

ISO 22000 :2005(E)

Introduction

Food safety is related to the presence of food-borne hazards in food at the point 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 participating in the food chain.

Organizations within the food chain range from feed producers and primary producers through food manufacturers, transport and storage operators and subcontractors to retail and food service outlets (together with inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients). Service providers are also included.

This International Standard specifies the requirements for a food safety management system that combines the following generally recognized key elements to ensure food safety along the food chain, up to the point of final consumption:

- interactive communication;
- system management;
- prerequisite programmes;
- HACCP principles.

Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain. This implies communication between organizations both upstream and downstream in the food chain. Communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements.

Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver safe food products to the final consumer. The most effective food safety systems are established, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization.

This provides maximum benefit for the organization and interested parties. This International Standard has been aligned with ISO 9001 in order to enhance the compatibility of the two standards. Cross-references between this International Standard and ISO 9001 are provided in Annex A.

This International Standard can be applied independently of other management system standards. Its implementation can be aligned or integrated with existing related management system requirements, while organizations may utilize existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard.

This International Standard integrates the principles of the Hazard Analysis and

Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission. By means of auditable requirements, it combines the HACCP plan with prerequisite programmes (PRPs). Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures. This International Standard requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Thus it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and why others need not.

1 General

The food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system.

2 Validation of control measure combinations

Prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change therein, the organization shall validate that

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

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed .

Modifications may include changes in control measures and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.

3 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures.

Where necessary to ensure valid results, the measuring equipment and methods used

- a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,
- b) shall be adjusted or re-adjusted as necessary,
- c) shall be identified to enable the calibration status to be determined,

- d) shall be safeguarded from adjustments that would invalidate the measurement results, and
- e) shall be protected from damage and deterioration.

Records of the results of calibration and verification shall be maintained.

In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting actions shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

4 Food safety management system verification

4.1 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the food safety management system

- a) conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this International Standard, and

- b) is effectively implemented and updated.

An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

4.2 Evaluation of individual verification results

The food safety team shall systematically evaluate the individual results of planned verification.

If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. Such action shall

include, but is not limited to, review of

a)existing procedures and communication channels ,

b)the conclusions of the hazard analysis, the established operational PRP(s) and the HACCP plan ,

c) the PRP(s) , and

d)the effectiveness of human resource management and of training activities .

4.3 Analysis of results of verification activities

The food safety team shall analyse the results of verification activities, including the results of the internal audits and external audits. The analysis shall be carried out in order

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

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

c)to identify trends which indicate a higher incidence of potentially unsafe products,

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

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

The results of the analysis and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review . It shall also be used as an input for updating the food safety management system .

4.5 Improvement

4.5.1 Continual improvement

Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication , management review , internal audit ,evaluation of individual verification results, analysis of results of verification activities ,validation of control measure combinations , corrective actions and food safety management system updating .

4.5.2 Updating the food safety management system

Top management shall ensure that the food safety management system is continually updated.

In order 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 , the established operational PRP(s) and the

HACCP plan.

The evaluation and updating activities shall be based on

- a) input from communication, external as well as internal, as stated in 5.6,
- 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 , and
- d) output from management review.