ISO 22000:2018
Food safety management systems

A PRACTICAL GUIDE

ISO/TC 34/SC 17

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Published in Switzerland

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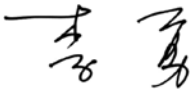
Foreword

The characteristic of food safety is the absence of foodborne hazards at the point of consumption. These hazards can occur at different stages of the food chain, therefore adequate controls throughout the network are essential. Food safety is ensured through the combined efforts of all the parties participating in the food chain, from feed producers and primary producers to food manufacturers, transport and storage operators and subcontractors, right through to retail and food service outlets. These work together with related organizations such as producers of equipment, packaging materials, cleaning agents, additives and ingredients, as well as service providers.

ISO 22000:2018, *Food safety management systems – Requirements for any organization in the food chain*, is recognized internationally as the most relevant document supporting the development of a food safety management system (FSMS). The International Standard defines what an organization needs to do in order to demonstrate its ability to control food safety hazards and ensure that food products are safe for consumption. This enables organizations to deliver food-related products and services with confidence throughout the supply chain. Authored by experts from SC 17, *Management systems for food safety*, a subcommittee of ISO's technical committee ISO/TC 34, *Food products*, this standard encapsulates the latest knowledge of food chain safety to support organizations in developing an effective FSMS.

Among the weaknesses identified by the subcommittee was the absence of adequate user assistance to implement ISO 22000:2018. In response to this need, a working group was formed, and they worked tirelessly to develop this handbook. ISO 22000:2018, *Food safety management systems – A practical guide*, offers a hands-on approach and a wide range of information for developing, documenting, implementing and maintaining a robust FSMS according to ISO 22000:2018. Readers will also come away with an in-depth understanding of the aim and outcome of the standard's different requirements.

Supporting the wider food industry, the International Organization for Standardization (ISO) and United Nations Industrial Development Organization (UNIDO) have joined forces to publish a handbook that will help users get the most from their food safety programme. We hope it will offer the support you need to implement the ISO 22000 management system in your organization.



LI Yong
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Introduction

This handbook provides guidance for the implementation of ISO 22000:2018, *Food safety management systems — Requirements for any organization in the food chain*, to develop a food safety management system (FSMS) for an organization. You must read it in conjunction with ISO 22000:2018. Appendix B contains cross-references from ISO 22000:2018 to this handbook.

For the purpose of this handbook, references to "ISO 22000" are to the 2018 edition, unless otherwise specified.

This handbook is intended to provide guidance to any organization that is directly or indirectly part of the food chain.

It is not intended to be used by certification bodies to audit organizations seeking ISO 22000 certification.

Extract from the scope of ISO 22000:2018

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:

1. to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use
2. to demonstrate compliance with applicable statutory and regulatory food safety requirements
3. to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them
4. to effectively communicate food safety issues to interested parties within the food chain
5. to ensure that the organization conforms to its stated food safety policy
6. to demonstrate conformity to relevant interested parties
7. 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

ISO decided to unify the structure of all management system standards (MSS) in order to facilitate their integration. For that purpose, a High Level Structure (HLS) was adopted. The HLS provides identical structure, text and common terms and definitions for all ISO MSSs facilitating full integration of several standards into one management system in a single organization (e.g. ISO 9001, ISO 14001, and ISO 45001).

ISO 22000, like other ISO MSS, is built around the concept of the PDCA (Plan-Do-Check-Act) cycle. In ISO 22000, this concept is applied at two levels (see Chapter 1, Topic 3).

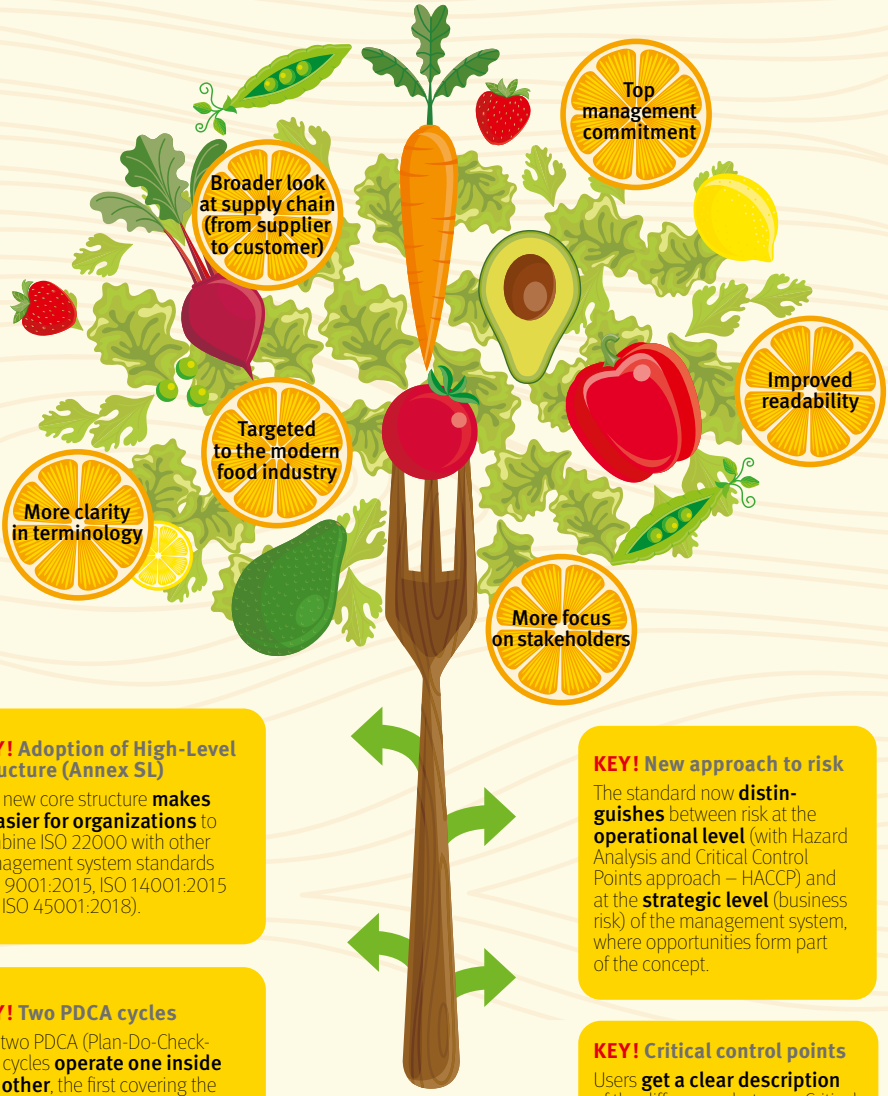
The FSMS is designed to reduce the risk of manufacturing a product that is not safe. This handbook is designed to help an organization to develop a robust FSMS according to ISO 22000.

An "expert panel" was formed as ISO/TC 34/SC 17/AG 1, with the purpose to support the users of standards within the ISO 22000 family. It consists of a selection of SC 17 delegates who are geographically diverse with different technical/business backgrounds across various food sectors.

Its role is to assist SC 17's secretariat in addressing generic questions that need official interpretation and to gain a greater understanding of the application of the ISO 22000 family of standards. Therefore, its role is not to address specific questions related to schemes, on how an organization will specifically address standard(s) requirements, and on non-ISO documents.

Questions to the expert panel may be sent via SC 17's secretary. More information can be found here : **https://committee.iso.org/sites/tc34sc17/home/projects/expert-panel.html**.

Source : ISO Focus 129



KEY! Adoption of High-Level Structure (Annex SL)

This new core structure **makes it easier for organizations** to combine ISO 22000 with other management system standards (ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018).

KEY! Two PDCA cycles

The two PDCA (Plan-Do-Check-Act) cycles **operate one inside the other**, the first covering the management system, the second the operations (described in Clause 8), which simultaneously cover the HACCP principles.

KEY! New approach to risk

The standard now **distinguishes** between risk at the **operational level** (with Hazard Analysis and Critical Control Points approach – HACCP) and at the **strategic level** (business risk) of the management system, where opportunities form part of the concept.

KEY! Critical control points

Users **get a clear description** of the differences between Critical Control Points (CCPs), Operational Prerequisite Programmes (OPRPs) and Prerequisite Programmes (PRPs).

What is new in ISO 22000:2018?

The following are new concepts introduced in ISO 22000:2018:

- The ISO 22000 standard has been restructured to align with other MSS (see **Chapter 1, Topic 1**)
- The concept of the process approach has been made explicit (see **Chapter 1**, **Topic 2**)
- The PDCA cycle is now introduced at two levels: organizational and operational (see **Chapter 1**, **Topic 3**)
- The concept of risks and opportunities (see **Chapter 1**, **Topic 4**) has been introduced
- The scope has been widened to include food for animals (food is intended for consumption by humans and animals and includes feed and animal food; feed is intended to be fed to food-producing animals; animal food is intended to be fed to non-food-producing animals, such as pets)
- The term "product" has been defined and clarified to include service (see Clause 3 of ISO 22000)
- New terms have been defined, e.g. "acceptable level", "action criterion", "significant food safety hazard", (see Clause 3 of ISO 22000)
- Some definitions have been revised and improved, e.g. for "control measure", "critical control point (CCP)", "operational prerequisite programme (OPRP)", and "prerequisite programme (PRP)" (see Clause 3 of ISO 22000)
- The understanding of interested parties needs and expectations has been introduced (see **Chapter 2**, **Task 2.2**)

- The leadership role of the top management (commitment, responsibilities and authorities) has been strengthened (see **Chapter 3**, **Tasks 3.1** and **3.2**).
- How to use and control the externally developed elements of the FSMS has been clarified (see **Chapter 3**, **Task 3.5**).
- The concept of documented information has been introduced (see **Chapter 3**, **Task 3.8**).
- The concept of a hazard control plan has been introduced (see **Chapter 5**, **Tasks 5.5** to **5.8**).

Scope

This handbook provides generic guidance to assist all organizations (including small and medium-sized) that recognize the potential benefits of implementing a FSMS in accordance with ISO 22000:2018.
Organizations, regardless of size and complexity, very often need support and/or clarification on how to develop, document, implement and maintain an FSMS using ISO 22000. In addition, organizations often underestimate the depth of commitment required to maintain such a system and the training required to do so. This handbook describes the ISO 22000 implementation process. For organizations considering certification, the handbook also provides information on the certification process. Each key step is explained in more detail in the relevant chapters of this handbook.

Structure of this handbook chapters

Structure of this handbook chapters

For the purpose of this handbook, references to "ISO 22000" are to the 2018 edition, unless otherwise specified.

The following structure is used in Chapters 2 to 6 of this handbook.

Key points

Summarizes the purpose of the chapter..

Objectives of this chapter

This paragraph explains how the chapter relates to ISO 22000.

Topics covered by the chapter

Each topic is divided into tasks and is presented as follows:

Task XX: Description of the required actions

- Reference(s): ISO 22000:2018, clause/subclause XX
- Your main aim should be to:
- Description of action(s) to be implemented.
- Practical advice:
- Practical explanations of why/how these actions could be implemented.
- Types of documented information supporting the implementation of the FSMS and related task(s): example(s)
- What questions do you need to ask yourself (to which an affirmative reply is required) before continuing?