



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 22000:2017**  
**01-junij-2017**

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**Sistemi vodenja varnosti živil - Zahteve za vsako organizacijo v prehranski verigi  
(ISO/DIS 22000:2017)**

Food safety management systems - Requirements for any organization in the food chain  
(ISO/DIS 22000:2017)

Managementsysteme für die Lebensmittelsicherheit - Anforderungen an Organisationen  
in der Lebensmittelkette (ISO/DIS 22000:2017)

Systèmes de management de la sécurité des denrées alimentaires - Exigences pour tout  
organisme appartenant à la chaîne alimentaire (ISO/DIS 22000:2017)

**Ta slovenski standard je istoveten z: prEN ISO 22000**

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03.100.70	Sistemi vodenja	Management systems
67.020	Procesi v živilski industriji	Processes in the food industry

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**en**



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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*

ICS: 67.020; 03.100.70

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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](http://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](http://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](http://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).

**ISO/DIS 22000:2017(E)****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.

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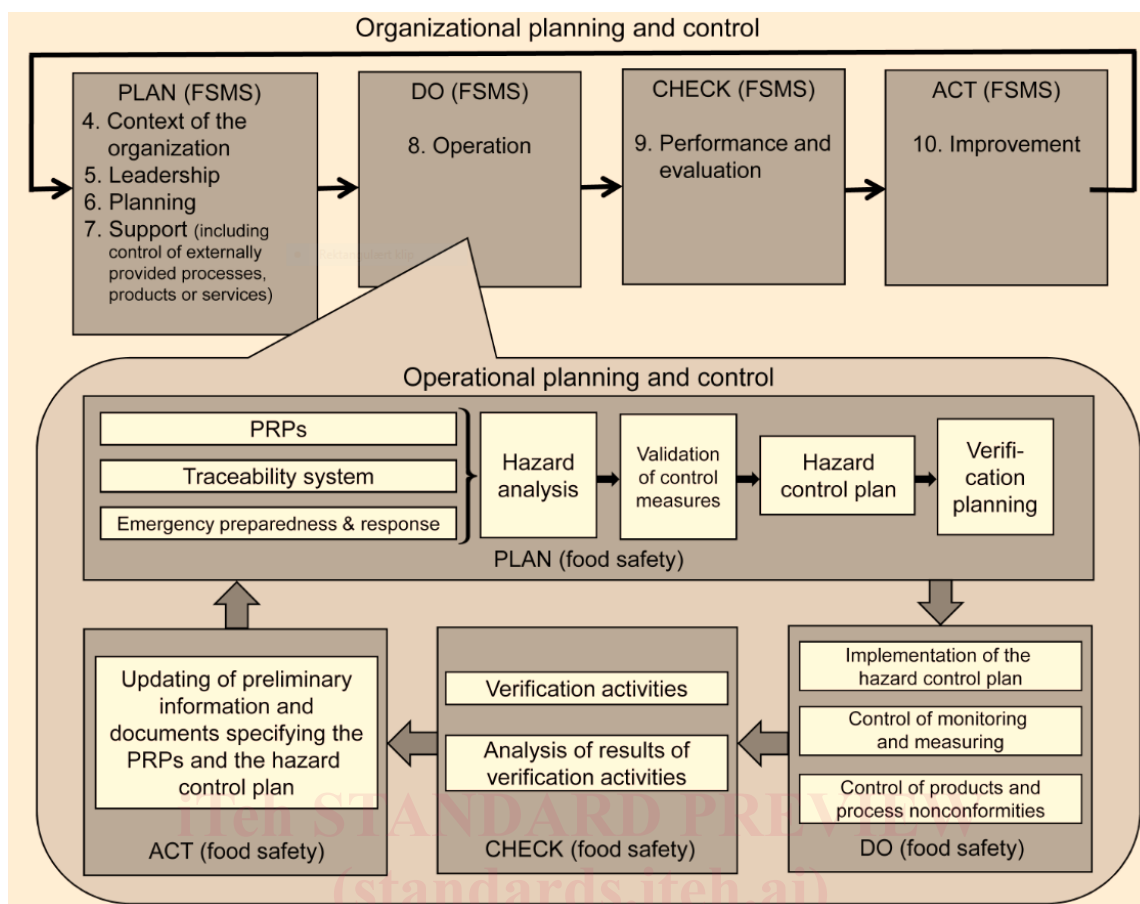


Figure 1 - Illustration of the two Plan-Do-Check-Act cycles

### 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 - Part 6: 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/>

**ISO/DIS 22000:2017(E)****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.