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

Systèmes de management de la sécurité des denrées alimentaires — Lignes directrices relatives à 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

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.

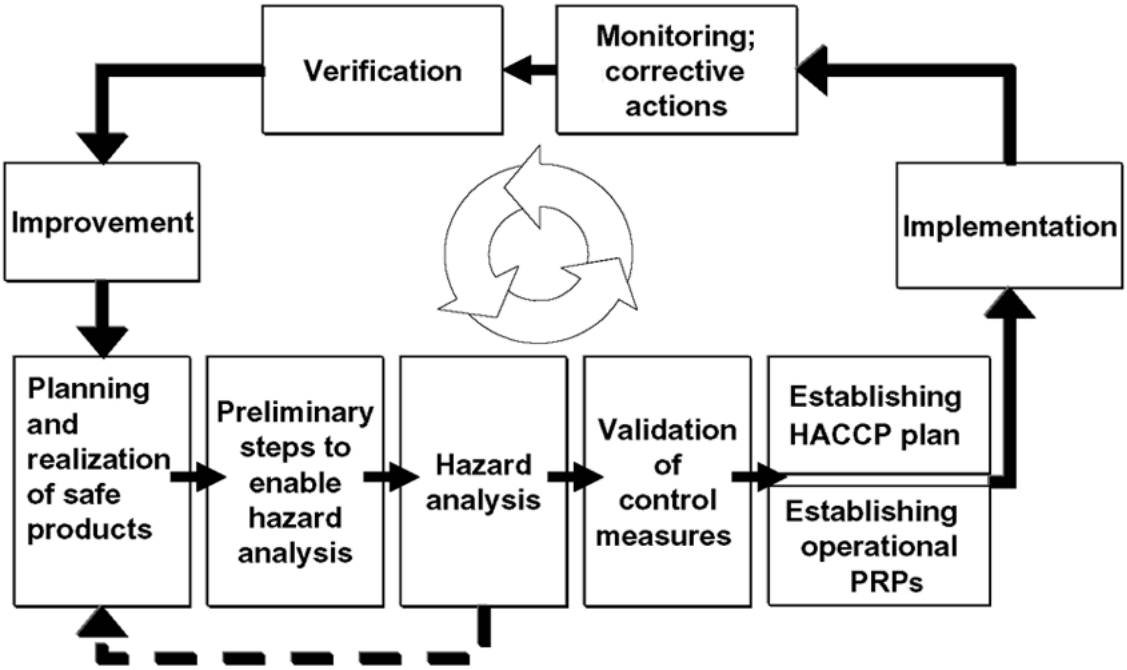


Figure 1 — Concept of continuous improvement

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.

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

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.

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.

6.2 Human resources

Training should be maintained at a level that ensures that all employees know their responsibilities to maintain the food safety management system. Details of training sessions should include, for example, programme content, name and qualifications of the trainer, final assessment of trainees, and establishment of the requirement for retraining.

6.3 Infrastructure

The infrastructure for the organization includes buildings, process equipment, utilities, surrounding areas and supporting services.

6.4 Work environment

The work environment can include measures to prevent cross contamination, work space requirements, protective work wear requirements, and the availability and location of employee facilities.

7 Guidance on the use of ISO 22000:2005, Clause 7: Planning and realization of safe products

7.1 General

ISO 22000 requires that the organization use a dynamic and systematic process approach to develop the food safety management system. This is achieved through effective development, implementation, monitoring of planned activities, maintenance and verification of control measures, updating the food processes and process environment, and through appropriate actions in the event of the production of nonconformities.

Clause 7 of ISO 22000:2005 addresses planning (see Figure 2) and operating phases, whereas Clause 8 addresses checking and acting phases. Maintenance and improvement of the system is addressed through a number of cycles of planning, validation, monitoring, verification and updating required in these two clauses. Within an operating system, system changes can be initiated at any of these phases.

ISO 22000 reorganizes the traditional concept of dividing control measures into two groups [prerequisites and measures applied at critical control points (CCPs)] in a logical order for the development, implementation and control of the food safety management system. Control measures are grouped into three groups, as follows:

a) prerequisite programmes (PRPs) that manage the basic conditions and activities; the PRPs are not selected for the purpose of controlling specific identified hazards but for the purpose of maintaining a hygienic production, processing and/or handling environment (see 7.2 of ISO 22000:2005);

b) operational prerequisite programmes (operational PRPs) that manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are not otherwise managed by the HACCP plan;

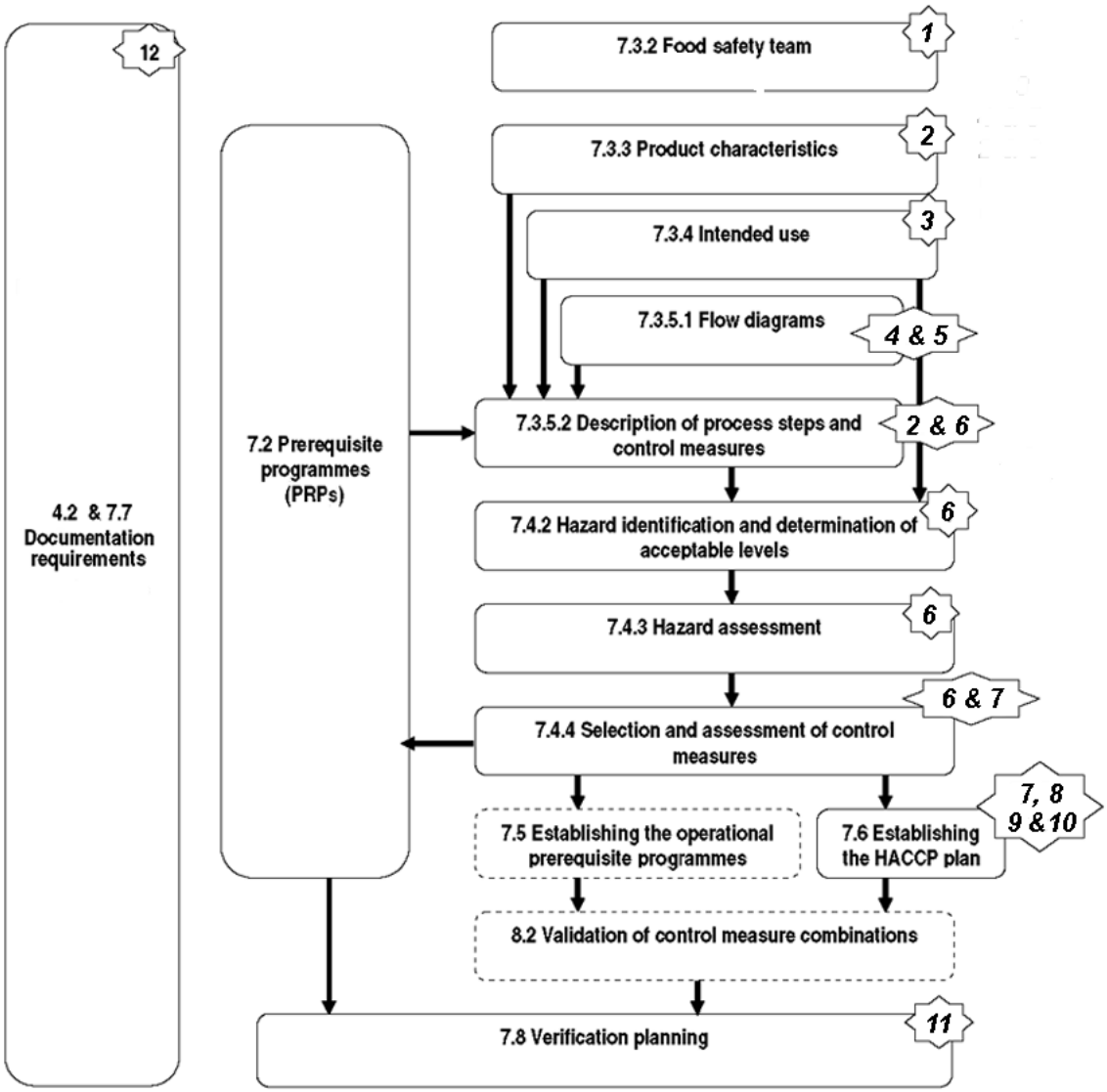
c) a HACCP plan to manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are applied at critical control points (CCPs).

Categorization of control measures facilitates the application of different management strategies to each group with respect to validation, monitoring, and verification of measures to control nonconformities, including handling of resulting products.

The core element of the planning is the conduct of the hazard analysis to determine those hazards that need to be controlled (see 7.4.3 of ISO 22000:2005), the degree of control required to meet acceptable levels and the combination of control measures that can deliver this (see 7.4.4 of ISO 22000:2005). To enable this, preliminary steps are needed (see 7.3 of ISO 22000:2005) to furnish and organize relevant information.

The hazard analysis determines the appropriate control measures and permits their categorization into those that are to be managed by the HACCP plan and/or operational PRPs, respectively, and will assist in the subsequent design of the details on how the measures are to be implemented, monitored, verified and kept updated (see 7.5 to 7.8 of ISO 22000:2005).

External competences may be used by the organization to develop the combination of control measures, provided that they meet the requirements of 7.2 to 7.8 of ISO 22000:2005.



Key

Steps addressed by the Codex Alimentarius HACCP Guidelines[4]

Steps specific to ISO 22000

NOTE Cross-references refer to ISO 22000:2005.

Figure 2 — Planning of safe foods

7.2 Prerequisite programmes

No guidance is given.

7.3 Preliminary steps to enable hazard analysis

The origin of the raw materials, ingredients and product contact materials should be taken into account when they might impact the evaluation of the occurrence of hazards and the levels of these hazards. The information to be taken into account may be different from the original information required to maintain traceability (see 7.9 of ISO 22000:2005).

The information to be taken into account with respect to the concept of “shelf life” is the period during which the product maintains its microbiological safety and suitability at a specified storage temperature and under other specified conditions, which may or may not be the same as the durability specifications used in product labelling.

The information on intended use is needed to assist in identifying appropriate acceptable levels of hazards and in selecting control measure combinations that achieve that level.

7.4 Hazard analysis

7.4.1 General

No guidance is given.

7.4.2 Hazard identification and determination of acceptable levels

Where statutory and regulatory authorities have established maximum limits, objectives, targets or end product and/or process criteria for a specific hazard/product combination, the hazard in question automatically becomes relevant for that product.

The “acceptable level” means the level of a particular hazard in the end product of the organization that is needed at the next step in the food chain to ensure food safety; it refers to the acceptable level in foods for direct consumption only when the next step is actual consumption. The acceptable level in the end product should be determined through information obtained from one or more of the sources below:

a) objectives, targets[1)] or end product criteria established by statutory and regulatory authorities in the country of sale;

b) specifications[2)] or other information communicated by the organization constituting the subsequent step in the food chain (often the customer), in particular for end products intended for further processing or use other than direct consumption;

c) the maximum levels found acceptable by the food safety team[2)], taking into account acceptable levels agreed on with the customer and/or established by law and, in the absence thereof, through scientific literature and professional experience.

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1) According to Codex Alimentarius, such targets can be expressed by authorities as Food Safety Objectives (FSO) and/or Performance Objectives (PO), where an FSO is the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of health protection (ALOP), and where a PO is the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a food safety objective or an appropriate level of health protection, as applicable.

2) According to Codex Alimentarius, such specifications can be expressed as Performance Objectives.

7.4.3 Hazard assessment

The role of hazard assessment is to assess the list of hazards identified according to 7.4.2 of ISO 22000:2005 in order to identify those hazards that need to be controlled by the organization. In conducting the hazard assessment, the following should be taken into consideration:

a) the source(s) of the hazard (e.g. where and how it can be introduced into the product and/or its environment);

b) the probability of occurrence of the hazard (e.g. qualitative and/or quantitative prevalence, such as frequency of occurrence and the typical levels, highest possible levels and/or statistical distribution of levels);

c) the nature of the hazard (e.g. ability to multiply, deteriorate and produce toxins);

d) the severity of the adverse health effects that can be caused by the hazard.

To the extent that the information required to conduct the hazard assessment is not available within the food safety team, additional information should be obtained from scientific literature, databases, statutory and regulatory authorities, and external competences.

When evaluating the probability of hazard occurrence, consideration should be given to steps preceding and following the specified operation within the same system, the process equipment, service activities and surroundings, as well as to the preceding and following links in the food chain and measures taken at preceding steps in the food chain (e.g. raw material suppliers, subcontractors). Similarly, relevant society initiatives (e.g. general environmental protection measures) and measures taken at subsequent steps in the food chain (e.g. further processing, transportation, distribution and consumers) should be taken into account.

The hazard analysis may determine that control of a hazard by the organization will not be needed. This may occur when, for example, the introduction or occurrence of an identified food safety hazard meets the defined acceptable level without any further intervention by the organization. This may, for instance, be the case where adequate controls have been implemented at other stages in the food chain and/or where introduction or occurrence within the organization is unlikely or so low that the acceptable level will be met anyway.

7.4.4 Selection and assessment of control measures

Selection of control measures: The control measures can be selected among those described in 7.2.3 (draft or previously applied operational PRPs), 7.3.3.1 a), d), e) and f), 7.3.3.2 b) to g), 7.3.5.1 (process steps) and 7.3.5.2 (externally required control measures) of ISO 22000:2005.

Assessment and combination of control measures: More than one control measure is often required to control specific food safety hazard(s) and more than one food safety hazard may be controlled by the same control measure (but not necessarily to the same extent). It is therefore advisable first to select suitable combinations of control measures for each of the hazards identified in accordance with 7.4.3 of ISO 22000:2005, followed by a consequential establishment of the whole range of control measures required to control them all.

The information required to assess the effect of a control measure includes the following:

a) how the food safety hazards are affected by the control measure (i.e. reduction, controlling increases, and/or controlling the frequency of occurrence)[3)];

b) to what extent the levels of food safety hazards are affected (qualitatively, semi-quantitatively or quantitatively); very often the effect depends upon the rigorousness of the control measure (e.g. temperature, time, concentration, frequency); in carrying out the assessment it may be useful to obtain data on the intensity-effect relationships;

3) According to Codex Alimentarius, the effect of a control measure can be expressed as a Performance Criterion; i.e. the effect on frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a Performance Objective or a Food Safety Objective.

c) the step or location where the control measure is intended to be applied; some control measures are more effective if applied after other control measures (e.g. after control measures that stress microorganisms);

d) operational parameters, including their operational uncertainty (e.g. fluctuation and/or probability of operational failure), and practical operational range of intensity.

Subclause 8.2 of ISO 22000:2005 requires that validation demonstrates that the combination of control measures is capable of achieving the intended level of control. Failure to demonstrate such capability must result in modification of the combination.

Where a control measure cannot be validated, it cannot be included within a HACCP plan or in operational PRPs, but it can be applied within PRPs.

The assessment and validation processes may yield the result that previously applied or drafted control measures are demonstrated to be in excess of what is actually required to deliver the necessary controls. Such control measures may be (re)considered with regard to their general relevance for the food safety management system of the organization or may be integrated in the PRPs if their (continuous) use is desired.

Categorization of control measures: The organization may focus on having as many of the control measures as possible managed by operational PRPs and only a few managed by the HACCP plan, or the opposite. It should be noted that, in certain cases, no CCP can be identified, for example because monitoring results cannot be provided within an adequate time frame.

As the effects of the combination of control measures are validated prior to categorization, food safety will be achieved in cases even when all control measures are to be managed through operational PRPs.

The following may guide the organization in the categorization process:

— the impact of a control measure on the hazard level or frequency of occurrence (the higher impact there is, the more likely the control measure belongs to the HACCP plan);

— the severity on consumer health of a hazard that the measure is selected to control (the more severe it is, the more likely it belongs to the HACCP plan);

— the need for monitoring (the more pressing the need, the more likely it belongs to the HACCP plan).

7.5 Establishing the operational prerequisite programmes

The development of the operational PRP(s) may follow the design of the HACCP plan (see 7.6.1 of ISO 22000:2005).

7.6 Establishing the HACCP plan

7.6.1 HACCP plan

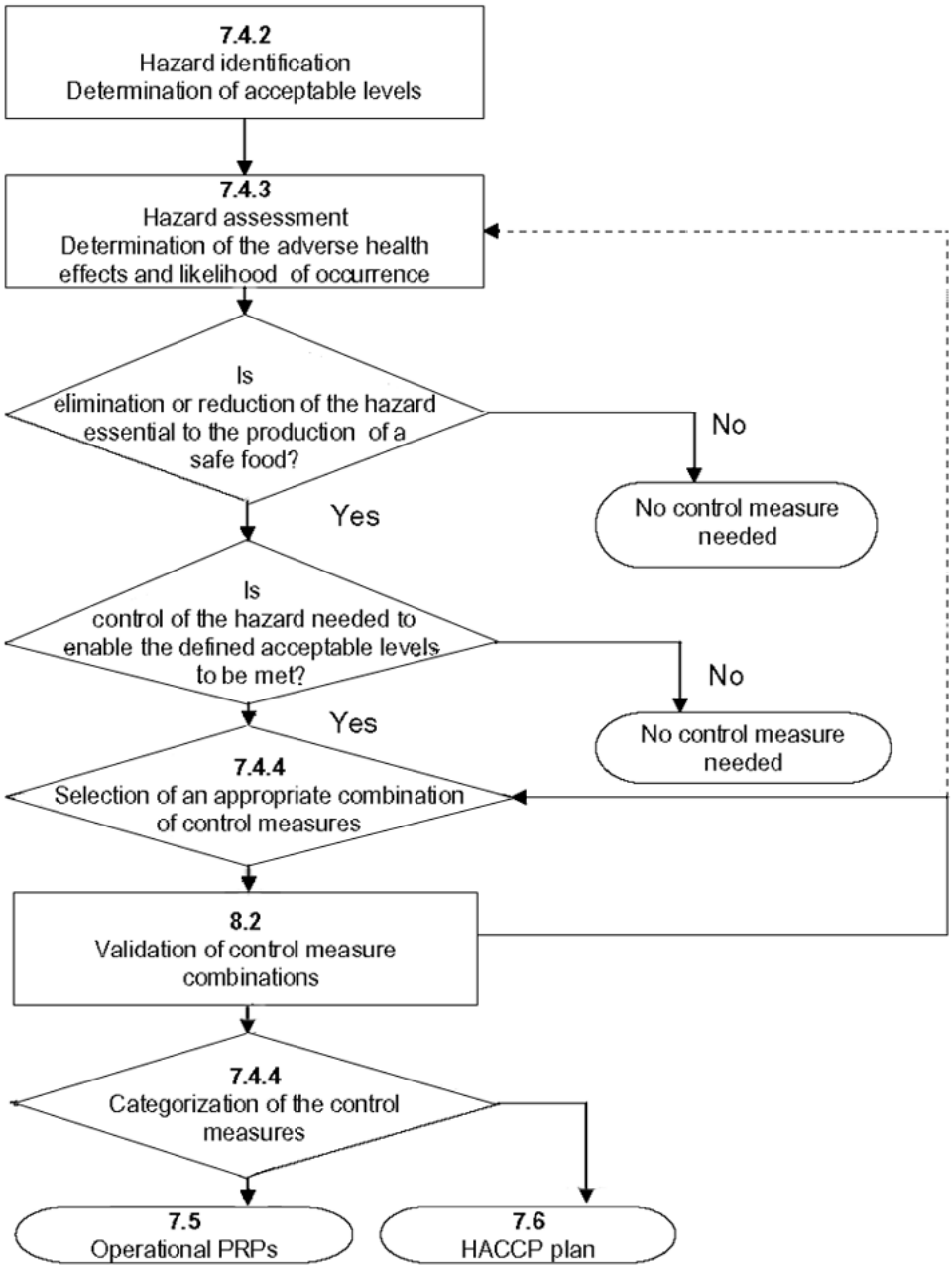
No guidance is given.

7.6.2 Identification of critical control points

CCPs are those steps where control measures to be managed by the HACCP plan are located. See Figure 3.

7.6.3 Determination of critical limits for critical control points

Critical limits should be designed to ensure control of the food safety hazard(s) for which they have been designated. For CCPs intended to control more than one food safety hazard, the critical limit(s) should be established relative to each food safety hazard.



NOTE Cross-references refer to ISO 22000:2005.

Figure 3 — Decision tree

7.6.4 System for the monitoring of critical control points

Most monitoring procedures for CCPs should provide real-time information related to on-line processes. Furthermore, monitoring should provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Therefore there may not be time for lengthy analytical testing. Physical and chemical measurements that give information about the degree of microbiological control are often preferred to microbiological testing because they can be done rapidly. For the validation and verification of such measurements, microbiological testing may be used.

7.6.5 Actions when monitoring results exceed critical limits

The critical limits are set at a point where the products become unsafe. In practice, therefore, it is common to work against limits that give an early warning that a process might become out of control. The organization may choose whether any actions are going to be taken when exceeding warning limits.

7.7 Updating of preliminary information and documents specifying the PRPs and the HACCP plan

No guidance is given.

7.8 Verification planning

The concepts of validation, verification and monitoring are often confused.

— Validation is an assessment prior to operation, the role of which is to demonstrate that individual (or a combination of) control measures are capable of achieving the intended level of control.

— Verification is an assessment carried out during and after the operation, the role of which is to demonstrate that the intended level of control has actually been achieved.

— Monitoring is a procedure to detect any failures in the control measure.

The frequency of verification depends on the degree of uncertainty in the effect(s) of the control measure(s) applied relative to the determined acceptable level(s) of food safety hazard(s) or predetermined performance(s), as well as on the ability of the monitoring procedures to detect loss of control. Hence, the frequency required will depend on the uncertainties associated with the result of validation and the functioning of the control measure (e.g. process variability). For instance, where validation demonstrates that the control measure delivers a hazard control significantly higher than the minimum required to meet acceptable levels, verification of the effectiveness of that control measure may be reduced or might not be required at all.

7.9 Traceability system

In developing the traceability system, consideration should be given to the activities of the organization that might impact on system complexity, such as the types of ingredient and their number, re-use of product, product contact material, batch versus continuous production, aggregation. The organization should also give consideration to the extent of its traceability system to identify better any potentially unsafe products that may need to be withdrawn. Further guidance will be given in ISO 22005[3].

7.10 Control of nonconformity

No guidance is given.

8 Guidance on the use of ISO 22000:2005, Clause 8: Validation, verification and improvement of the food safety management system

8.1 General

The requirements in Clause 8 of ISO 22000:2005 address those activities that are needed to demonstrate that the food safety management system, as designed, is reliable, is able to deliver and actually delivers the level of control that is expected of it.

It is the responsibility of the organization's management to make certain that the food safety management system is designed to produce the desired controls, is operated as designed, and is updated as new information is provided.

The food safety management system should be developed using sound scientific principles. The means to collect the necessary information for the system design can usually be obtained from academic institutions, regulatory agencies, trade associations, consultants, or any party that has educated expertise in the food process and product. Once the control measure combination is designed on paper, it must be validated.

8.2 Validation of control measure combinations

The validation process provides assurance that the combination will deliver products that meet identified acceptable levels. The validation usually includes such activities as

a) reference to validations carried out by others, to scientific literature, or to historical knowledge,

b) experimental trials to simulate process conditions,

c) biological, chemical and physical hazard data collected during normal operating conditions,

d) statistically designed surveys,

e) mathematical modelling, and

f) use of a guide approved by competent authorities.

If relying upon validations carried out by others, care should be taken to ensure that the conditions of the intended application are consistent with those identified in the referenced validations. Generally accepted industrial practices may be used. Scaling up of laboratory-based experimental trials in a pilot plant may be required to ensure that the trials properly reflect actual processing parameters and conditions. Intermediate and/or finished product sampling and testing based on the use of statistical sampling plans and validated testing methodology may be used. Validations may be conducted by external parties, and microbiological or analytical testing can effectively be used to verify that a process is in control and that acceptable product is being produced.

If additional control measures, new technology or equipment, changes in the control measures, product (recipe) changes, identification of new or emerging hazards or changes in their frequency of occurrence, or unexplained failures of the system occur, revalidation of the system might be necessary.

8.3 Control of monitoring and measuring

The concept of calibration is complex and can depend on the type of process, type of equipment and how prone they are to loose calibration. Thermometers and metal detection units are commonly used in the food industry and can be used as examples. Calibration of thermometers may differ depending on

a) the type of thermometer,

b) the degree of accuracy needed, or

c) the thermometer range over which the thermometer will operate.

Thermometers should be checked against a traceable reference thermometer. Electronic thermometers can be adjusted, whilst mercury thermometers should be labelled with the deviation from the reference. It may be sufficient to calibrate annually or biannually. Metal detection units can be verified or calibrated by the use of metal dummies with a known topography/mass/iron content and adjusted on site. The frequency of verification/calibration can be substantially higher than for thermometers due to unit stability and changes in the monitored product (e.g. moisture content).

Optimal calibration frequency depends on the type, condition and past performance of the monitoring instrument. ISO/IEC 17025 gives further guidance on intercalibration surveys and other laboratory quality assurance techniques.

8.4 Food safety management system verification

Verification of the food safety management system assures that it is functioning as designed and is updated based upon currently available information. A food safety system that is functioning properly minimizes the need

for extensive product sampling and testing. Verification occurs in two stages that may be loosely classified as ongoing and periodic.

Ongoing activities use methods, procedures or tests separate from, and in addition to, those used in monitoring of the system. Verification reports should include information about

— the system,

— the persons administering and updating it,

— the status of records associated with monitoring activities,

— certification that monitoring equipment is properly calibrated and in working order, and

— results of records review and any samples analysed.

Training records of the personnel should be reviewed and the results should be documented as well.

A schedule of verification activities is developed as part of the food safety management system (planned according to 7.8 and evaluated according to 8.4.2 of ISO 22000:2005). This schedule should include the procedures or methods to be utilized, the frequency and the person(s) responsible for performing the activity. Examples of verification activities that should be considered as part of the system include

— reviewing monitoring records,

— reviewing deviations and their resolution or corrective action, including the handling of affected product,

— calibrating thermometers or other critical measuring equipment,

— visually inspecting operations to observe if control measures are under control,

— analytically testing or auditing monitoring procedures,

— randomly collecting and analysing samples of in-process or end product,

— sampling for environmental and other concerns, and

— reviewing consumer or customer complaints to determine whether they relate to the performance of the control measures or reveal the existence of unidentified and/or need for additional control measures.

When conducting internal audits (see 8.4.1 of ISO 22000:2005) for these verification activities, sound audit principles should be observed. Auditors should be competent to perform the audit. They should be independent of the work or processes being audited, although they may be from the same work area or department. For example, in a small business where there might be only one or two people in the management structure, this requirement may not be achievable. It is suggested that, in such cases, in carrying out the duties of an auditor, the manager tries to step back from direct involvement in the business operations and to be very objective about the audit.

Another approach might be to seek the cooperation of another small business and each provide the internal audit for the other. This can prove attractive if there are good relations between the two businesses. Alternatively, external parties (e.g. chamber of commerce, consultant, inspection agencies) might be able to provide independent auditors.

The periodic verification activities involve the overall assessment of the system (see 8.4.3 of ISO 22000:2005). This is usually performed during a management or verification team meeting, and all the above evidence over a period of time is reviewed to ascertain if the system is functioning as planned and if updating or improvement is necessary. Notes of the meeting should be kept and should include any decisions made regarding the system. At a minimum, verification of the entire system in this manner should take place on an annual basis.

8.5 Improvement

No guidance is given.

Bibliography

[1] ISO 9001, *Quality management systems — Requirements*

[2] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

[3] ISO 22005:—[4)], *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*

[4] CAC/RCP 1-1969 (Rev.4-2003), *Recommended International Code of Practice — General Principles of Food Hygiene* [incorporates Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application]

[5] *Procedural Manual of the Codex Alimentarius Commission,* 14th edition, 2005

4) To be published.

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