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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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. It also incorporates the Technical Corrigendum ISO 22000:2005/Cor.1:2006.

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

— Annex A: cross references between the CODEX HACCP principles and this document;

— Annex B: cross reference between this document and ISO 22000:2005.

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Introduction

0.1 General

The adoption of a food safety management system (FSMS) 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 FSMS based on this document are:

a) the ability to consistently provide safe foods and 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 FSMS requirements.

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

"NOTES" provide guidance in understanding or clarifying the requirements in this document.

0.2 FSMS principles

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

— interactive communication;

— system management;

— prerequisite programmes;

— hazard analysis and critical control point (HACCP) principles.

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

— customer focus;

— leadership;

— engagement of people;

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— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This document adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting 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, 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, analyse and evaluate information and data from monitoring, measuring and verification 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 uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other level (operational planning and control) covers the operational processes within the food safety system as described in Clause 8. Communication between the two levels is therefore essential.

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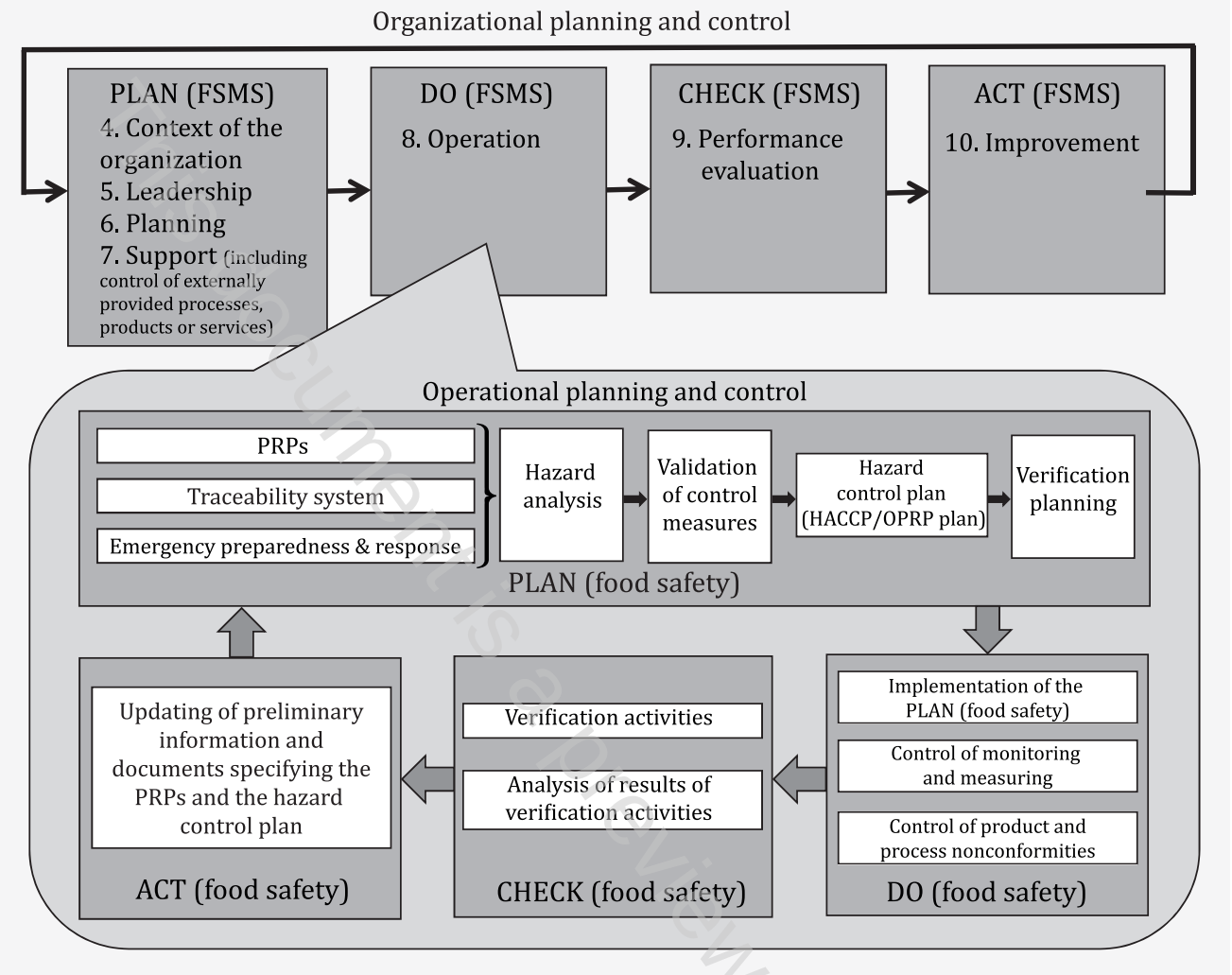

Figure 1 — Illustration of the Plan-Do-Check-Act cycle at the two levels

0.3.3 Risk-based thinking

0.3.3.1 General

Risk-based thinking is essential for achieving an effective FSMS. In this document, risk-based thinking is addressed on two levels, organizational (see 0.3.3.2) and operational (see 0.3.3.3), which is consistent with the process approach described in 0.3.2.

0.3.3.2 Organizational risk management

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, 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 (Clause 6). Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

0.3.3.3 Hazard analysis — Operational processes

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in this document.

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

Decisions taken in the application of 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 has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between 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 FSMS approach with the requirements of other management systems and supporting standards.

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

In addition, ISO has developed a family of associated documents. These include documents for:

— prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;

— requirements for auditing and certification bodies;

— traceability.

ISO also provides guidance documents for organizations on how to implement this document and related standards. Information is available on the ISO website.

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

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1 Scope

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;

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

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

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;

g) to seek certification or registration of its FSMS 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. Organizations that are directly or indirectly 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, and organizations providing food services, catering services, cleaning and sanitation services, transportation, storage and distribution services, 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 their FSMS.

Internal and/or external resources can be used to meet the requirements of this document.

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 https://www.iso.org/obp

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

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