (3.19).

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

Note 3 to entry: The food chain also includes service providers.

3.21
food safety
assurance that food will not cause adverse health effect to the consumer when it is prepared and/or consumed according to its intended use

Note 1 to entry: Food safety is related to the occurrence of *food safety hazards* (3.22) in *end products* (3.15) and does not include other health aspects related to, for example, malnutrition.

Note 2 to entry: It is not to be confused with the availability of, and access to, food (food security).

Note 3 to entry: This includes feed and animal food.

[SOURCE: CAC/RCP 1-1969, modified – The word “concept” changed to “assurance”, “harm” changed to “adverse health effect and Notes to entry have been added]

3.22
food safety hazard
biological, chemical or physical agent in *food* (3.18) with the potential to cause an adverse health effect

Note 1 to entry: The term "hazard" is not to be confused with the term "*risk*" (3.39) 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 etc.) when exposed to a specified hazard.

Note 2 to entry: Food safety hazards include allergens and radiological substances.

Note 3 to entry: 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 through animal consumption of feed be transferred to food and may thus have the potential to cause an adverse health effect to the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants, etc.), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.3).

Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to animal species for which the food is intended.

[SOURCE: CAC/RCP 1-1969, modified – The text “or condition of” has been deleted from the definition and Notes to entry have been added]

3.23
food safety management system
FSMS
set of interrelated or interacting elements of an *organization* (3.32) to establish *food safety policies* (3.24) and *objectives* (3.30) and *processes* (3.36) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines (quality management system, environmental management system, etc.).

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organizations, or one or more functions across a group of organizations.

3.24
food safety policy
intentions and direction of an *organization* (3.32) related to *food safety* (3.21) as formally expressed by its *top management* (3.41)

3.25
interested party
person or *organization* (3.32) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.26
lot
a defined quantity of a *product* (3.37) produced and/or processed or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product.

[SOURCE: CODEX STAN 1, modified – Reference to "processed and packaged" has been included in the definition and Notes to entry have been added]

3.27
measurement
process (3.36) to determine a value

3.28
monitoring
determining the status of a system, a *process* (3.36) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

Note 3 to entry:
- *Validation* (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;
- *Monitoring* (3.28) is applied during an activity and provides information for action within a specified time-frame;
- *Verification* (3.45) is applied after an activity and provides information for confirmation of conformity.

3.29
nonconformity
non-fulfilment of a *requirement* (3.38)

3.30
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product, and *process* (3.36)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, a purpose, an operational criterion, as a food safety management system objective, or by the use of other words with similar meaning (e.g. aim, goal or target).

Note 4 to entry: In the context of food safety management systems, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.

3.31
operational prerequisite programme
OPRP
control measure(s) (3.8) or combinations of control measures having defined *action criteria* (3.2), where *measurement* (3.27) or observation enables effective control of the *process* (3.36) and/or *product* (3.37)

3.32
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.30)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.33
outsource (verb)
make an arrangement where an external *organization* (3.32) performs part of an organization's function or *process* (3.36)

Note 1 to entry: An external organization is outside the scope of the *food safety management system* (3.23), although the outsourced function or process is within the scope

3.34
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.36), *products* (3.37) (including services), systems or *organizations* (3.32).

3.35
prerequisite programme
PRP
basic conditions and activities that are necessary to maintain food safety within the *organization* (3.32) and throughout the *food chain* (3.20)

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. 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).

Note 2 to entry: Where PRPs are used to control *significant food safety hazards* (3.40), they are *control measure(s)* (3.8), which will be categorized either as *CCPs* (3.11) or as *OPRPs* (3.31).

3.36
process
set of interrelated or interacting activities which transforms inputs to outputs

3.37
product
output that is a result of a *process* (3.36)

Note 1 to entry: Product can be a service.

3.38
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

3.39
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected – positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in *food* (3.18) (as defined in Codex Procedural Manual).

3.40
significant food safety hazard
food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by *control measures* (3.8)

3.41
top management
person or group of people who directs and controls an *organization* (3.32) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *food safety management system* (3.23) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.42
traceability
ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the *food* (3.18).

Note 2 to entry: An object can be a *product* (3.37), a material, a unit, equipment, a service etc.

[SOURCE: CAC/GL 60-2006, modified – Notes to entry have been added]

3.43
update
immediate and/or planned activity to ensure application of the most recent information.

Note 1 to entry:
- Maintain - to keep something on-going / to keep in good condition;
- Retain – to keep something that is retrievable;
- Update – immediate and/or planned activity to ensure application of the most recent information.

3.44
validation
⟨food safety⟩ obtaining evidence that a *control measure* (3.8) (or combination of control measures) will be capable of effectively controlling the *significant food safety hazard (3.40)*

Note 1 to entry: This definition is more useful for the field of *food safety* (3.21) than the definition given in ISO 9000.

Note 2 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 3 to entry:
- *Validation* (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;
- *Monitoring* (3.28) is applied during an activity and provides information for action within a specified time-frame;
- *Verification* (3.45) is applied after an activity and provides information for confirmation of conformity.

3.45
verification
confirmation, through the provision of objective evidence, that specified *requirements* (3.38) have been fulfilled

Note 1 to entry:
- *Validation* (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;
- *Monitoring* (3.28) is applied during an activity and provides information for action within a specified time-frame;
- *Verification* (3.45) is applied after an activity and provides information for confirmation of conformity.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended ~~outcome(s)~~ results of its food safety management system.

The organization shall identify, review and update information related to these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the context can be facilitated by considering external and internal issues not limited to legal, technological, competitive, market, cultural, social, economic environments, cybersecurity and food fraud, food defence and intentional contamination, knowledge and performance of the organization, whether international, national, regional or local.

4.2 Understanding the needs and expectations of interested parties

To ensure that the organization has the ability to consistently provide products and services that meet applicable statutory/regulatory and customer requirements with regard to food safety, the organization shall determine:

a) the interested parties that are relevant to the food safety management system;

b) the ~~relevant~~ requirements of the interested parties that are relevant to the food safety management system.

The organization shall identify, review and update information related to the interested parties and their requirements.

4.3 Determining the scope of the food safety management system

The organization shall determine the boundaries and applicability of the food safety management system to establish its scope. The scope shall specify the products and services, processes and production sites that are addressed by the food management system and shall include the activities, processes, products or services that can have an influence on the food safety of the end products.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements referred to in 4.2.

The scope shall be available and maintained as documented information.

4.4 Food safety management system

The organization shall establish, implement, maintain, update and continually improve a food safety management system, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the food safety management system by:

a) ensuring that the food safety policy and the objectives of the food safety management system are established and are compatible with the strategic direction of the organization;

b) ensuring the integration of the food safety management system requirements into the organization's business processes;

c) ensuring that the resources needed for the food safety management system are available;

d) communicating the importance of effective food safety management and of conforming to the food safety management system requirements, statutory/regulatory requirements, and mutually agreed customer requirements related to food safety;

e) ensuring that the food safety management system is evaluated and maintained to achieve its intended ~~outcome(s)~~ results (see 4.4);

f) directing and supporting persons to contribute to the effectiveness of the food safety management system;

g) promoting continual improvement;

h) supporting other relevant management roles to demonstrate their food safety leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Food safety policy

5.2.1 Establishing the food safety policy

Top management shall establish, implement and maintain a food safety policy that:

a) is appropriate to the purpose and context of the organization;

b) provides a framework for setting and reviewing the objectives of the food safety management system;

c) includes a commitment to satisfy applicable food safety requirements including statutory/ regulatory requirements and mutually agreed customer requirements related to food safety;

d) addresses internal and external communication;

e) includes a commitment to continual improvement of the food safety management system;

f) addresses the need to ensure competencies related to food safety.

5.2.2 Communicating the food safety policy

The food safety policy shall:

a) be available and maintained as documented information;

b) be communicated, understood, and applied at all levels within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

5.3.1 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the food safety management system conforms to the requirements of this document;

b) reporting on the performance of the food safety management system to top management;

c) appointing the food safety team and the food safety team leader;

d) designating persons with defined responsibility and authority to initiate and document action(s).

5.3.2 The food safety team leader shall be responsible for:

a) ensuring the food safety management system is established, implemented, maintained and updated;

b) managing and organising the work of the food safety team; and

c) ensuring relevant training of and competencies for the food safety team (see 7.2).

d) reporting to the top management on the effectiveness and suitability of the food safety management system.

All persons shall have responsibility to report problem(s) with the food safety management system to identified person(s).

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the food safety management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the food safety management system can achieve its intended ~~outcome(s)~~ results;

b) prevent, or reduce, undesired effects;

c) achieve continual improvement.

NOTE In the context of this document, the concept of risks and opportunities is limited to events and their consequences relating to the performance and effectiveness of the food safety management system. Organizations are not required to directly address public health risks which are under the responsibility of the appropriate authorities. However, they are required to manage food safety hazards (see 3.22) and the requirements related to this process are laid down in Clause 8.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its food safety management system processes;

2) evaluate the effectiveness of these actions.

6.1.3 The actions taken by the organization to address risks and opportunities shall be proportionate to:

a) the potential impact on food safety requirements, and;

b) the conformity of food products and services to customers, and;

c) requirements of interested parties in the food chain.

NOTE 1 Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or accepting the presence of risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices (modification of products or processes), using new technology and other desirable and viable possibilities to address the organization's or its customers' food safety needs.

6.2 Objectives of the food safety management system and planning to achieve them

6.2.1 The organization shall establish objectives of the food safety management system at relevant functions and levels.

The objectives of the food safety management system shall:

a) be consistent with the food safety policy;

b) be measurable (if practicable);

c) take into account applicable food safety requirements including statutory/regulatory and customer requirements;

d) be monitored and verified;

e) be communicated;

f) be maintained and updated as appropriate.

The organization shall retain documented information on the objectives of the food safety management system.

6.2.2 When planning how to achieve its objectives of the food safety management system, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the food safety management system, including personnel changes, the changes shall be carried out and communicated in a planned manner.

The organization shall consider:

a) the purpose of the changes and their potential consequences for the supply and maintenance of safe food production;

b) the integrity of the food safety management system;

c) the availability of resources to effectively implement the changes;

d) the allocation or re-allocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, updating and continual improvement of the food safety management system.

The organization shall consider:

a) the capability of and any constraints on existing internal resources; and

b) resources required from external sources.

7.1.2 People

The organization shall determine and provide the competent persons (7.2) that are necessary to operate and maintain an effective food safety management system.

Where the assistance of external experts is used for the development, implementation, operation or assessment of the food safety management system, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.

7.1.3 Infrastructure

The organization shall provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity with the requirements of the food safety management system.

NOTE Infrastructure can include:

- land, vessels, buildings and associated utilities;
- equipment, including hardware and software;
- transportation resource;
- information and communication technology.

7.1.4 Work environment

The organization shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the food safety management system.

NOTE A suitable environment can be a combination of human and physical factors.

7.1.5 Externally developed elements of the food safety management system

When an organization establishes, maintains, updates and continually improves its food safety management system by using externally developed elements of a food safety management system including PRPs and the hazard control plan, the organization shall ensure that the provided elements are:

a) developed in conformance with requirements of this document;

b) applicable to the sites, processes and products of the organization;

c) specifically adapted, by the food safety team to the processes and products of the organization; and,

d) implemented, maintained and updated as required by this document;

e) retained as documented information.

7.1.6 Control of externally provided processes, products or services

The organization shall:

a) establish and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers of processes, products or services;

b) ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of its food safety management system;

c) ensure adequate communication of requirements to the external provider(s);

d) ensure that external providers conform to the established criteria (see 7.1.2);

e) retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

7.2 Competence

The organization shall:

a) determine the necessary competence (see 3.4) of person(s) including external providers doing work under its control that affects its food safety performance and effectiveness of the food safety management system;

b) ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate education, training, or experience;

c) ensure that the food safety team has a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes but are not limited to the organizations products, processes, equipment and food safety hazards within the scope of the food safety management system;

d) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

e) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

The organization shall ensure that all relevant persons doing work under the organization's control shall be aware of:

a) the food safety policy;

b) the objectives of the food safety management system relevant to their task(s);

c) their individual contribution to the effectiveness of the food safety management system, including the benefits of improved food safety performance;

d) the implications of not conforming with the food safety management system requirements.

7.4 Communication

7.4.1 General

The organization shall determine the internal and external communications relevant to the food safety management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

The organization shall ensure that the requirement for effective communication is understood by all persons whose activities have an impact on food safety.

7.4.2 External communication

The organization shall ensure that sufficient information is communicated externally and is available for interested parties of the food chain.

The organization shall establish, implement and maintain effective communications with:

a) external providers and contractors;

b) customers and/or consumers, in relation to:

   1) product information to enable the safe handling, display, storage, preparation, distribution and use of the product within the food chain or by the consumer;

   2) identified foods safety hazards that need to be controlled by other organizations in the food chain, and/or consumers;

   3) contractual arrangements, enquiries and orders including their amendments; and

   4) customer and/or consumer feedback including complaints;

c) statutory/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.

Designated persons shall have defined responsibility and authority for the external communication of any information concerning food safety. Where relevant, information obtained through external communication shall be included as input for management review (see 9.3) and for updating the food safety management system (see 4.4).

Evidence of external communication shall be retained as documented information.

7.4.3 Internal communication

The organization shall establish, implement and maintain effective arrangements for communicating between persons on issues having an impact on food safety.

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) competencies and/or allocation of responsibilities and authorizations;

h) statutory/regulatory requirements;

i) knowledge regarding food safety hazards and control measures;

j) customer, sector and other requirements that the organization observes;

k) relevant enquiries and communications from external interested parties;

l) complaints, risks and alerts indicating food safety hazards associated with the end product;

m) other conditions that have an impact on food safety.

The food safety team shall ensure that this information is included when updating the food safety management system (see 4.4).

Top management shall ensure that relevant information is included as input to the management review (see 9.3).

7.5 Documented information

7.5.1 General

The organization's food safety management system shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the food safety management system;

c) documented information and food safety requirements required by statutory/regulatory authorities and customers.

NOTE The extent of documented information for a food safety management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the food safety management system and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention time and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the food safety management system shall be identified, as appropriate, and controlled.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions determined in 6.1 by:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria;

c) keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 7.1.6).

8.2 PRPs

8.2.1 The organization shall establish, implement, maintain and update PRP(s):

a) to prevent and/or reduce the likelihood of introducing contaminants (including food safety hazards) to the product;

b) to prevent and/or reduce the biological, chemical and physical contamination of products, including cross contamination between products, and;

c) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products and product processing environment.

8.2.2 The PRP(s) shall:

a) be appropriate to the organization and its context 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.

NOTE PRPs are established and designed before proceeding to the hazard analysis. However, verification of the PRPs and updating other parts of the food safety management system may identify the need for changes or improvements to the PRPs.

8.2.3 When selecting and/or establishing PRP(s), and in addition to statutory/regulatory requirements, the organization shall consider:

a) applicable Technical Specification of the ISO/TS 22002-series;

b) applicable codes of practice and guidelines;

c) customer requirements.

8.2.4 The organization shall consider, when establishing PRPs, the following:

a) construction and lay-out of buildings and utilities;

b) lay-out of premises, including workspace and employee facilities;

c) supplies of air, water, energy and other utilities;

d) pest control, waste and sewage disposal and supporting services;

e) the suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;

f) supplier approval and assurance processes (e.g. raw materials, ingredients, chemicals and packaging);

g) receiving of incoming materials, storage, transportation and handling of products;

h) measures for the prevention of cross contamination;

i) cleaning and disinfecting;

j) personal hygiene;

k) product information/consumer awareness;

l) others as appropriate.

Documented information shall specify the selection, establishment, applicable monitoring and verification of the PRP(s).

8.3 Traceability

The traceability system shall be able to uniquely identify incoming material from the suppliers and the initial distribution route of the end product.

When establishing and implementing the traceability system, the following shall as a minimum be considered:

a) the relation of lot of received materials, ingredients and intermediate products in relation to the end products;

b) reworking of materials/products;

c) distribution route of the end product;

d) compliance with statutory/regulatory and customer requirements.

Documented information as evidence of the traceability system shall be retained for a defined period. This includes as a minimum shelf-life of the end product. The organization shall verify and test the effectiveness of the traceability system.

NOTE Where appropriate, the verification of the system is expected to include the reconciliation of quantities of end products with the quantity of ingredients as evidence of effectiveness.

8.4 Emergency preparedness and response

8.4.1 General

Top management shall prepare and plan to identify preventive actions that deal with potential emergency situations and incidents that may have an impact on food safety and which are relevant to the role of the organization in the food chain.

Documented information shall be established and maintained to manage these situations and incidents.

8.4.2 Handling of emergencies and incidents

The organization shall:

a) respond to actual emergency situations and incident by:

   1) complying with statutory/regulatory requirements;

   2) communicating internally;

   3) communicating externally (e.g. suppliers, customers, appropriate authorities, media);

b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;

c) periodically test procedures where practical;

d) review and, where necessary, update the documented information, in particular, after the occurrence of any incident, emergency situation or tests.

NOTE Examples of emergency situations that can affect food safety and/or production are natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents like interruption of essential services such as water, electricity or refrigeration supply.

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

In order to carry out the hazard analysis preliminary information shall be collected, updated and maintained by the food safety team. This shall include but not be limited to:

a) the organization's products, processes, customers' requirements, equipment; and

b) food safety hazards relevant to the food safety management system.

8.5.1.1 Characteristics of raw materials, ingredients and product contact materials

The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials.

The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis (see 8.5.2), including the following, as appropriate:

a) biological, chemical and physical characteristics;

b) composition of formulated ingredients, including additives and processing aids;

c) source, origin or provenance, as applicable (see the note);

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 use.

NOTE When the organization determines origin, it includes the place of provenance and source (e.g. animal origin, plant origin).

8.5.1.2 Characteristics of end products

The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all the end products intended to be produced.

The organization shall maintain documented information concerning the characteristics of end products to the extent needed to conduct the hazard analysis (see 8.5.2), 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 its intended use;

g) method(s) of distribution.

8.5.1.3 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 maintained as documented information to the extent needed to conduct the hazard analysis (see 8.5.2).

Where appropriate, groups of consumers/users shall be identified for each product.

Groups of consumers/users known to be especially vulnerable to specific food safety hazards shall be identified.

8.5.1.4 Flow diagrams and description of processes

8.5.1.4.1 Preparation of the flow diagrams

The food safety team shall establish, maintain and update flow diagrams as documented information for the products or product categories and the processes covered by the food safety management system.

The flow diagrams shall be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes and subcontracted work;

c) where raw materials, ingredients, processing aids, packaging materials and intermediate products enter the flow;

d) where reworking and recycling take place; and

e) where end products, intermediate products, by-products and waste are released or removed.

8.5.1.4.2 On-site confirmation of flow diagrams

The food safety team shall confirm on-site the accuracy of the flow diagrams, update where appropriate and retain as documented information.

8.5.1.4.3 Description of processes and process environment

The food safety team shall describe, to the extent needed to conduct the hazards analysis:

a) layout of premises including food and non-food handling areas, processing equipment and contact materials, processing aids and flow of materials;

b) existing PRPs, process parameters, control measures if any and/or the strictness with which they are applied, or procedures that may influence food safety;

c) external requirements (e.g. from statutory/regulatory authorities or customers) that may impact the choice and the strictness of the control measures.

The variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

The descriptions shall be updated as appropriate and maintained as documented information.

8.5.2 Hazard analysis

8.5.2.1 General

The food safety team shall conduct a hazard analysis, based on the preliminary information (see 8.5.1.1-8.5.1.4), to determine the hazards that need to be controlled. The degree of control shall ensure food safety. Where appropriate a combination of control measures shall be used.

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

The identification shall be based on:

a) the preliminary information and data collected according to 8.5.1.1 to 8.5.1.4;

b) experience;

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

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; and

e) statutory/regulatory and customer requirements.

NOTE 1 Experience can include staff and external experts who are familiar with the product and/or processes in other facilities.

NOTE 2 Statutory/regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)".

8.5.2.2.2 The organization shall identify step(s) (e.g. receiving raw materials, processing and distribution) at which each food safety hazard can be present, introduced, increased or persist.

When identifying hazards, the organization shall consider:

a) the steps preceding and following in the process;

b) the process equipment, utilities/services, process environment and personnel;

c) the stages preceding and following in the food chain.

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible.

When determining acceptable levels, the organization shall consider:

a) statutory/regulatory and customer requirements;

b) intended use of end products;

c) any other relevant information.

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

8.5.2.3 Hazard assessment

The organization shall conduct for each identified food safety hazard, a hazard assessment to determine, whether its prevention or reduction to an acceptable level (see 3.1) is essential.

The organization shall evaluate each food safety hazard with regard to:

a) the likelihood of its occurrence prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use (see 8.5.1.3).

The organization shall identify any significant food safety hazards (3.40).

The methodology used shall be maintained, and the result of the hazard assessment shall be maintained as documented information.

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1 Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels.

The organization shall categorize the selected identified control measure(s) to be managed as OPRPs (3.31) or at CCPs (3.11).

The categorization shall be carried out using a systematic approach that for each of the control measures includes assessment of the following:

a) the likelihood of failure of its functioning or significant processing variability;

b) the severity of the consequence in the case of failure of its functioning. This assessment shall include:

   1) the effect on identified significant food safety hazards;

   2) the location in relation to other control measure(s);

3) whether it is specifically established and applied to eliminate or significantly reduce the level of hazards;

4) whether it is a single measure or is part of combination of control measure(s), i.e. if there is interaction in this combination that creates synergistic effects being higher than the sum of their individual effects.

8.5.2.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to meet critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of such failure.

The decision making process and results of the selection and categorization shall be maintained as documented information.

External requirements (e.g. statutory/regulatory and customer requirements) that may impact the choice and the strictness of the control measures shall also be maintained as documented information.

8.5.3 Validation of control measure(s) and combination(s) of control measure(s)

Prior to implementation of control measure(s) to be included in the hazard control plan (see 8.5.4) and after any change therein (see 7.4.2, 7.4.3, 10.2, 10.3), the food safety team shall validate that:

a) the selected control measures are capable of achieving the intended control of the food safety hazards(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.

When the result of the validation study shows that control is not effective, the food safety team shall modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

The food safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended results as documented information.

NOTE Modification may include changes in control measure(s) (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 products.

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.1 General

The organization shall establish, implement and maintain a hazard control plan where control measure(s) is (are)categorized at CCPs or as OPRPs (see 8.5.2.4).

The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP:

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

b) critical limit(s) at CCP or action criteria for OPRP;

c) monitoring procedure(s);

d) corrections and corrective action(s) to be taken if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) records of monitoring.

8.5.4.2 Determination of critical limits and action criteria

Critical limits at CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.

Critical limits at CCPs shall be measurable. Conformance with critical limits shall assure that the acceptable level is not exceeded.

Action criteria for OPRPs shall be measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.

8.5.4.3 Monitoring systems at CCPs and for OPRPs

At each CCP, a monitoring system shall be established for each control measure or combination of control measure(s) to detect any failure to meet critical limits. The system shall include all scheduled measurements relative to the critical limit(s).

For each OPRP, a monitoring system shall be established for each control measure or combination of control measure(s) to demonstrate that action criteria are met.

The monitoring system, at each CCP and for each OPRP, shall consist of documented information including procedures, instructions and records and shall include but is not limited to:

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

b) monitoring methods or devices used;

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations (see 8.7);

d) monitoring frequency;

e) monitoring results;

f) responsibility and authority related to monitoring and evaluation of monitoring results.

At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to meet critical limits, to allow timely isolation and evaluation of the product (see 8.9.4).

For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

When monitoring an OPRP is based on subjective data from observations (e.g. visual inspection), it shall be supported by instructions or specifications.

8.5.4.4 Actions when critical limits or action criteria are not met

The organization shall specify in the hazard control plan the corrective actions (see 8.9.2) and corrections (8.9.3) to be taken when critical limits or action criteria are not met. The actions shall ensure that:

a) the cause of nonconformity is identified;

b) the parameter(s) controlled at the CCP or by the OPRP is returned within the critical limits or action criteria; and,

c) recurrence is prevented.

The organization shall take corrective actions in accordance with 8.9.2 and corrections according with 8.9.3.

8.5.4.5 Implementation of the hazard control plan

The hazard control plan shall be implemented and maintained, and relevant evidence retained as documented information.

8.6 Updating the information specifying the PRPs and the hazard control plan

Following the establishment of the hazard control plan, the organization shall update the following information, if necessary:

a) characteristics of raw materials, ingredients and product-contact materials;

b) characteristics of end products;

c) intended use;

d) flow diagrams and descriptions of processes and process environment.

When required, the hazard control plan and/or the PRP(s) shall be updated.

8.7 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment in use is adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.

The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results; and

e) protected from damage and deterioration.

The results of calibration and verification shall be retained as documented information. The calibration of all the equipment shall be traceable to international or national measurement standards; where no

standards exist, the basis used for calibration or verification shall be retained as documented information.

The organization shall assess the validity of the previous measurement results when the equipment or process environment is found not to conform to requirements. The organization shall take appropriate action on the equipment or process environment and any product affected.

The assessment and resulting action shall be maintained as documented information.

Software used in monitoring and measuring within the food safety management system shall be validated by the organization, software supplier, or third party prior to use. Documented information on validation activities shall be maintained by the organization and the software shall be updated in a timely manner.

Whenever there are changes, including software configuration/modifications to commercial off-the-shelf software they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

The organization shall establish, implement and maintain verification activities that define the purpose, methods, frequencies and responsibilities for the verification activities.

The individual verification activities shall confirm that:

a) the PRP(s) are implemented and effective;

b) input to the hazard analysis is updated periodically;

c) the hazard control plan is implemented and effective;

d) hazard levels are within identified acceptable levels; and

e) other actions determined by the organization are implemented and effective.

The organization shall ensure that verification activities are not carried out by the person responsible for monitoring the activity or the control measures.

Verification results shall be maintained as documented information and shall be communicated to the food safety team.

Where verification is based on testing of end product samples or direct process samples and where such test samples show nonconformity with the acceptable level of the food safety hazard (8.5.2.2), the affected lots of product shall be handled as potentially unsafe (see 8.9.4).

The organization shall apply corrective actions according to 8.9.2.

8.8.2 Analysis of results of verification activities

The food safety team shall systematically evaluate the individual results of the verification plan including internal and external audits. Where verification does not demonstrate conformance with the planned arrangements, the organization shall take appropriate actions.

The analysis of the results of verification shall be an input to the verification of the food safety management system (see Clause 9).

8.9 Control of product and process nonconformities

8.9.1 General

The organization shall ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons with sufficient competence and authority to initiate corrective actions and corrections.

8.9.2 Corrective actions

The need for corrective actions shall be evaluated when critical limits at CCP(s) and/or action criteria for OPRPs are not met.

The organization shall establish and maintain documented information that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.

These actions shall include:

a) reviewing nonconformities identified by customer and/or consumer complaints/regulatory inspection reports;

b) reviewing trends in monitoring results that may indicate loss of control;

c) determining the cause(s) of nonconformities;

d) determine and implement actions to ensure that nonconformities do not recur;

e) documenting the results of corrective actions taken; and

f) reviewing corrective actions taken to ensure that they are effective.

Documented information on all corrective actions shall be retained.

8.9.3 Corrections

8.9.3.1 The organization shall ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.

The organization shall establish, maintain and update documented information that includes:

a) method of identification, assessment, correction for affected products to ensure their proper handling; and

b) arrangements for review of the corrections carried out.

8.9.3.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (se 8.9.4).

8.9.3.3 Where action criteria for an OPRP is not met, the following shall be carried out:

a) identification of the affected products and handling (see 8.9.4);

b) determination of the cause(s) of failure;

c) determination of the consequences of that failure with respect to food safety.

The results of the evaluation shall be retained as documented information.

8.9.3.4 Documented information shall be retained to describe corrections taken on nonconforming products and processes including:

a) the nature of the nonconformity;

b) the cause(s) of the nonconformity;

c) the consequences as a result of the nonconformity; and

d) the traceability information related to the lots of nonconforming products.

8.9.4 Handling of potentially unsafe products

8.9.4.1 General

The organization shall take action(s) to prevent potentially unsafe products from entering the food chain unless it is possible to demonstrate that:

a) the food safety hazard(s) of concern is (are) reduced to the defined acceptable levels;

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering 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.

Products that have been identified as potentially unsafe 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/recall (see 8.9.5).

The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

8.9.4.2 Evaluation for release

Each lot of products affected by the non-conformity shall be evaluated.

Products affected by failure to meet critical limits at CCPs shall not be released but be handled in accordance with 8.9.4.3. Products affected by failure to meet action criteria for OPRPs 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 conforms with the performance intended (i.e. identified acceptable levels);

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

Results of evaluation for release of products shall be retained as documented information.

8.9.4.3 Disposition of nonconforming products

Products that are not acceptable for release shall either be:

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is prevented or reduced to acceptable levels; or

b) redirected for other use as long as food safety in the food chain is not affected; or

c) destroyed and/or disposed as waste.

Documented information on the disposition of nonconforming products including the identification of designated approving authority shall be retained.

8.9.5 Withdrawal/Recall

The organization shall be able to ensure the complete and timely withdrawal/recall of lots of end products that have been identified as potentially unsafe by:

a) appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall; and

b) establishing and maintaining documented information for:

1) notifying relevant interested parties (e.g. statutory/regulatory authorities, customers and/or consumers);

2) handling withdrawn/recalled products as well as products still in stock; and

3) performing the sequence of actions to be taken.

Withdrawn/recalled products and end products still in stock shall be secured or held under control of the organization until they are managed in accordance with 8.9.4.3.

The cause, extent and result of a withdrawal/recall shall be retained as documented information and reported to the top management as input for the management review (9.3).

The organization shall verify the implementation and effectiveness of withdrawals/recalls through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain documented information.

9 Performance evaluation of the food safety management system

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated;

e) who shall analyse and evaluate the results from monitoring and measurements.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the food safety management system (see Clause 8).

9.1.2 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurements including the results of verification activities related to PRPs and the hazard control plan (see 8.8), the internal audits (see 9.2) and external audits.

The analysis shall be carried out in order to:

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

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

c) identify trends which indicate a higher incidence of potentially unsafe products or process failures;

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

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

The results of the analysis and any resulting activities shall be retained as documented information and shall be reported to top management and used as input to the management review (see 9.3) and the updating of the food safety management system (see 10.2).

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the food safety management system:

a) conforms to:

1) the organization's own requirements for its food safety management system;

2) the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes in the food safety management system, and the results of monitoring, measurements and previous audits;

b) define the audit criteria and scope for each audit;

c) select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to the food safety team and relevant management;

e) retain documented information as evidence of the implementation of the audit programme and the audit results;

f) take necessary correction and corrective action within agreed timelines;

g) determine if the food safety management system meets the intent of the food safety policy (see 5.2), and objectives of the food safety management system (see 6.2).

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

NOTE 1 The organization may audit the entire food safety management system annually. The organization can choose to audit the parts of the food safety management system at predetermine times according to the audit program.

NOTE 2 ISO 19011 provides guidance for management system audits.

9.3 Management review

9.3.1 General

Top management shall review the organization's food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review input

The management review shall include consideration of:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the food safety management system including changes in the organization and its context (see 4.1);

c) information on the performance and the effectiveness of the food safety management system, including trends in:

- result of system-updating activities (see 4.4 and 10.2);

- monitoring and measurement results;

- analysis of the results of verification activities related to PRPs and the hazard control plan (see

8.8.2);

- nonconformities and corrective actions;

- audit results (internal and external);

- inspections (e.g. regulatory, customer);

- performance of external providers;

- review of risks and opportunities and of the effectiveness of actions taken to address them (see 6.1); and

- extent to which objectives of the food safety management system have been met;

d) the adequacy of resources;

e) any emergency situation, incidents (see 8.4.2) or withdrawal/recall (see 8.9.5) that occurred;

f) relevant information obtained through external (7.4.2) and internal (see 7.4.3) communication, including requests and complaints from interested parties;

g) opportunities for continual improvement.

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.

9.3.3 Management review output

The outputs of the management review shall include:

a) decisions and actions related to continual improvement opportunities; and

b) any need for updates and changes to the food safety management system, including resource needs and revision of the food safety policy and objectives of the food safety management system.

The organization shall retain documented information as evidence of the results of management review.

10 Improvement

10.1 Nonconformity and corrective action

10.1.1 When a nonconformity to the requirements of this document occurs, the organization shall:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing the nonconformity;

2) determining the causes of the nonconformity;

3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the food safety management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.1.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.2 Updating the food safety management system

Top management shall ensure that the food safety management system is continually updated. 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 8.5.2), the established hazard control plan (see 8.5.4) and the established PRPs (see 8.2). The updating activities shall be based on:

a) input from communication, external as well as internal (see 7.4);

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 Clause 9); and

d) output from management review (see 9.3).

System updating activities shall be retained as documented information and reported as input to the management review (see 9.3).

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the food safety management system to enhance the operation of the organization.

Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication (see 7.4), management review (see 9.3), internal audit (see 9.2), analysis of results of verification activities (see 8.8.2), validation of control measure(s) and combination(s) of control measure(s) (see 8.5.3), corrective actions (see 8.9.2) and food safety management system updating (see 10.2).

Annex A
(informative)

Cross references between the CODEX HACCP and ISO 22000:XXXX

Table A.1 – Cross references between the CODEX HACCP principles and application steps and clauses of ISO 22000:XXXX

CODEX HACCP Principles	CODEX HACCP application steps[a]		ISO 22000:XXXX	
	Assemble HACCP team	Step 1	**8.5.2.1**	Food safety team
	Describe product	Step 2	**8.5.1.1** **8.5.1.2**	Characteristics of raw materials, ingredients and product-contact Materials Characteristics of end products
	Identify intended use	Step 3	**8.5.1.3**	Intended use
	Construct flow diagram On-site confirmation of flow diagram	Step 4 Step 5	**8.5.1.4**	Flow diagrams and descriptions of processes
Principle 1 Conduct a hazard analysis.	List all potential hazards Conduct a hazard analysis Consider control measures	Step 6	**8.5.2** **8.5.3**	Hazard analysis Validation of control measure(s) and combinations of control measure(s)
Principle 2 Determine the critical control points (CCPs).	Determine CCPs	Step 7	**8.5.4**	Hazard control plan
Principle 3 Establish critical limit(s).	Establish critical limits for each CCP	Step 8	**8.5.4**	Hazard control plan
Principle 4 Establish a system to monitor control of the CCP.	Establish a monitoring system for each CCP	Step 9	**8.5.4** **9.1**	Hazard control plan Monitoring, measurement, analysis and evaluation
Principle 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.	Establish corrective actions	Step 10	**8.5.4** **8.9.2** **8.9.3**	Hazard control plan Corrective actions Corrections
Principle 6 Establish procedures for verification to confirm that the HACCP system is working effectively.	Establish verification procedures	Step 11	**8.7** **8.8** **9.2** **9.3**	Control of monitoring and measuring Verification related to PRPs and hazard control plan Internal audit Management review
Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application.	Establish documentation and record keeping	Step 12	**7.5**	Documented information
[a] CODEX publications are available via Reference [10] in the Bibliography.				

Annex B
(informative)

Comparison of ISO/DIS 22000 versus ISO 22000:22005

Table B.1 – Main structure

ISO/DIS 22000	ISO 22000:2005
4 Context of the organization	New heading
4.1 Understanding the organization and its context	New
4.2 Understanding the needs and expectations of interested parties	New
4.3 Determining the scope of the food safety management system	4.1 (& new)
4.4. Food safety management system	4.1
5 Leadership	New heading
5.1 Leadership and commitment	5.1, 7.4.3 (& new)
5.2 Food safety policy	5.2 (& new)
5.3 Organizational roles, responsibilities and authorities	5.4, 5.5, 7.3.2 (& new)
6 Planning	New heading
6.1 Actions to address risks and opportunities	New
6.2 Objectives of the food safety management system and planning to achieve them	5.3 (& new)
6.3 Planning of changes	5.3 (& new)
7 Support	New heading
7.1 Resources	1, 4.1, 6.2, 6.3, 6.4 (& new)
7.2 Competence	6.2, 7.3.2 (& new)
7.3 Awareness	6.2.2
7.4 Communication	5.6, 6.2.2
7.5 Documented information	4.2, 5.6.1
8 Operation	New heading
8.1 Operational planning and control	New
8.2 PRPs	7.2
8.3 Traceability system	7.9 (& new)
8.4 Emergency preparedness and response	5.7 (& new)
8.5 Hazard control	7.3, 7.4, 7.5, 7.6, 8.2 (& new)
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	7.8, 8.4.2
8.9 Control of product and process nonconformities	7.10
9 Performance evaluation of the food safety management system	New heading
9.1 Monitoring, measurement, analysis and evaluation	New heading
9.1.1 General	New

9.1.2 Analysis and evaluation	8.4.2, 8.4.3
9.2 Internal audit	8.4.1
9.3 Management review	5.8 (& new)
9.3.1 General	5.2, 5.8.1
9.3.2 Management review input	5.8.2 (& new)
9.3.3 Management review output	5.8.1, 5.8.3
10 Improvement	New heading
10.1 Nonconformity and corrective action	New
10.2 Updating the food safety management system	8.5.2
10.3 Continual improvement	8.1, 8.5.1

Table B.2 - Clause 7 Support

ISO/DIS 22000	ISO 22000:2005
7 Support	New heading
7.1. Resources	6
7.1.1 General	6.1
7.1.2 People	6.2, 6.2.2 (& new)
7.1.3 Infrastructure	6.3
7.1.4 Work environment	6.4
7.1.5 Externally developed elements of the food safety management system	1 (& new)
7.1.6 Control of externally provided processes, products or services	4.1 (& new)
7.2 Competence	6.2.1, 6.2.2, 7.3.2
7.3 Awareness	6.2.2
7.4 Communication	5.6
7.4.1 General	6.2.2 (& new)
7.4.2 External communication	5.6.1
7.4.3 Internal communication	5.6.2
7.5 Documented information	4.2
7.5.1 General	4.2.1, 5.6.1
7.5.2 Creating and updating	4.2.2
7.5.3 Control of documented information	4.2.2, 4.2.3 (& new)

Table B.3 – Clause 8 Operation

ISO/DIS 22000	ISO 22000:2005
8 Operation	New heading
8.1 Operational planning and control	7.1 (& new)
8.2 PRPs	7.2
8.3 Traceability system	7.9 (& new)
8.4 Emergency preparedness and response	5.7

8.4.1 General	5.7
8.4.2 Handling of emergencies and incidents	New
8.5 Hazard control	New heading
8.5.1 Preliminary step to enable hazard analysis	7.3.1
8.5.1.1 Characteristics of raw materials, ingredients and product contact materials	7.3.3.1
8.5.1.2 Characteristics of end products	7.3.3.2
8.5.2 Intended use	7.4
8.5.1.4 Flow diagrams and description of processes	7.3.5.1
8.5.1.4.1 Preparation of flow diagrams	7.3.5.1
8.5.1.4.2 On-site confirmation of flow diagrams	7.3.5.1
8.5.1.4.3 Description of processes and process environment	7.2.4, 7.3.5.2 (& new)
8.5.2 Hazard analysis	7.4
8.5.2.1 General	7.4.1
8.5.2.2 Hazard identification and determination of acceptable levels	7.4.2
8.5.2.3 Hazard assessment	7.4.3, 7.6.2 (& new)
8.5.2.4 Selection and categorization of control measure(s)	7.3.5.2, 7.4.4 (& new)
8.5.3 Validation of control measure(s) and combination(s) of control measure(s)	8.2
8.5.4 Hazard control plan (HACCP/OPRP plan)	New heading
8.5.4.1 General	7.5, 7.6.1
8.5.4.2 Determination of critical limits and action criteria	7.6.3 (& new)
8.5.4.3 Monitoring systems at CCPs and for OPRPs	7.6.3, 7.6.4 (& new)
8.5.4.4 Actions when critical limits or action criteria are not met	7.6.5
8.5.4.5 Implementation of the hazard control plan	New
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	New heading
8.8.1 Verification	7.8, 8.4.2
8.8.2 Analysis of results of verification activities	8.4.3
8.9 Control of product and process nonconformities	7.10
8.9.1 General	7.10.1, 7.10.2
8.9.2 Corrective actions	7.10.2
8.9.3 Corrections	7.10.1
8.9.4 Handling of potentially unsafe products	7.10.3
8.9.4.1 General	7.10.3.1
8.9.4.2 Evaluation for release	7.10.3.2
8.9.4.3 Disposition of nonconforming products	7.10.3.3
8.9.5 Withdrawal/Recall	7.10.3.4

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