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Sistemi vodenja varnosti živil - Smernice za uporabo ISO 22000:2005

Food safety management systems -- Guidance on the application of ISO 22000:2005

Systèmes de management de la sécurité des denrées alimentaires -- Recommendations pour l'application de l'ISO 22000:2005

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 22004 was prepared by Technical Committee ISO/TC 34, *Food products*.

Introduction

0.1 General

The adoption of a food safety management system by an organization involved in the food chain is a useful tool for ensuring compliance with requirements specified by law, statute, regulation and/or customers.

The design and implementation of an organization's food safety management system are influenced by varying factors, in particular food safety hazards, the products provided, the processes employed and the size and structure of the organization. This Technical Specification gives guidance on the use of ISO 22000, which is based on the principles of HACCP as described by the Codex Alimentarius Commission [4] and is designed to be applied together with relevant standards published by that organization.

0.2 Food chain and process approach

ISO 22000 promotes the adoption of a food chain approach when developing, implementing and improving the effectiveness and efficiency of a food safety management system. In this regard, in ISO 22000 the organization is required to consider the effects of the food chain prior to and subsequent to its operations when developing and implementing the food safety management system.

For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification of interactions and the management of these processes can be referred to as the "process approach."

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

When used within a food safety management system, such an approach emphasizes the importance of

a) understanding and fulfilling the requirements,

b) the need to consider processes in terms of food safety and traceability,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

Interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires evaluation of information relating to their perception of whether the organization has met their requirements or not.

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The model of a process-based food safety management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8 of ISO 22000:2005. The model shown in Figure 1 does not show the processes at a detailed level.
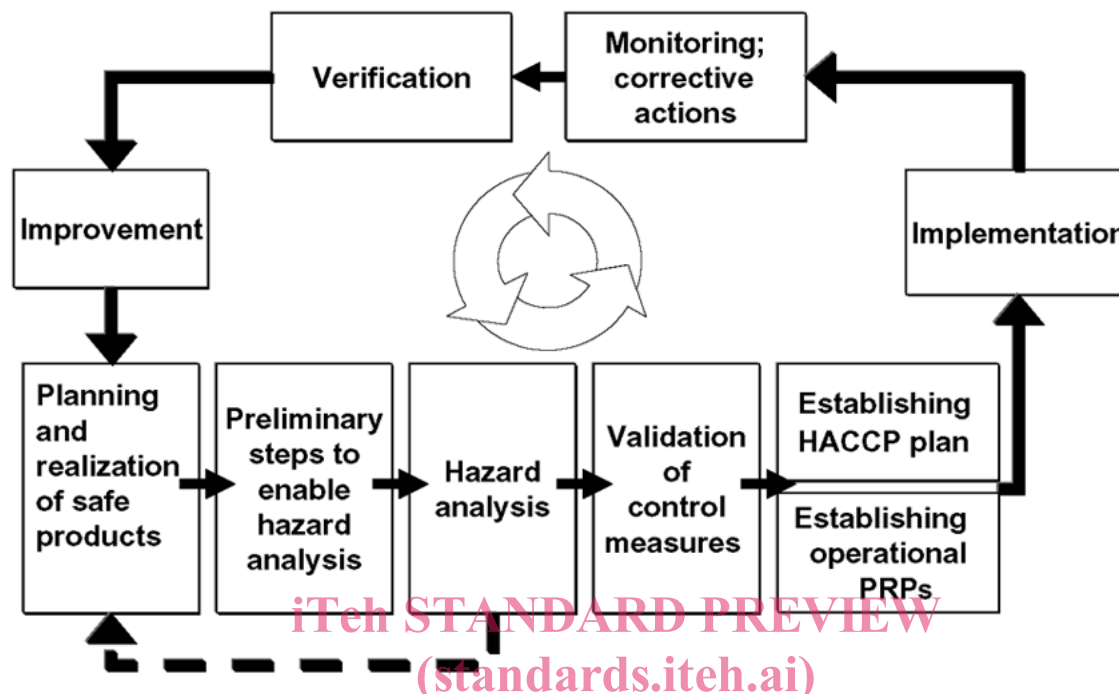
Figure 1 — Concept of continuous improvement

0.3 Relationship with ISO 9001

ISO 22000 has been designed to work in harmony with ISO 9001 and its supporting standards. ISO 9001 provides requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements. ISO 22000 provides the essential elements of a food safety management system for similar purposes.

0.4 Compatibility with other management systems

This Technical Specification does not include guidance specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management, or risk management. However, ISO 22000 enables an organization to align or integrate its own food safety management system with related management systems. It is possible for an organization to adapt its existing management system(s) in order to establish a food safety management system that follows the requirements of ISO 22000.

TECHNICAL SPECIFICATION   **ISO/TS 22004:2005(E)**

Food safety management systems — Guidance on the application of ISO 22000:2005

1 Scope

This Technical Specification provides generic guidance that can be applied in the use of ISO 22000.

NOTE   Where a subclause of ISO 22000 is not mentioned, guidance is not given.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

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For the purposes of this document, the terms and definitions given in ISO 22000 apply.

4 Guidance on the use of ISO 22000:2005, Clause 4: Food safety management system

4.1 General requirements

External competences may be used by the organization to develop and implement a food safety management system according to ISO 22000 provided that it is ensured that such outsourced processes have been developed and are implemented, monitored, maintained and updated in compliance with the requirements of ISO 22000.

Moreover, ISO 22000 allows any organization, in particular a small and/or less developed organization, to implement an externally developed and established combination of prerequisite programme(s) [PRP(s)], operational PRP(s) and Hazard Analysis and Critical Control Point (HACCP) plans provided that it can be demonstrated that

a) this combination has been developed in compliance with the requirements of ISO 22000 specified for the hazard analysis, PRP(s) and HACCP plan,

b) specific measures have been undertaken to adapt the externally developed combination to the organization, and

c) this combination has been implemented and is operated in accordance with the other requirements of ISO 22000.

4.2 Documentation requirements

The organization should use documents of external origin relevant for food safety in its various activities, for example in meeting statutory, regulatory and customer requirements. In some situations, electronic documentation may be required to comply with regulatory requirements.

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The type and extent of documentation will probably differ from one organization to another due to the size and complexity of the activity and the competence of personnel, as well as the extent of the use of externally developed combinations of PRPs, operational PRPs and HACCP plans.

If externally developed combinations of PRPs, operational PRPs and HACCP plans are used, their suitability should be documented and this documentation should be a part of the food safety management system.

Where ISO 22000 refers to a documented procedure or statement, this should be interpreted to mean that the procedure or statement is established, documented, implemented, reviewed and maintained by the organization as part of the food safety management system. Documents that usually form part of the system include product specifications, HACCP plans, operational PRPs and PRPs and other required operating procedures, including contracts for any outsourced processes (e.g. pest control, product testing). The documents used by the organization should be available when and where required and may be in any valid format (e.g. paper, electronic or picture).

A critical activity for any organization is the retention of appropriate records for specified periods and under controlled conditions. The organization should base its decision on record retention when it has considered the intended use of its products and the expected shelf-life along the food chain.

5 Guidance on the use of ISO 22000:2005, Clause 5: Management responsibility

5.1 Management commitment

The method whereby the organization provides evidence of top management commitment to the food safety management system includes the setting of awareness and leadership initiatives linked to the development and implementation of the system.

5.2 Food safety policy

The food safety policy is the basis of any organization's food safety management system. Measurable objectives and targets are defined in this policy. Measurable activities may include identification and implementation of activities to improve any aspect of the system (e.g. reduce the number of recalls/withdrawals, decrease the occurrence of foreign bodies).

Objectives should be specific, measurable, achievable, relevant and time-framed.

5.3 Food safety management system planning

No guidance is given.

5.4 Responsibility and authority

No guidance is given.

5.5 Food safety team leader

The food safety team leader is central to the food safety management system of any organization and should be a member of the organization and should understand its food safety issues. Where the food safety team leader has other responsibilities within the organization, these should not conflict with food safety responsibilities.

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

It is recommended that the food safety team leader have a basic knowledge of hygiene management and application of the HACCP principles.

5.6 Communication

The purpose of any communication is to ensure that the necessary interactions occur.

ISO 22000 requires that both external and internal communication takes place as part of the food safety management system.

External communication aims to exchange information in order to ensure that any relevant hazard is controlled at one step through the food chain by interaction, for example,

a) up and down the food chain, for food safety hazard(s) that may not or cannot be controlled by the organization and which consequently need(s) to be controlled at other steps in the food chain,

b) with customers as the basis for mutual acceptance of the level of food safety required (by the customer), and

c) with statutory and regulatory authorities and other organizations.

External communication is the method whereby the organization and the external organization agree by contract or other means upon the level of food safety required and on the capability of delivering to the agreed requirements. Channels of communication with statutory and regulatory authorities and other organizations should be established as a basis for providing public acceptance of the level of food safety and for ensuring the reliability of the organization.

Training of designated personnel in communication skills may be an important aspect as well.

The internal communication system of the organization should ensure that sufficient and relevant information and data are available to all personnel involved in the various operations and procedures. The food safety team leader has a major role in the area of the internal communication of food safety issues within the organization. Communication to personnel within in the organization should be carried out in a clear and timely manner on the development and launch of new products, as well as intended changes in raw materials and ingredients, production systems and processes and/or customers and customer requirements. In particular, attention should be given to the communication of changes in statutory and regulatory requirements, new or emerging food safety hazards, and the method of control of these new hazards.

Any member of the organization seeing something which may have an impact on food safety should know how to report this event.

5.7 Emergency preparedness and response

The organization should be aware of potential emergency situations which may include, for example, fire, flooding, bioterrorism and sabotage, energy failure, vehicle accidents and contamination of the environment.

5.8 Management review

The management reviews provide management with an opportunity to assess the performance of the organization in meeting the objectives with respect to its food safety policy and the overall effectiveness of the food safety management system.

6 Guidance on the use of ISO 22000:2005, Clause 6: Resource management

6.1 Provision of resources

No guidance is given.