BRITISH STANDARD

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Guidelines on the application of ISO 9001:2000 for the food and drink industry

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National foreword

This British Standard reproduces verbatim ISO 15161:2001 and implements it as the UK national standard.

The UK participation in its preparation was entrusted to Technical Committee AW/90, Quality systems for the food industry, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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INTERNATIONAL STANDARD

ISO 15161

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Guidelines on the application of ISO 9001:2000 for the food and drink industry

Lignes directrices relatives à l'application de l'ISO 9001:2000 aux industries de l'alimentaire et des boissons

Reference number
ISO 15161:2001(E)

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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 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15161 was prepared by Technical Committee ISO/TC 34, *Food products*.

Annex A of this International Standard is for information only.

A list of standards and other publications related to this International Standard is given in the Bibliography.

Introduction

ISO 9001:2000, Quality management systems — Requirements

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9004:2000 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, 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, can be 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 and interactions of these processes, and their management, 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 over their combination and interaction.

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

a) understanding and fulfilling requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

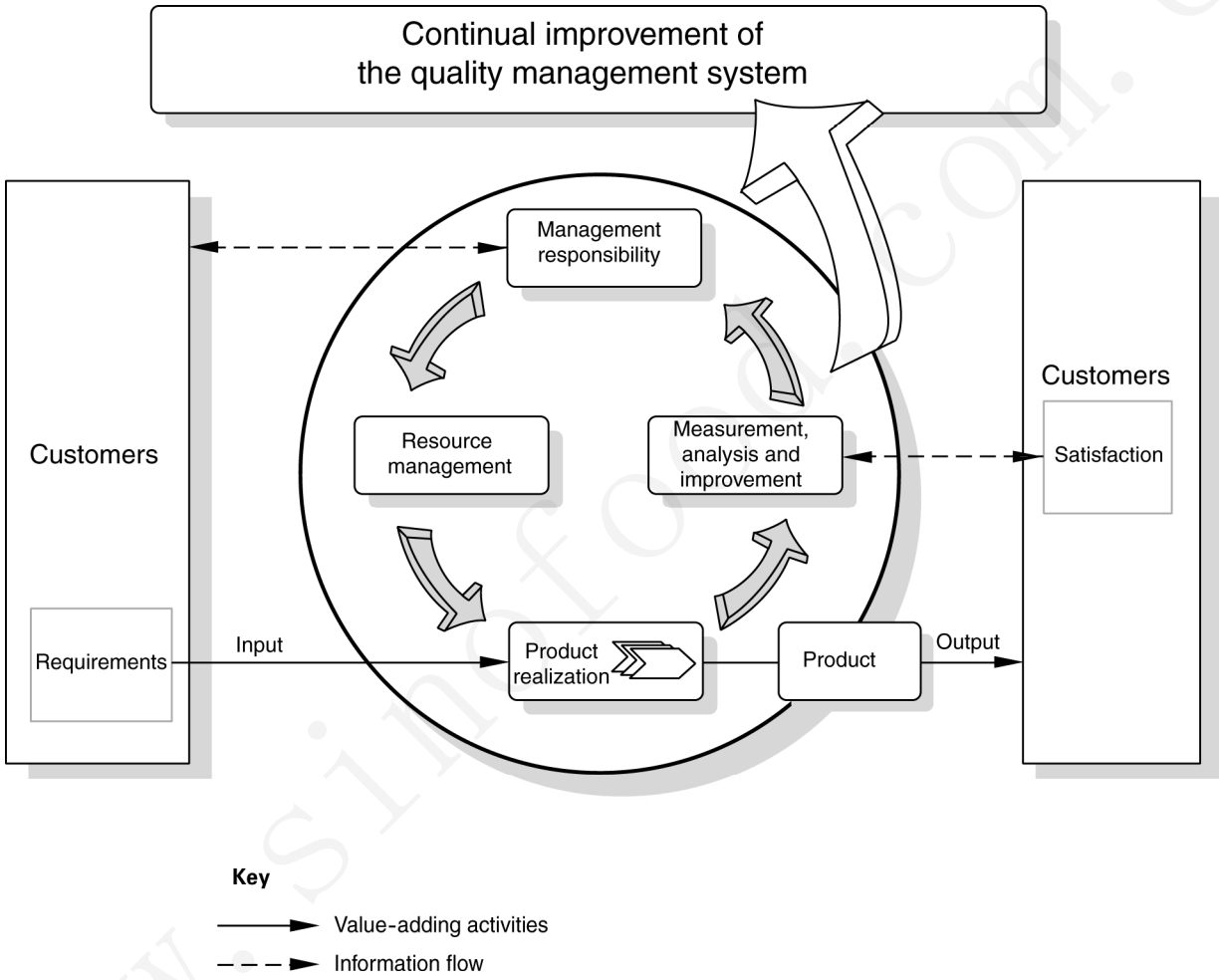

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies 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 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

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

There is a need for guidance on implementing the requirements of ISO 9001 for organizations involved in all aspects of the food and drink industry. This includes organizations involved in sourcing, processing and packaging food and drink products. This International Standard aims to encourage the use of the ISO 9000 series of standards within the food and drink industry – the use of these standards alongside other common systems in use in this sector may assist an organization to better address customer satisfaction and organizational effectiveness by the effective implementation of a quality management system.

ISO 9001 also requires organizations to seek to continually improve their quality management systems, an aspect often missing from other models of food safety management commonly used in the food and drink industry.

The adoption of a quality management system needs to be a strategic decision of the organization. The design and the implementation of an organization's quality management system is influenced by varying needs: the particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the purpose of ISO 9001 to imply uniformity in the structure of quality management systems or uniformity of the documentation. The process-oriented base of ISO 9001 makes it easier to envisage how different systems within a business link together; often it is at the interfaces between internal customers and suppliers or between different systems that problems occur. Any model which clarifies these critical areas for an organization will assist in the smooth running of its business.

ISO 9001 focuses on customers' needs and expectations. One of the most important customer expectations (and often one which is implicit rather than stated directly) is to have safe food products. ISO 9001 allows an organization to integrate its quality management system with the implementation of food safety systems such as HACCP (hazard analysis and critical control point). The internationally recognized principles and steps of HACCP are defined by the Codex Alimentarius Commission in its recommended international code of practice on general principles of food hygiene. Any other accepted food safety system can, of course, also be integrated into the quality management system. However, considering the fact that HACCP is widely used comprehensively, this system was chosen to demonstrate how integration may be achieved.

The application of HACCP within a quality management system conforming to ISO 9001 can result in a food safety system that is more effective than the application of either ISO 9001 or HACCP alone, leading to enhanced customer satisfaction and improved organizational effectiveness. As an example, the application of HACCP for the identification of hazards and control of risks is related to quality planning and preventive actions required by ISO 9001. Once the critical points have been identified, the principles of ISO 9001 can be used for control and monitoring. Procedures for conducting an HACCP study can easily be documented within the quality system.

To assist the user, the requirements of ISO 9001 are given in boxed text in this International Standard, followed by relevant guidance.

Linkages between the basic HACCP principles and specific clauses of ISO 9001 are shown in annex A.

This International Standard represents an attempt to identify the specific issues to be considered when establishing a quality management system in the field of the food and drink industry. Therefore, users of this International Standard are encouraged to gather any experience gained in connection with its application and inform the ISO/TC 34 Secretariat accordingly, so that their views can be taken into account in the first revision.

Guidelines on the application of ISO 9001:2000 for the food and drink industry

1 Scope

This International Standard gives guidance to organizations in applying the requirements of ISO 9001 during the development and implementation of a quality management system in the food and drink industry.

This International Standard gives information on the possible interactions of the ISO 9000 series of standards and the hazard analysis and critical control point (HACCP) system for food safety requirements.

This International Standard is not intended for certification, regulatory or contractual use.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 and the following apply.

3.1
contract
agreed requirements between a supplier and a customer, transmitted by any means

3.2
corrective action
action to eliminate the cause of a detected nonconformity or other undesirable potential situation, including any action to be taken when the results of monitoring at any critical control point indicate a loss of control

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action. Correction is the elimination of the nonconformity, while corrective action eliminates its cause.

NOTE 4 Definitions of “nonconformity”, “correction” and “preventive action” can be found in ISO 9000.

NOTE 5 This definition is a combination of the definitions given in ISO 9000 and reference [20].

3.3
critical control point
CCP
step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

NOTE Taken from reference [20].

3.4
critical limit
criterion which separates acceptability from unacceptability

NOTE Taken from reference [20].

3.5
flow diagram
systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item

NOTE Taken from reference [20].

3.6
good manufacturing practice
combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources

3.7
hazard
biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

NOTE Taken from reference [20].

3.8
hazard analysis
process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

NOTE Taken from reference [20].

3.9
primary production
those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing

NOTE Taken from reference [20].

3.10
step
point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption

NOTE Taken from reference [20].

3.11
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled, including evidence that the elements of the HACCP plan are effective

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The conditions of use for validation can be real or simulated.

NOTE 3 Definitions of the terms “objective evidence” and “requirements” can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

3.12
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled, including the application of methods, procedures, tests and other evaluations, and monitoring to determine compliance with the HACCP plan

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design specification with a similar proven design specification,

— undertaking tests and demonstrations other than mentioned in the definition, and

— reviewing documents prior to issue.

NOTE 3 Definitions of the terms "specification" and "tests" can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

4 Quality management system

4.1 General requirements

ISO 9001:2000, Quality management systems — Requirements

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

The strong process aspect of this clause should be familiar to organizations operating within the food and drink sector. It is common practice to use process flow charts and other tools to "map" the process of manufacture – indeed the first stage of a HACCP study requires such a definition of the process. The structure of the quality management system should be right for the organization, meeting its needs as much as the organization does for its customers. The quality system should ensure that all those activities within the organization that could impact on the quality and safety of the product are consistently defined (which usually means documented) and effectively implemented. Useful inclusions are relevant codes of practice and legislative requirements, such as weight control, hazard analysis, hygiene, good manufacturing practice (GMP) and good laboratory practice (GLP).

4.2 Documentation requirements

4.2.1 General

ISO 9001:2000, Quality management systems — Requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

Documents needed by the organization to ensure the effective planning, operation and control of its processes may include the current issue of relevant legislation pertaining to food and drink manufacture. This legislation could cover the following areas:

— safety;

— compositional standards;

— metrology;

— additives;

— lot identification and traceability;

— labelling and packaging information.

There could be other examples, and customer documents may also be included.

4.2.2 Quality manual

ISO 9001:2000, Quality management systems — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The requirement to produce a quality manual need not mean a top-level document which stands alone. A quality manual should clearly describe the structure of the quality management system and, ideally, act as a “road-map” through it. All associations and links to other systems or documents, which the organization may be required to operate to, should be detailed within the quality manual. The association with HACCP documentation (such as the HACCP plan) is particularly important and the linkage between the HACCP study and the quality manual should be very clear. It is this document which most clearly shows how the HACCP study is integrated with the quality management system and how the outcomes of the HACCP study are incorporated in the way the organization usually operates.

4.2.3 Control of documents

ISO 9001:2000, Quality management systems — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Other documentation (in paper or electronic formats) utilized in the food and drink industry, which may be part of the quality management system, could include the following:

a) specifications (e.g. for raw materials, processing, recipes and products);

b) drawings (e.g. artwork for packaging);

c) current legislation and codes of practice;

d) other externally generated documents (e.g. equipment manuals);

e) HACCP plan and HACCP documentation.

These should also be under document control, although the mechanism for control may differ from that used to control procedural documents. Errors often occur where recipes and/or specifications have been re-issued but communication has been poor and part of the organization is operating to a different issue.

The approval of documents before issue (and subsequent same-party review of changes) ensures that the content of documents will not clash with any other document in the system, fits into the organization's objectives and is agreed by the correct people. Careful review of documents before issue is the key to creating a documented quality management system which has value, rather than one which is over-administered and serves little useful purpose.

Electronic documents, databases and systems, are included in this subclause. The food and drink industry makes increasing use of electronic-based documents and the same rules of control apply as they would to any paper based documents.

4.2.4 Control of records

ISO 9001:2000, Quality management systems — Requirements

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Records demonstrate the effectiveness of the quality management system. Retaining appropriate records for a specified period of time, under controlled conditions, is a critical activity. If an organization were challenged at a later date about a product or process, which had occurred previously, it is unlikely that without effective retention and retrieval systems of records any proof of operational control or test results could be established.

Within the food and drink industry, the retention periods for records may be stipulated as a customer requirement, and this normally includes as a minimum the product's shelf-life period. There could also be statutory regulations to comply with. These will vary from short (1 to 2 day) life products, right through to canned or dried products stable at ambient temperatures, which can have up to a 2-year shelf-life. Even for short-life products, claims from customers can be made after the shelf life has expired, so the retention time for records is an area to be considered carefully. A blanket retention period of several years for all records generated may not be appropriate. Careful selection of the most appropriate retention period for each identified quality record is therefore advised.

Particular consideration should be given to the retention of management system records (e.g. internal audit, management review, system changes, HACCP documentation), as they contain important historical data.

5 Management responsibility

5.1 Management commitment

ISO 9001:2000, Quality management systems — Requirements

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

ISO 9001 begins with five clear requirements which immediately require the “top management” within an organization to demonstrate its commitment to a number of principles. This is common to all industries, not only food and drink. The “top management” may be the most senior management group at an individual production site, or the leaders at a global level of an international organization. Either way, it is clear that without this visible commitment at the outset, all that follows would be extremely difficult to create, implement and maintain.

Within the food and drink industry, the requirement to produce safe food, with the required level of quality, whilst remaining economic is of paramount importance.

Management should be committed to develop, maintain and operate the HACCP system and continually improve its effectiveness and provide the required resources. One of the tasks of top management is to nominate members of the HACCP team and support their activities.

5.2 Customer focus

ISO 9001:2000, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

The customer may be the immediate retailer, the transporter, any other intermediary of the downstream food chain, or the wider community of consumers. Consequently, there can be different customer requirements.

NOTE Requirements concerning customer needs and expectations, or customer requirements, appear frequently in ISO 9001 and are further expanded in 7.2.1 and 7.3.2.

Any statutory requirements applicable to the organization’s activities should be identified and be incorporated into the way that organization functions. Whilst statutory requirements vary between countries, this industry has an overriding requirement to produce safe food products with minimal risk to public health. Many pieces of legislation are available covering this point, and any food or drink manufacturer has a legal obligation to comply with them.

The maintenance of an appropriate quality management system such as that specified in ISO 9001 with the associated due considerations and controls given to the processes, people and records can assist in showing compliance with customers' requirements.

5.3 Quality policy

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

The organization's policy should make statements to indicate that the organization is fully aware of which segment of the food supply chain is involved, by including references to food hygiene, safety and other aspects of food quality.

The position in the food supply chain is important since companies in this sector can be primary processors (taking raw materials direct from the farmer or grower for initial processing) or can manufacture food ingredients. The organization should consider its responsibilities carefully, depending on the size and nature of its operation.

5.4 Planning

5.4.1 Quality objectives

ISO 9001:2000, Quality management systems — Requirements

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

The establishment of quality objectives throughout the organization may be through the dissemination of the organization’s overall strategy. This usually refers to the defined quality policy and provides goals or objectives for different functions within the organization. It is important that objectives are aligned throughout the organization. It is advisable that the quality objectives indicate the nature of the hazards that the organization considers critical for the safety of foodstuffs.

5.4.2 Quality management system planning

ISO 9001:2000, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality planning ensures that the organization is clear what its requirements (inputs) are and is therefore more likely to meet them successfully (outputs). This is mirrored in the whole process approach of ISO 9001. Techniques of quality planning vary, but typically include flowcharts, worksheets, quality control plans, product specifications and hazard identification. The HACCP plan, resulting from an HACCP study, should be considered in planning activities. Once the first two HACCP principles have been met (conducting a hazard analysis and the determination of CCPs), this may be used as part of the quality plan for that process. It should be clear from that first stage what areas need control and to what level.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2000, Quality management systems — Requirements

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

It should be remembered that quality management resides within every function throughout the organization. All personnel should be aware of the role they play in achieving the stated policies and objectives, and meeting customer requirements both in safety and quality.

5.5.2 Management representative

ISO 9001:2000, Quality management systems — Requirements

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

The management representative could be supported by other people in the day-to-day operation of the system, but would be the central point of contact for outside bodies on matters relating to the system. It is important to avoid or remove potential sources of conflict of interest with any other role the management representative may have. The management representative has a requirement to communicate effectively, both up and down, throughout the organization.

5.5.3 Internal communication

ISO 9001:2000, Quality management systems — Requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Good internal communication will promote the effective operation of a quality management system. All organizations should ensure that the pathways for effective internal communication are established and that everyone knows about them. The preventive actions identified under hazard analysis and deviation procedures, including product disposition, should be known and communicated at appropriate levels and functions.

In this sector of industry, as in any other, it is particularly important to communicate clearly about the development and launch of new products, changes in raw materials, changes in production systems or equipment, changes in customer, sector or other requirements, and changes in personnel qualification level and responsibilities. Particular attention should be paid to new statutory and regulatory requirements, the ideas of risks, new hazards and new ways of handling them.

5.6 Management review

ISO 9001:2000, Quality management systems — Requirements

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

In addition to the above list, these reviews should take into account, as a minimum, the results of the internal quality audit, corrective and preventive actions, the control of suppliers, customer complaints, hygienic conditions, HACCP and other indicators (e.g. statistical data on product quality) of the effectiveness of the quality management system.

The management review provides the overview of the company; i.e. is the direction in which the company is moving still in line with long-term goals or aspirations? Management reviews are common to all companies in all industry areas. The common feature is that successful companies usually take the opportunity at management review to review critically the effectiveness of their systems and to change those things which do not assist in the development of the company.

The quality management system should ensure that all those activities within the organization that could impact on the quality of the product are consistently defined (which usually means documented) and effectively implemented.

6 Resource management

6.1 Provision of resources

ISO 9001:2000, Quality management systems — Requirements

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

One of the tasks of the HACCP team is to provide management with an estimate on resource requirements in terms of time, money and labour requirements for the HACCP study and implementation.

6.2 Human resources

6.2.1 General

ISO 9001:2000, Quality management systems — Requirements

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

ISO 9001:2000 — Quality management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

In any organization it is important to ensure that all tasks are given to the most appropriately trained persons. The food and drink sector is not an exception to this requirement. The required competency level for personnel should be established in line with overall quality policies and plans. It could be appropriate for certain specified activities to be carried out by personnel trained to a basic level; other activities could need much higher levels of training. It is very important that all staff working in food areas be trained to an appropriate level in hygiene procedures.

Staff should be adequately trained and provided with the relevant work instruction/standards/specifications/ legislation (or any other suitable means).

Training in sensory evaluation or analysis is an important requirement in this sector. The type and extent of such sensory training should be in line with the overall requirements of the organization.

Identification of training needs should be carried out and any gaps in training should be filled. The effectiveness of training should be measured. The maintenance of appropriately concise training records is important. There can be working areas where it is not appropriate to have written instructions to hand (due to excessive moisture, etc.). Effective delivery, thorough training, of the correct protocol is therefore essential.

Employees within an organization with a quality management system should be aware of the quality policy and objectives (couched in appropriate language) and how their actions can affect the quality performance of the business. It is beneficial to explain the reasons for doing an activity in a certain way (e.g. for hygiene or food safety reasons) and to explain what may happen if they do not (e.g. spoilage, food poisoning). The completion of an effective HACCP study requires the individuals involved to have been appropriately trained. This could include training in the identification of hazards and associated controls specific to the type of food and drink business, or a more general appreciation of more typical hazards and their control.

6.3 Infrastructure

ISO 9001:2000, Quality management systems — Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

The facilities refer to the area, equipment and services which support and enable the organization to meet its agreed objectives for product conformity and food safety. In this industry, the appropriate design and maintenance of the work areas has a major effect on food safety. Inappropriate design, construction and layout of food processing areas can introduce hazards into the process and/or product, as can inappropriate design of process equipment. The appropriate maintenance of equipment can also ensure that hazards do not affect the process. This should comply with good manufacturing practice and good hygienic practice.

6.4 Work environment

ISO 9001:2000, Quality management systems — Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

The organization should adequately review its facilities and work environment so that its policies and planned quality objectives are not compromised. Information needed can be that required to run processes, customer information, supplier information and competitor information.

The following list highlights certain aspects whose relevance should be considered at all stages, from raw material reception to product delivery. However, this list is neither exhaustive nor prescriptive.

a) Environment

Atmosphere, soil, potable source of water, drainage, pest control and invasive life forms from microbes to mammals.

b) Buildings

All buildings, including facilities for storage, manufacture, personal hygiene, packing, handling, testing and despatch, as well as administration offices in the proximity, should be considered, especially from the hygienic design standpoint.

c) Plant equipment and utilities

This includes hygienic design of plant and equipment as well as the cleaning processes required. Equipment should have suitable maintenance to ensure it remains capable of processing to the specified standards. Consideration should be given to potential cross-contamination points.

d) Personnel

This includes provision of appropriate work wear (coats, boots, hats, etc.) and training in appropriate hygienic practices.

An appropriate working environment will include those factors which bear on the employees' ability to operate safely and effectively. Poor health and safety, conditions of working, non-ethical practices and inappropriate working methods all have an adverse effect on producing an acceptable product.

e) Legislation

This covers the requirements of relevant legislation applicable to personal hygiene and protective clothing to be used.

f) Health screening

This includes evidence of screening procedures (where legally or otherwise specified) and their maintenance for food handlers with respect to product safety.

g) Waste and by-products

Consideration should be given to the segregation and disposal of such material.

h) Pest control.

7 Product realization

7.1 Planning of product realization

ISO 9001:2000, Quality management systems — Requirements

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

All processes within the organization which combine to meet customer requirements and the stated policies and plans should be designed, implemented and maintained effectively. The results from quality planning can give an indication of the typical controls needed within a process. The use of HACCP is defined as an internationally accepted means to carry out this task with respect to food safety. The results of the HACCP study and CCPs should be entered into process planning; this identifies critical areas and shows their correct direction.

In the food and drink industry, the processes from raw material delivery, through the main manufacturing process and out to packaging, storage and despatch, are generally easy to visualize and follow through. However, processes function throughout an organization, through all other departments and service activities which support the main manufacturing process. Although these processes, in areas such as Accounts, Planning, Personnel and Administration, may not be as visible as manufacturing and may not require any specialized equipment, they are as critical to the smooth and effective operation of the business and achievement of policies and plans as any manufacturing process.

These processes should be clearly defined, inputs, outputs and links to other processes understood, measurement of the process defined, and appropriate records maintained. This will link back to the HACCP plan in which CCPs were identified and the methods of controlling them.

In planning, problems which can occur during processing should be also taken into consideration, such as the following.

a) Risk of cross-contamination

The risks arising from contamination should be considered and systems installed to reduce this risk. (Hazard analysis can be part of this system.) This should be considered for raw materials, additives, work-in-progress and final products and packaging material.

b) Automated control system failure

There are situations where the failure of automated control or computer systems can have an adverse effect on the product.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

ISO 9001:2000, Quality management systems — Requirements

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

Potential users and consumers should be identified and documented, as far as is known for each product/product category. For some products, consumer groups known to be especially vulnerable (e.g. babies or children, pregnant women, patients, elderly people and diabetics) should be identified and continual attention given to them.

The organization should, where appropriate, demonstrate that it has been evaluated as to whether the storage conditions and the intended use with these groups of population could include a CCP.

To ensure optimum consumer safety, unintended handling and use of the product shall be taken into consideration by the provision of preparation instructions and distinctive product labelling.

The relevant statutory and regulatory requirements should also be identified.

7.2.2 Review of requirements related to the product

ISO 9001:2000, Quality management systems — Requirements

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

Elements of Principle 2 and Principle 3 of the logical sequence for the application of HACCP (determine the critical control points and establish critical limits) may be integrated. Once the process flowchart has been established, the CCP determination should be clear. Often the customer will clearly state in the specification which tests have to be done (microbiological, chemical, etc.) and may even give targets and acceptable tolerances related to the product.

In any situation where there are tenders, contracts or orders between a supplier and a customer, contract review applies. This clause of ISO 9001 is the key to establishing customers' requirements and, most importantly, clarifying whether the company has the capability to meet those requirements.

Customers' requirements will vary from simple sales orders for standard products, call-off against a pre-agreed long-term contract, variable demands made against a sales forecast, or requirements to produce to technical product specifications and quality control inspection specifications. All contract requirements should be agreed between the customer and the supplier before the contract is accepted. If the supplier cannot meet any or all of the stated requirements, the customer should be notified. The methods used to demonstrate contract review will vary, but can include notes of telephone messages, sales order information, signed tender documents, minutes of meetings, or internal orders released by the commercial department for production.

Consideration should also be given to the internal customer-supplier relationships in an organization; the principles of contract review apply equally to these situations.

Safeguarding the customer against unintended use of a food product (possibly caused by incorrect storage conditions) should also be considered.

Compliance with current legislation is an inherent product requirement. When exporting, consideration should be given to the legislative requirements of individual countries.

7.2.3 Customer communication

ISO 9001:2000, Quality management systems — Requirements

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

When designing the process for managing a product recall, a specific individual should be nominated to manage the process and to be the sole point of contact with the customer and, if required, the consumer.

7.3 Design and development

7.3.1 Design and development planning

ISO 9001:2000, Quality management systems — Requirements

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

The intention of this clause of ISO 9001 is to ensure that the specifications of materials, processes, packaging, product and labelling arrived at through the development process, meet the identified needs of the customer. There can be a great deal of creativity involved in such a process, in addition to technical expertise, and the design control system adopted should allow creativity, but within a clearly defined set of procedures which allow the process to be managed and controlled.

Food safety must be paramount during any new product development. HACCP Principle 1 (conduct a hazard analysis) and Principle 2 (determine the critical control points) are of extreme importance. Applying the principles of hazard analysis during design should help to ensure that the potential new product will be able to be made safely and is within the capability of the particular company. Investing more time at this phase of the process to iron out problems before the product goes on-line will save time and money. Design control has also been linked into HACCP Principle 3 (establish critical limits).

The terminology of this clause of ISO 9001 could be unfamiliar to many in the food industry. However, the processes involved are those that are commonly applied during product development; for example, the statement of customer requirements in a product development brief; the designation of development milestone meetings where development samples are assessed before approval is given to proceed to the next development stage; verification through challenge testing or shelf-life determination; and validation through market research and transit tests.

The disciplines of the design process should ensure that appropriate control limits are set which will adequately control the critical point identified.

The design process under an ISO 9001 system has many checks and balances, which are all relevant to the establishment and development of a comprehensive HACCP system. Where particular HACCP principles have not been identified directly, there may well be links to the whole hazard analysis process.

7.3.2 Design and development inputs

ISO 9001:2000, Quality management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

A plan should be prepared describing all development activity. Key points to be included in any plan are the identification of those responsible for carrying out the development processes, and all key stages in the process. As the design (or new product, or new recipe) evolves, the plan will need to be updated.

There are many design input requirements relating to a product. As a minimum, these include statutory and regulatory requirements, and any requirements which derive from contract review, such as shelf life, compositional claims, style of packaging and price point. All these input requirements should be accurately captured in the design process, and any which are conflicting or ambiguous should be resolved quickly with the relevant personnel, group or organization.

7.3.3 Design and development outputs

ISO 9001:2000, Quality management systems — Requirements

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

Problems tend to occur at interfaces between different functional groups, usually due to communication difficulties and one group not realizing that they are part of an internal “customer-supplier” chain. Care should be taken to ensure that all members of the design process are clear as to their requirements, and that effective communication systems are in place.

The results of the development process (a new product or new recipe, for example) should be measured against clear acceptance criteria (such as food safety and hygiene requirements, good manufacturing practice and relevant regulations). Verification and validation of the new product need to be included in the development plan. Table 1 compares these activities, including design review.

Table 1 — Comparison of design activities

Design control "tool"	How to use	Further notes
Review	Where appropriate, to check progress of the design plan against key parameters.	Review ensures that things are progressing as expected. This can involve a multidisciplinary team, such as development staff, technical staff, and should generate records.
Verification	Ongoing process, which can include testing at stages in the process, or comparisons with known, proven products.	Verification will check that any product claims can be substantiated, such as formal nutritional analysis, ingredients. This activity should generate records.
Validation	At the end of the design process, to ensure that the new product meets customer needs.	Validation may be performed with specific target user groups (e.g. children's foods) or by test marketing. This should check that all customers' stated requirements can be met by the new product. This activity should generate records.

7.3.4 Design and development review

ISO 9001:2000, Quality management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

The frequency and composition of the team or particular individual performing the review will differ for each organization and possibly each new design activity. The reviews should ensure that the design process stays relevant to input requirements and on target.

7.3.5 Design and development verification

ISO 9001:2000, Quality management systems — Requirements

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

Within the food and drink industry, verification activities may include physical, chemical, microbiological and shelf-life testing, as well as sensory evaluations by selected user panels.

7.3.6 Design and development validation

ISO 9001:2000, Quality management systems — Requirements

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

The final validation of the product will confirm (or not) the acceptability of the product to the defined customer group. In the food and drink industry, design validation may include test marketing, trial production runs, and invited consumer test panels.

7.3.7 Control of design and development changes

ISO 9001:2000, Quality management systems — Requirements

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

In some circumstances, modifications to a product can be of a trivial nature and the customer requirements are not compromised. In these instances, the initiation of such a change may not require the full implementation of the design process. However, the criteria and authority for permitting minor modifications, and the methods of verification and validation, should be clarified in the quality system. Procedures should be written to describe the way in which control and verification take place during design so that product requirements are met.

Changes to the design after an effective design control activity has been carried out are common. Records should be available to address the change control process, ensuring that any changes will not adversely affect product safety or methods of manufacture, or contravene legislative requirements.

7.4 Purchasing

7.4.1 Purchasing process

ISO 9001:2000, Quality management systems — Requirements

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

All materials and services used to meet customer requirements in the manufacture of product should be purchased in a controlled manner that reflects the importance of that material or service to the finished product. Within the food and drink industry, this could include the following:

a) ingredients;

b) processing aids;

c) water (processing water and water treatment);

d) maintenance, equipment, packaging and food contact materials;

e) subcontract operations (i.e. contract packing);

f) primary producers (e.g. animal husbandry, primary crop processing);

g) testing and laboratory services;

h) hygiene services (including the purchase of cleaning chemicals used on product contact surfaces) and pest control;

i) training;

j) transport and distribution;

k) warehousing (of both raw materials and finished products).

The level of control a company wishes to exert over a supplier will depend on the nature and intended use of the material. Anything used as an ingredient, or coming into direct contact with the product, will probably need tighter controls than items such as office equipment. It should be remembered that declarations of compliance with legislation do not necessarily mean that the component is safe.

The hazard analysis assessment of the process will identify raw materials and other inputs which need to be controlled, and will be identified as a “critical control point” (CCP). This can then result in the need for increased control over the supplier. Suppliers of materials or services should be selected carefully, with a full investigation into their capability to supply to the organization’s stated requirements. The criteria for acceptance of a supplier should be clearly established and recorded. Suppliers' performance should be monitored for all parameters, including quality, delivery and shelf-life. The monitoring methods should be recorded, together with methods for the selection of suppliers and, if necessary, the removal of unsatisfactory suppliers.

Purchasing has been linked to Principle 3 of the HACCP process (establish critical limits). To identify potential hazards in a process, having assessed whether or not special procedures are required for the process to be under control, consideration should be given to the raw materials (of all types) used in the process. The establishment of appropriate specifications for raw materials, and the use of only those suppliers with the capability to adhere to these specifications, will ensure that hazards are not introduced into the process at an early stage, where a later process step is then necessary to reduce that hazard to an acceptable level.

7.4.2 Purchasing information

ISO 9001:2000, Quality management systems — Requirements

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Purchasing information may take the form of paper or electronic orders, verbal orders or a pre-established delivery schedule. Any order, however placed, should be clear and covered by a purchasing specification. The specification will clearly state the organization's requirements and accommodate the inherent variability of such products, and encompass the need for any special controls necessary to guarantee their conformity, including the requirement to meet current legislation.

7.4.3 Verification of purchased product

ISO 9001:2000, Quality management systems — Requirements

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

ISO 9001:2000, Quality management systems — Requirements

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

Appropriate control could include, for example, the use of notices of “pass/fail”, “accepted/not accepted”, “conforming/nonconforming” or “waiting for inspection/testing”, in order to identify clearly the status of incoming, in-process products, available for delivery and delivered products, batches or lots, etc.

These notices may include marks, labels, identified physical location or data in written records, computer databases, in-line testing data, electronic code systems on products, etc.

7.5.2 Validation of processes for production and service provision

ISO 9001:2000, Quality management systems — Requirements

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

There are some processes where verification of results can be uneconomical or impossible without a destructive test. Examples include pasteurization, sterilization in canning, and clean-in-place (CIP) processes. As inspection and testing techniques and technology develop, it could become possible to verify some of these processes – although there could still be unacceptable delays in obtaining results or the cost could be prohibitive. The key in these situations is the complete control of the process, including verifying the process before product is made (during process design), ensuring all personnel are adequately trained, that machinery and equipment are adequate and well maintained, and that the “in-process” records are complete and can record the processing parameters.

Reliance on post-process inspection and testing should be minimal. The process should be designed, executed and controlled to ensure that all possible hazardous inputs are removed (or reduced to an acceptable hazard level). The importance of the link of validation into the hazard analysis process is obvious: using this technique all negative inputs on quality (including hazardous ones) into the process are identified and the process is controlled to minimize the risk before the product is manufactured. This should ensure no unpleasant surprises when the final test results are obtained.

7.5.3 Identification and traceability

ISO 9001:2000, Quality management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Due regard should be given to the identification of systems which are necessary to comply with any legal requirements or codes of practice, such as national product recall procedures. Lot identification is important in product recall and helps effective stock rotation. Food products should carry adequate information to enable the next person in the food chain to handle, display, store, and prepare and use the product safely and correctly. Any procedures for product recall should include a definition of responsibilities.

Where the customer requires the product to be identified by a specific mark or code, a system should be implemented for the verification of that mark or code.

It is a legal requirement in this industry that there be a system for batch or lot traceability. It is the responsibility of the organization to determine what constitutes a batch or lot, other than when it is specified as a customer requirement. This will vary depending on the industry, and the potential risk of the product.

Product identification and traceability may be regarded as prerequisite conditions before the application of HACCP.

7.5.4 Customer property

ISO 9001:2000, Quality management systems — Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

Customer property can be a raw material or packaging material supplied by the customer for processing with a particular product, or could also cover specific additional items to be incorporated into the finished product, such as a “promotional object” added into the final pack. Risk analysis should be carried out on the promotional object to ensure it will not pose an unacceptable risk to the rest of the organization. There should be suitable controls to ensure that this material is protected as well as any material owned by the organization itself. Consideration should be given to such products when performing HACCP analysis.

7.5.5 Preservation of product

ISO 9001:2000, Quality management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

NOTE “Preservation” does not refer to the addition of preservatives into a food or drink product, it refers to storage or warehousing after packing.

The organization should ensure that products are handled, stored, packed, preserved and delivered under the right conditions to maintain the specified quality.

Factors to be considered can include the following:

a) contract packing;

b) specified artwork for packaging materials;

c) storage conditions, including temperature and humidity;

d) stock rotation;

e) shelf life or customer requirements;

f) delivery conditions, including temperature and humidity;

g) statutory and regulatory requirements;

h) contamination hazards;

i) environment, design, construction and layout of buildings;

j) hygiene and infestation control, before or after production and packaging.

Procedures in this area need to ensure that hazards are not introduced after production by poor handling or storage. This is part of product realization and should be considered during the HACCP study. This should also consider inadvertent contamination during processing: work in progress should be safeguarded to ensure that hazards are not introduced which could affect the quality or safety of the finished product. How and where products are stored and transported should all be considered.

7.6 Control of monitoring and measuring devices

ISO 9001:2000, Quality management systems — Requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) 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) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

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 reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

Calibration certificates should indicate the measurement accuracy of equipment at the time of calibration (the “as-found” reading).

In the food and drink sector, sensory evaluations have special importance. These are carried out by sensory panels which can provide objective results if the members are selected and the tests are conducted in accordance with the relevant International Standards (see, for example, ISO 6658 and ISO 10399). In this case the sensory panel works as a "measuring device", therefore its performance should be checked regularly, which is a special form of calibration. For this purpose suitable International Standards are also available (see, for example, parts 1 and 2 of ISO 8586).

The verification of measuring and monitoring devices in the food and drink industry in some cases can only be carried out using data from interlaboratory studies.

As many organizations become more reliant on software-based processes, it is important to include this within a calibration system. Any software used to verify a process (such as calculation of nutritional content or the relative quantities of raw materials in a product using a quantitative ingredient) should be treated in the same way as measuring equipment.

8 Measurement, analysis and improvement

8.1 General

ISO 9001:2000, Quality management systems — Requirements

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Just as a product is checked for conformance to specification after manufacture, the quality management system itself should be inspected or measured to ensure it still conforms to requirements detailed in the policies, goals and quality plans agreed.

It is sometimes easier to develop appropriate methods of measurement for a product than for a process. Measuring the process system itself is more difficult, and will require careful selection of the many measurement tools available.

Measuring whether a process is operating effectively within this industry can (if it is a production process) require the use of some kind of statistical tool or model. A process is designed to meet a particular need or requirement, whether from a customer or derived internally. A process which is not capable of delivering product within specification can be the root cause of many nonconforming products. It is no use retraining staff if the process cannot make product within the specification. Verifying that a process is capable of meeting requirements may be done by process capability studies. The use of such studies and statistical process control will assist organizations in understanding the "fingerprint" for operation of a process, and can assist in the production of products which are always within specification.

NOTE Detailed guidance on statistical techniques is given in ISO/TR 10017 [17].

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

ISO 9001:2000, Quality management systems — Requirements

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

High or low customer satisfaction could be measured by the number of compliments (or complaints) received, but a more proactive approach is to develop with the customer some key performance indicators (KPIs) and measures. Typical KPIs in the food industry include

— new product development,

— commercial management,

— speed of product launches,

— planning and promotions,

— adherence to technical standards,

— product quality,

— responsiveness to problems, and

— people and service levels (delivery performance).

8.2.2 Internal audit

ISO 9001:2000, Quality management systems — Requirements

8.2.2 Internal audit

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

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure 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 (see 4.2.4) 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 verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

It is important that the internal audit system ensures that the agenda for management review takes into account the HACCP system and its associated outputs, since the quality management system is used to manage the HACCP process. If these outputs of the HACCP are integrated into the foundation for the quality management system, the internal audit programme will also audit them through verification of the effective operation of the system.

8.2.3 Monitoring and measurement of processes

ISO 9001:2000, Quality management systems — Requirements

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Monitoring and measurement are extremely important in the application of an HACCP system. This is referenced in HACCP Principle 4 (establish a system to monitor control of the CCP), and Principle 6 (establish procedures for verification to confirm that the HACCP system is working effectively).

The overriding principle behind the establishment of an HACCP system is to ensure that safe products are produced. It could be argued that “after-the-fact” inspection will not contribute to this principle, although gathering information as to whether the controls identified and executed have been successful or not is extremely important. The results of the monitoring exercises will show whether the control activities have been effective. However, where possible, rapid or on-line quality control methods should be used.

The monitoring plan is the output of the HACCP plan and should include product, process and service. Monitoring and measurement records should form the backbone of a documented HACCP system, as the records generated provide evidence that a product has passed the defined acceptance criteria.

8.2.4 Monitoring and measurement of product

ISO 9001:2000, Quality management systems — Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The quality plan should identify check points for raw materials, packaging, and in-process and finished product testing. The mechanism for release of material should be defined. Hazard analysis could be used to identify critical control points.

Two categories requiring special attention are the following.

a) Tests based on senses

Tests that are based on sight, odour, taste and texture (i.e. any organoleptic tests) should combine the following elements:

1) the holding of standard reference batches, where appropriate;

2) qualification, screening, training and re-evaluation of testing personnel;

3) procedures to ensure long-term consistency.

b) Special tests

Occasionally in-house tests are developed internally by an organization by modifying generally accepted or standard test methods. This can be as a response to a defined business need, or possibly an amendment to a process will result in a corresponding test having to be amended also. As is the case with standard tests, these "bespoke" tests should be documented and validated to ensure they are effective.

Records of all inspection and tests should be maintained.

Another important area for consideration is the retention of samples of manufactured product. Many companies keep samples of finished products, generally for the period of the stated shelf-life. The storage and control of these samples (to ensure safekeeping and to prevent deterioration) should be considered carefully. There could be customer requirements concerning sample retention which should be taken into account.

8.3 Control of nonconforming product

ISO 9001:2000, Quality management systems — Requirements

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

Nonconforming products can be identified by inspection at various stages of the process, internal quality audits or as a result of any other type of audit (such as hygiene, housekeeping). It is always preferable for the supplier to find the problem before the customer does. Systems should prevent inadvertent use of such products until a decision

has been made as to how to deal with them. The three most usual methods of dealing with nonconforming product are

a) an agreement is made with the customer for a concession,

b) the product is safely disposed of in accordance with any relevant regulations and guidance, or

c) it is retained for alternative use.

If product has been identified as nonconforming and there is a possible risk that it is unsafe, steps should be taken to ensure the disposal of this product is adequately controlled.

It should be noted that the disposition of nonconforming product might be controlled by legislation.

The development of a product recall plan and associated procedures is covered in this clause. The plan should consist of detailed procedures, which should be followed by the organization and its personnel in the event of a product having to be recalled. A plan developed in advance of any such incident will assist the organization in managing such a situation with minimal disruption to normal business.

8.4 Analysis of data

ISO 9001:2000, Quality management systems — Requirements

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

Previous subclauses (particularly 8.2.1 and 8.2.2) require measurement of system performance and customer satisfaction. Add to this the data obtained from product performance (number of nonconforming products, customer complaints, data from rejects or reworks) and there is a great deal of data available as a result of measuring all facets of organizational activity. Turning this data into useful information requires careful analysis and the use of suitable methods will assist this process. Areas for improvement can be identified from this data: every nonconformity is an opportunity for improvement.

8.5 Improvement

8.5.1 Continual improvement

ISO 9001:2000 — Quality management systems — Requirements

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

ISO 9001:2000, Quality management systems — Requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken.

Systems should be in place to ensure the application of corrective actions when things go wrong, to record the actions taken and (most importantly) to prevent their recurrence or occurrence. When a problem has been identified, there is a need not only to correct the immediate situation but also to identify the underlying cause. Once this has been identified, action should be taken to prevent recurrence. Corrective action should also be addressed in other areas (e.g. hygiene audits, pest control reports). Nonconforming service (e.g. late deliveries) should also be addressed. The concept of corrective action in the HACCP method describes the processing of nonconforming products and the nonconformities and the correction of the situation. The concept of corrective action in ISO 9001 is based on searching for causes in such a way as to perpetuate the elimination of the problem at the source of the nonconformity.

8.5.3 Preventive action

ISO 9001:2000, Quality management systems — Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 4.2.4), and

e) reviewing preventive action taken.

Causes of problems, when clearly identified, should be captured within the organization and used to re-engineer processes and/or procedures to avoid recurrence of the nonconformity.

This information can be useful in predicting areas of potential problems and in amending working practices to ensure that problems do not occur. Preventive action can also lead to improvement of working practices as the

systems develop. In order to improve the system, it is important that information derived from preventive action is fed back for management review.

Where appropriate, the use of hazard analysis techniques should be applied to meet the preventive aspects of ISO 9001. For this reason, HACCP is the priority tool when taking preventive action.

Preventive action should be used to ensure the HACCP system improves over time and could also be linked to the identification of potential hazards, especially in times of change and development of the production processes.

Annex A
(informative)

Interrelationship between the HACCP and ISO 9001 systems

The following are the five initial steps and seven recognized principles of HACCP as identified by Codex Alimentarius Commission.

— Step 1: assemble the HACCP team.

— Step 2: describe the product.

— Step 3: identify its intended use.

— Step 4: construct a flow diagram.

— Step 5: confirm the flow diagram on-site.

The above five steps should be taken prior to the HACCP being started. The HACCP is then carried out according to the seven principles as follows.

— Principle 1: conduct a hazard analysis.

— Principle 2: determine the critical control points (CCPs).

— Principle 3: establish critical limit(s).

— Principle 4: establish a system to monitor control of the CCP.

— Principle 5: establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

— Principle 6: establish procedures for verification that the HACCP system is working effectively.

— Principle 7: establish documentation concerning all procedures and records appropriate to these principles and their application.

The Food Hygiene Basic Texts of Codex Alimentarius [20] states:

“The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.”

It also states:

“Prior to the application of HACCP to any sector of the food chain, that sector should be operating according Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation.”

Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) are also useful procedures and can provide a basis for systems such as ISO 9001 and HACCP.

Figure A.1 shows the main relationships between ISO 9001 and the seven principles of HACCP. The clauses shown either particularly support the HACCP principle or the output from the HACCP study can be aligned and managed by with a clause of ISO 9001.

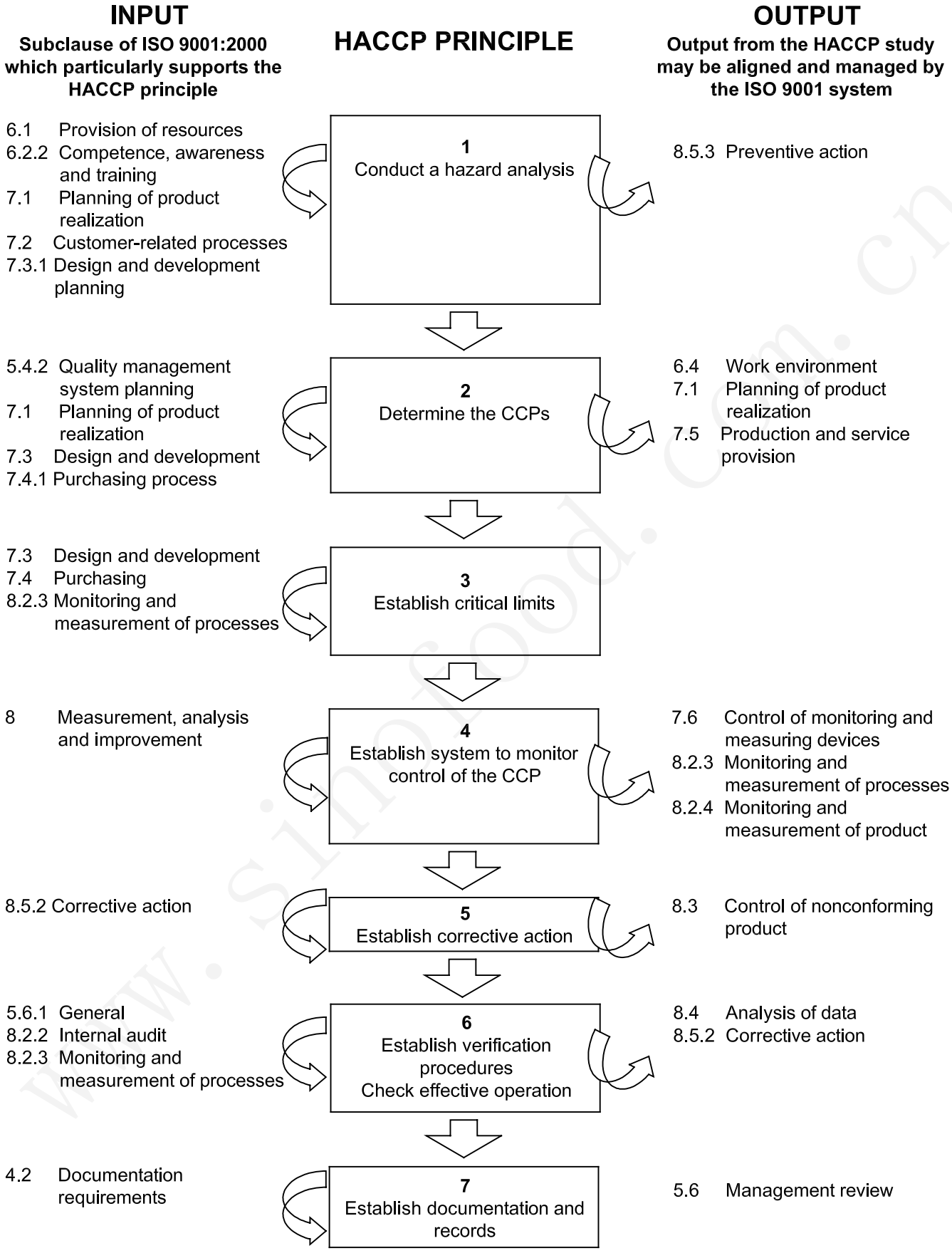

Figure A.1 — Linkages between the HACCP method and the ISO 9001 system

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