

# ISO 22000:2018 – A guide to the new requirements.



## **Overview**

This guide will explain some of the most important changes in the new ISO22000:2018 standard. While this client information note only gives a brief overview of the most significant requirements, it is highly recommended to review the requirements in detail in the official ISO 22000 scheme document, which can be found at [www.iso.org](http://www.iso.org).

## **Transition**

ISO 22000:2018 was published on June 19, 2018. The revised version cancels and replaces ISO 22000:2005. Organisations have three years from the date of publication to transition to the new version. This means that you have until 18 June 2021 to transition and comply with ISO 22000:2018 to remain ISO 22000 certified.

As we are waiting for announcements from the International Accreditation Forum (IAF), the global association of accreditation bodies, we cannot yet provide further information on the exact details for the transition to the new version. Further information about timescales for transition to the revised ISO 22000 standard will follow.

The ISO 22000 standard is a major part of the FSSC 22000 certification standard. The FSSC foundation has informed us that they will announce a detailed plan on how to include the new ISO 22000 standard in its FSSC 22000 normative requirements in October 2018.

## **Main changes**

The major changes to the standard include modifications to its structure as well as clarifying key concepts such as:

- The high-level structure: In order to make life easier for businesses using more than one management system standard, the new version of ISO 22000 will follow the same structure as all the other ISO management system standards, the High Level Structure (HLS).
- The risk approach: the standard now includes a different approach to understanding risk. Not only addresses it risk-based thinking on an operational level, but also on an organisational level.
- The PDCA cycle: the standard clarifies the Plan-Do-Check-Act cycle, by having two separate cycles in the standard working together: one covering the management system and the other covering the principles of HACCP
- The operation process: a clear description is given of the differences between key terms such as: Critical Control Points (CCPs), Operational Prerequisite Programmes (OPRPs) and Prerequisite Programmes (PRPs)

## **Implementation of the High Level Structure (HLS)**

In 2012, ISO decided that all management systems standards should be adjusted to the extent that they have as many identical clauses, titles, sequence of clauses, definitions and identical text as possible. This new format will help to standardize the used terms and management principles.

The generic parts of the management system norm are what ISO calls the High Level Structure (HLS). This includes the clauses with requirements that have been standardized for all these types of standards. The classification is also standardized according to the following chapters that come back in every ISO standard:

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

In comparison with ISO 22000:2005 you now have to consider seven (clause 4-10) main clauses, instead of five.

### **Risk-based thinking on two levels**

The incorporation of the HLS into ISO 22000:2018 drives a risk-based approach to thinking and acting. The standard distinguishes between risk at the operational level and the organisational level of the management system.

Risk at the **operational** level refers to the HACCP principles. The subsequent steps in HACCP are the necessary measures to prevent, or reduce, hazards to acceptable levels to ensure food is safe at the time of consumption. This risk approach in ISO 22000:2018 is still in full alignment with the HACCP principles from Codex Alimentarius and is not new in comparison with ISO 22000:2005.

Risk at the **organisational** level, however, is a new approach to risk in ISO 22000 and requires organisations to consider risk from the beginning and throughout the entire food safety management system (FSMS). This greater focus on risk throughout the business processes is aimed at taking advantage of opportunities and preventing undesirable effects.

### **How will this affect the FSMS at your company?**

The adoption of risk-based thinking and the HLS has resulted in some key changes to the standard. A brief overview of the most significant changes is given below of clauses 4-7 and 9-10. Clause 8 will be discussed separately under “The operation process”.

### **Context of the organization (Clause 4)**

This is where the concept of organisational risk-based thinking is first introduced. It requires you to determine relevant issues (both external and internal) that can have negative or positive impact on your FSMS, such as culture, changes in demographics and food fraud. Additionally, you are required to consider and understand the needs and expectations of “interested parties” (i.e. stakeholders), such as customers, regulatory authorities and competitors.

### **Leadership (Clause 5)**

Most of the requirements in this clause were already available through section 5 Management Commitment in ISO 22000:2005. However, the responsibilities of top management have been extended – there are now more areas where top management needs to demonstrate their involvement and engagement with the FSMS. A separate section has been added for communicating the food safety policy.

### **Planning (Clause 6)**

In this section ISO wants you to do some strategic planning. In terms of risk-based thinking you are required to identify which issues (as determined in clause 4) have the greatest risk for your organisation and which provide opportunities. Once you have done that, you have to plan actions on how you are going to address these risks and opportunities. Strong focus is also placed on the objectives of the FSMS. These should be measurable, monitored, communicated, in line with the policy of the FSMS and updated when needed.

### **Support (Clause 7)**

There are no significant changes, but you need to consider new requirements related to communications which have been added, including determination of what, when and how to communicate. There are also less strict requirements regarding document control. Furthermore, suppliers and sub-contractors need to be evaluated, selected, monitored and re-evaluated according to defined criteria.

## Performance evaluation (Clause 9)

There are extra topics to be discussed during management review meetings, such as changes in the context, review of risks and opportunities and the effectiveness of actions taken to address them, performance of suppliers,

complaints of interested parties and the adequacy of resources.

There is also a new clause that requires you to analyse and evaluate data and information arising from monitoring and measurement, including the results of verification activities. The results shall be maintained as documented information.

## Improvement (Clause 10)

No significant changes in comparison with ISO 22000:2005. There is however a new clause where you are required to react whenever nonconformity occurs, by taking action to control and correct it, and deal with the consequences.

## The operation process (Clause 8)

The operation process (Clause 8) is dedicated to operational planning and control related to the HACCP plan. The clause opens with the requirement to implement processes to address the risks and opportunities as determined in Clause 6.

In Clause 8 you are further required to manage the operational processes, such as PRPs, traceability, emergency preparedness and response, hazard control, verification and control of product and process nonconformities. The following major changes are introduced:

- When selecting and/or establishing PRPs, the applicable technical specification in the ISO/TS 22002 series should be considered.
- Traceability requirements have been added and the system shall be tested and verified for its effectiveness.
- Extra criteria for handling emergencies and incidents have been added. You are now required to periodically test procedures where practical.
- Now also to be added to the required documented flow diagrams are: processing aids, packaging and utilities.
- Regarding the characteristics of raw materials, ingredient and packaging, the source needs now also to be defined and documented.

A major change in the standard is the introduction of **significant** food safety hazards. These are the hazards, identified through hazard assessment (likelihood × severity), which have been identified as being significant and which need to be controlled by control measures. Control measures are now related only to significant hazards and not managed at a PRP level. Control measures are now categorized to be managed as OPRPs or at CCPs. In other words: if you have a significant hazard you have to have either an OPRP or a CCP in place as a control measure.

Additionally, ISO has enhanced and clarified the differences between a CCP and OPRP. The words underlined emphasize the differences between the two:

### **Critical control point – CCP:**

Step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enables the application of corrections.

### **Operational prerequisite programme – OPRP:**

Control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product.

It has been made very clear that a CCP is now explicitly related to a ‘step in the process’, such as pasteurizing, sieving and metal detection. Whereas an OPRP relates to a control measure or combination of control measures, such as specific cleaning activities or specific glass breakage procedures.

In addition, a CCP has a critical limit and an OPRP an action criterion, which is a measurable or observable specification for the monitoring of an OPRP.

### **PDCA approach on two levels**

The standard clarifies the Plan-Do-Check-Act cycle. The illustration below shows that there are two separate cycles in the standard working together: one covers the management system and the other, covers the principles of HACCP.

The first covers the overall frame of the FSMS (Clause 4-7 and Clause 9-10). The other level (operational planning and control) covers the operational processes within the food safety system as described in Clause 8.

Communication between the two levels is therefore essential.

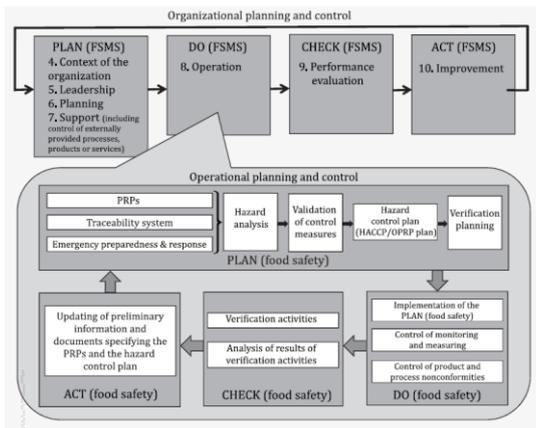


Figure 1: Illustration of the PDCA cycle at two levels (ISO22000:2018)

### Changes to terms and definitions

With regards to the terms and definitions section of the new ISO 22000:2018, quite a few changes have been made. In comparison to the previous version (17 definitions) 45 definitions are now in place.

Examples of added items cover: acceptable level, contamination, interested parties, nonconformity and objective.

Examples of changed items are: distinction between food, feed and animal food, significant food safety hazard, control measure (now linked to significant food safety hazard only), validation (linked to significant food safety hazard), action criterion for OPRP (this used to be limit), and as discussed in this note, the difference between a CCP and OPRP.

Additionally the term 'HACCP plan', which in ISO 22000:2005 refers only to CCPs, is no longer applicable. In the new standard the term *Hazard control plan* has been added and shall include information regarding each CCP and/or OPRP, such as critical limit(s)/action criteria, corrections to be made, records of monitoring and responsibilities.

### Where should you start?

Start with the published version of the revised standard and focus on the areas that are completely new or have been revised. Those are the areas that are likely to be included in your transition plan. Also, make sure that food safety managers and internal auditors understand the differences that the HLS (common text and structure) will bring to the design, operation and performance of your FSMS and any other management system standards in your organisation.

Begin formalising a transition plan and process and ensure that top management is involved from the start.

### Further information

To find out more about how LR can help you to increase performance and reduce risk, please visit our website [www.lr.org](http://www.lr.org). From here you can also visit one of our country specific websites to find out about Lloyd's Register in your country.



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