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**Sistemi vodenja kakovosti - Smernice za uporabo ISO 9001:2008 v proizvodnji pridelkov**

Quality management systems -- Guidelines for the application of ISO 9001:2008 to crop production

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Systèmes de management de la qualité -- Lignes directrices pour l'application de l'ISO 9001:2008 pour la production des récoltes

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# INTERNATIONAL STANDARD

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## Quality management systems — Guidelines for the application of ISO 9001:2008 to crop production

*Systèmes de management de la qualité — Lignes directrices pour  
l'application de l'ISO 9001:2008 pour la production des récoltes*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

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

ISO 22006 was prepared by Technical Committee ISO/TC 34, *Food products*.

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## Introduction

This International Standard gives guidelines to assist crop-producing farm operations in the application of ISO 9001:2008<sup>[1]</sup>.

In the context of this International Standard, a quality management system (QMS) is about how a farm operation is managed. The ultimate goal of implementing ISO 9001:2008<sup>[1]</sup> in a farm operation should be a combination of improved performance, financial results, and customer confidence and satisfaction. Farmers should focus on what is practical and work to implement a QMS with these results in mind. QMSs are built from existing activities and should not cause excessive paperwork or lack of flexibility. QMSs are not just for large farm operations. The guidelines given in this International Standard are also relevant to small farm operations. Adjustments in implementation and interpretation of this International Standard may be needed in small farm operations. While there may be effort involved in the implementation of ISO 9001:2008<sup>[1]</sup>, the ultimate goal is to achieve net benefits.

This International Standard specifies a set of activities that need to be included; however, it does not specify how to carry them out. Listing all of the farm operation activities on a flow diagram aids in determining whether they fit together well or whether some aspects need to be changed to make the processes work better. ISO 9001<sup>[1]</sup> and ISO 9004<sup>[3]</sup> are based on eight management principles — customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships — all of which can be used to improve the performance of the farm operation.

This International Standard does not include requirements specific to other management systems such as those particular to food safety, the environment or occupational health and safety, and does not imply that a farm operation is obliged to implement management systems for food safety, the environment or occupational health and safety.

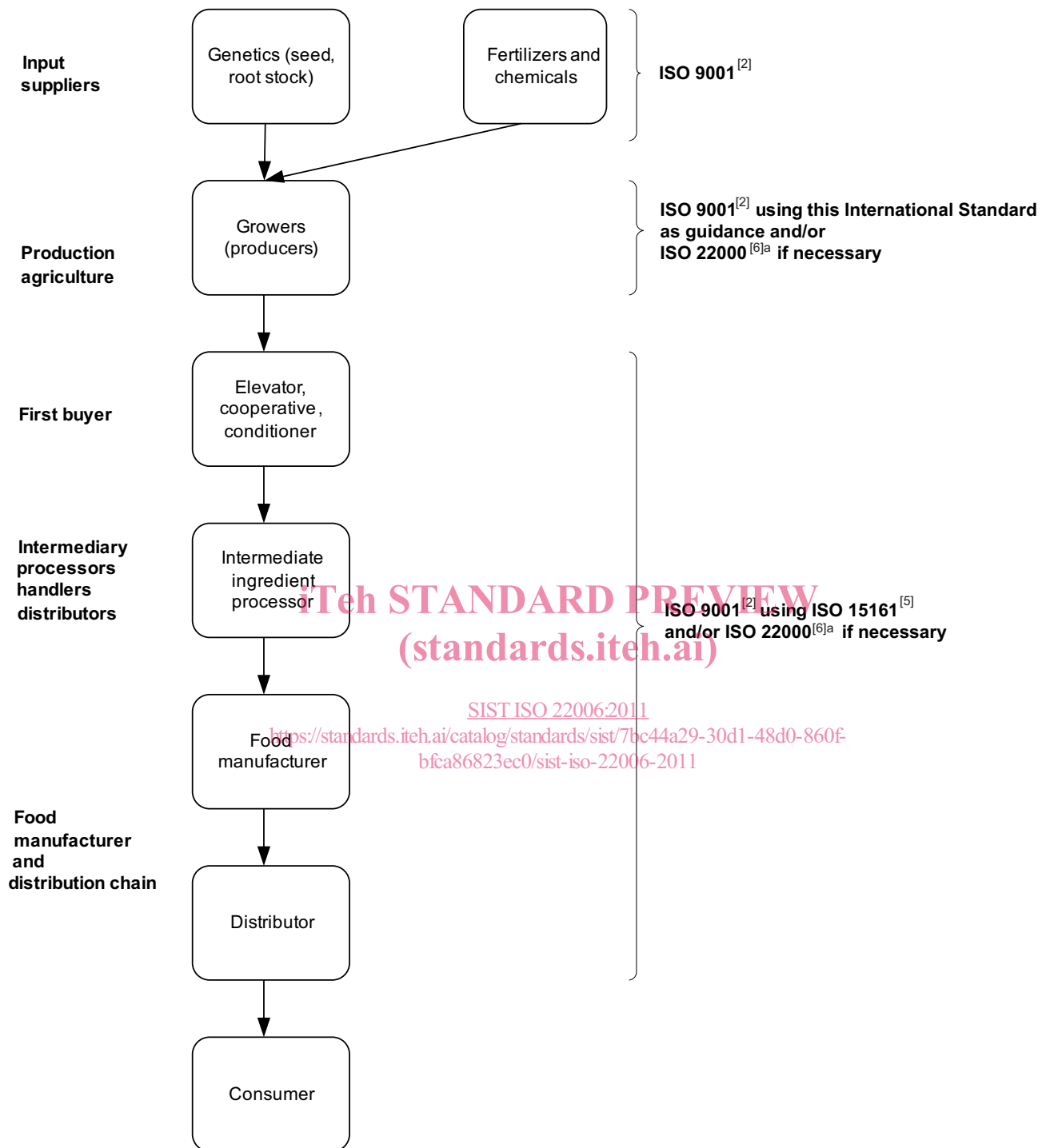
The complexity of documents, records, training, etc. depends on:

- a) the number of people working or involved in the farm operation, both on a permanent and seasonal basis;
- b) necessary skills or competencies to perform tasks;
- c) complexity of processes;
- d) number of distinct processes;
- e) types and complexity of tools and equipment used.

A QMS on its own does not lead to improvement of work processes or product or service quality. It is a means to achieve the objectives of the farm operation.

A schematic diagram of QMSs in food supply chains is given in Figure 1.

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NOTE ISO 9001:2008<sup>[1]</sup> and ISO 22000:2005<sup>[6]</sup> can be used for certification. This International Standard and ISO 15161:2001<sup>[4]</sup> are not intended for certification purposes.

<sup>a</sup> The requirements specified in ISO 22000<sup>[6]</sup> include those of a hazard analysis critical control plan (HACCP).

**Figure 1 — Example: quality management system in food supply chains**



The guidance provided clarifies the clause of the International Standard which it follows.

Examples have been used wherever possible to aid in understanding the requirements. Effective communications and familiarity with all parts of the farm operation may be all that is needed.

When reading ISO 9001:2008<sup>[1]</sup>, certain words and phrases have particular significance or meaning. Explanations of some of the more important of these are given below.

shall	Whenever this word occurs, there is an obligation to fulfil a requirement in order to demonstrate an effective QMS.
should/may	These words are not to be interpreted as requirements, but as recommendations or permissions.
appropriate	This word means that the organization can decide how the requirements apply to the farm operation. In some cases, the organization may decide that the guidance does not apply to the farm operation (see the exclusions in 1.2).

NOTE In this International Standard, “appropriate” and “suitable” are also used to indicate where such decisions are necessary. Also, “adequate” is used to indicate that the actions, decisions, etc. are fully sufficient to fulfil requirements.

**The ISO 22000 family of documents** focuses on food, feed and related supply chains, and at the time of publication includes:

- ISO 22000<sup>[6]</sup>, which is a food safety management system standard for the food manufacturing and distribution industries which was developed using HACCP and its prerequisites as a base. ISO 22000 covers the critical control points in the processes of food production, manufacture, and delivery relating to food safety;
- ISO 15161<sup>[4]</sup>, which is a guidance document for the application of ISO 9001:2000<sup>[1]</sup> for the food and drink industries;
- ISO/TS 22003<sup>[7]</sup>, which is a requirement document for organizations that provide food safety audit services;
- ISO/TS 22004<sup>[8]</sup>, which gives guidance on the implementation of ISO 22000:2005;
- ISO/TS 22005<sup>[9]</sup>, which is intended to be a tool for traceability that can be coordinated within the context of a broader management system (such as ISO 9001:2008<sup>[1]</sup>);
- ISO 22006 (this International Standard), which is not intended to duplicate the requirements of ISO 22000.

Additional documents in the ISO 22000 family are planned.

**This International Standard** has been designed to explain how ISO 9001:2008<sup>[1]</sup> applies to crop production (food, feed and non-food crops). This International Standard does not set any requirements, nor does it add to or otherwise change the requirements of ISO 9001:2008<sup>[1]</sup>. It is intended to provide help in the application of ISO 9001:2008<sup>[1]</sup>. This International Standard contains ISO 9001:2008<sup>[1]</sup> requirements in framed boxes. Guidance paragraphs specific to agricultural crop production follow the requirement boxes and are not intended to be requirements nor are they expected to be applicable to all farm operations. In addition, help boxes (see example below), highlighted by a grey tint, contain guidance or suggestions and are included in places where they are deemed appropriate.

**HELP** The clauses of ISO 9001<sup>[1]</sup> are written to be adapted to a wide range of organizational activities and sizes. To aid in the understanding of ISO 9001:2008<sup>[1]</sup> within the context of crop production, help boxes have been created. These help boxes are specifically designed to help with selected clauses throughout this International Standard. Help boxes may be of particular value when relating the ISO 9001:2008<sup>[1]</sup> requirements to a wide variety of farm operations including those that are large, small, mechanized or labour intensive. Help boxes are highlighted by a gray tint to differentiate them from other text used in this International Standard.

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This International Standard is consistent with ISO 22000<sup>[6]</sup> and ISO/TS 22005<sup>[9]</sup> requirements; it is not intended to duplicate the requirements of these published documents. This International Standard is not a guidance document for the application of ISO 22000<sup>[6]</sup> or ISO/TS 22005<sup>[9]</sup>.

This International Standard provides guidance to crop producers to aid in the preparation for ISO 9001:2008<sup>[1]</sup> certification or for self-declaration to ISO 9001:2008<sup>[1]</sup>. Text that is unique to this International Standard does not contain requirements associated with certification and registration. This International Standard is not intended to replace ISO 9004:2009<sup>[2]</sup> which addresses performance improvement. The use of this International Standard does not require the implementation of ISO 9004:2009<sup>[2]</sup>.

### 0.1 General

#### ISO 9001:2008, *Quality management systems — Requirements*

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

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

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, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004<sup>[2]</sup> have been taken into consideration during the development of this International Standard.

**Guidance:** ISO 9001:2008<sup>[1]</sup> specifies requirements for a QMS. When implementing ISO 9001:2008<sup>[1]</sup> using the guidelines in this International Standard, the organization should consider and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices including national, international or sector standards].

Processes employed may include: good agricultural practices (GAP) as well as good hygiene practices (GHP) as appropriate to the needs of the farm operation and its customers. This is particularly important for those practices that are generally acceptable for the specific crop, international, national, local regulations or specific customer needs.

## 0.2 Process approach

### ISO 9001:2008, *Quality management systems — Requirements*

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 determine and manage numerous linked activities. An activity or set of activities 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 to produce the desired outcome, 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 meeting 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 [2] 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 [2] 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.

**Guidance:** A process approach is a way of organizing and managing activities to create value for the customer and/or interested parties. Customers and interested parties may be either internal or external to the farm operation.

Each process has customers and/or other interested parties that are affected by the process and who define the required outputs according to their needs and expectations. Many of these processes are farm operation activities (see Annex A) while others provide support to these farm operation activities, such as inspection and employee training.

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For example, in cases where customers expect crops to be produced organically, the specific processes to analyse soil, select crop varieties, choose cropping season, etc., may be an “input” of the next process in the process approach. Inputs and intended outputs may be tangible (such as equipment, facilities) or intangible (such as energy or information). Outputs can also be unintended; such as waste or pollution.

All processes should be aligned with the objectives of the farm operation and be designed to add value, relative to the scope and complexity of the farm operation.

At the heart of ISO 9001:2008<sup>[1]</sup> is a conceptual model shown in Figure 2, which explains a process-based QMS including the main processes that are integral to its success.

The process approach allows management to identify the steps involved in an activity, devise a control strategy, and implement a system of continuous improvement. The driver for each process is the recognition of the customer's requirements, and their fulfilment. [The process approach is customer driven.] Note in Figure 2 that the customer is shown on both the left and the right. Figure 2 shows that what the customer wants enters on the left, and the crop that meets those requirements exits on the right.

The process flow that produces the crop is shown across the lower part of the figure (product realization). This box covers the various activities that the farm operation needs to do to produce a crop. Crops are the output from the farm operation.

In addition, Figure 2 shows the importance of obtaining information on customer “satisfaction” (the dotted arrow on the right points back to “measurement, analysis and improvement”). This and other measurements and evaluations become vital to the performance of a farm operation.

The “management responsibility” box is there to explain the importance of the leadership role in the QMS. Action is required on the information and data that show how well or poorly the system is working, and provides or adjusts the resources needed to maintain and improve it.

Resources are represented by the box at the left of the circle. Adequate resources help assure the quality of crops. Resources include, for example, land, workspace, equipment, materials (inputs), and people. Assurance that people are trained and competent to do the tasks required of them is also part of providing resources.

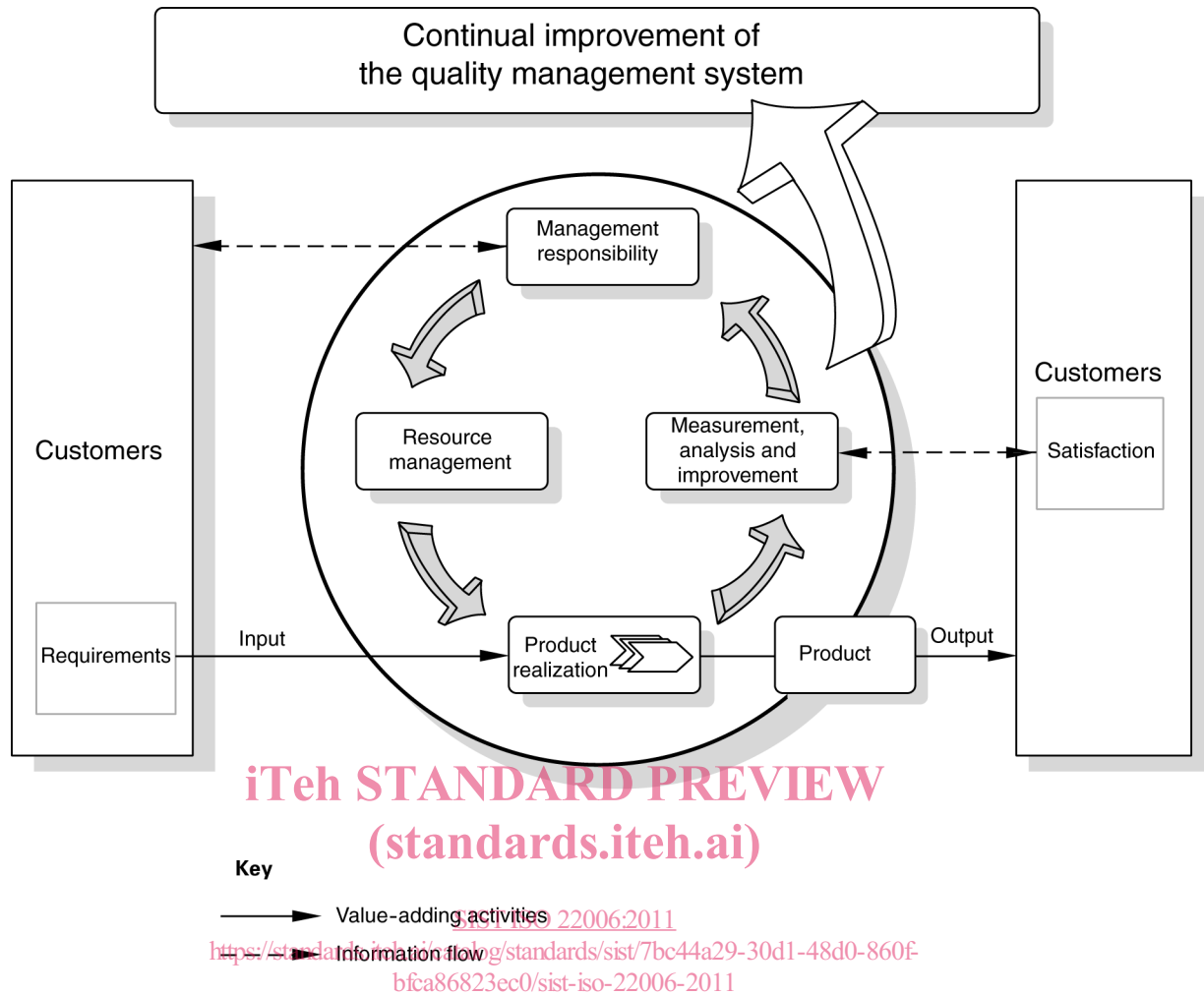


Figure 2 — Process-based QMS

### 0.3 Relationship with ISO 9004<sup>[2]</sup>

#### ISO 9001:2008, *Quality management systems — Requirements*

ISO 9001<sup>[1]</sup> and ISO 9004<sup>[2]</sup> are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001<sup>[1]</sup> 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.

[The following paragraph has been updated as ISO 9004:2009<sup>[2]</sup> was published after ISO 9001:2008<sup>[1]</sup>.]

ISO 9004:2009<sup>[2]</sup> provides guidance to management for achieving sustained success for any organization in a complex, demanding, and ever-changing environment. ISO 9004<sup>[2]</sup> provides a wider focus on quality management than ISO 9001<sup>[1]</sup>; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

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## 0.4 Compatibility with other management systems

**ISO 9001:2008, *Quality management systems — Requirements***

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004<sup>[3]</sup> to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008<sup>[1]</sup> and ISO 14001:2004<sup>[3]</sup>.

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.

**Guidance:** Other management systems' activities and processes may be associated with the paragraphs listed above. Wherever practical, these other management systems should be considered for integration whenever integration provides benefits to the farm operation and stakeholders or by contractual requirements. These management systems may include, for example, ISO 14001<sup>[3]</sup>, ISO 22000<sup>[6]</sup> and other management systems that may be relevant such as occupational health and safety. While opportunities for integration may occur in several numbered ISO 9001<sup>[1]</sup> clauses, document control, record keeping, management review, employee training, internal audits, corrective action and preventive action may provide the greatest cost and operational savings.

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# Quality management systems — Guidelines for the application of ISO 9001:2008 to crop production

## 1 Scope

This International Standard gives guidelines to assist crop producers in the adoption of ISO 9001:2008<sup>[1]</sup> for crop production processes. The term “crop” includes seasonal crops (such as grains, pulses, oilseeds, spices, fruit and vegetables), row-planted crops that are cultivated, perennial crops that are managed over a period of time, and wild crops that are not formally planted or managed. Horticultural crops provide an even broader range of types from annual and perennial fruits, vegetables, and ornamental flowering plants, to perennial shrubs and trees, and root crops. These diverse crops require a broad range of planting, cultivating, pest control, and harvesting methods and practices. Decisions regarding planting, growing, and harvesting activities can be similar, although specific steps can be quite different when considering the range of crops.

This International Standard gives guidelines on the use and application of ISO 9001:2008<sup>[1]</sup> to the establishment and management of a quality management system (QMS) by an organization involved in crop production.

This International Standard is not intended to change, add or reduce the requirements of ISO 9001:2008<sup>[1]</sup>, nor is it intended for certification.

Further down the supply chain, in manufacturing processes, the language of ISO 9001:2008<sup>[1]</sup>, ISO 15161<sup>[4]</sup>, or ISO 22000<sup>[6]</sup> is considered more appropriate. The need for an ISO 9001:2008<sup>[1]</sup>-based system containing agricultural terminology became apparent due to difficulties in the interpretation of the language of ISO 9001:2008<sup>[1]</sup> for crop production applications.

### 1.1 General

#### ISO 9001:2008, *Quality management systems — Requirements*

This International Standard specifies requirements for a quality management system where an organization:

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term “product” only applies to

- a product intended for, or required by, a customer, and
- any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.