

ISO 22000

**Food Safety Management Systems
Gap Analysis**

ISO 22000:2018 Gap Analysis

The ISO 22000:2018 Food Safety Management Systems standard helps organisations monitor and improve the production of food and food products in a systematic and consistent manner.

ISO 22000:2018 is the revision of the 2005 standard and was published in June 2018. ISO 22000:2005 will be withdrawn in June 2021. The main objective of the revision was to align the standard with other management system standards.

This Gap Analysis allows you to determine where you are on your journey from ISO 22000:2005 to ISO 22000:2018. It may also prove useful if you have no FSMS at all.

This document, which highlights clauses which were not previously covered or have significantly changed from ISO 22000:2005, should be used in conjunction with the ISO 22000:2018 standard.

You should use this Gap Analysis as an aid towards confirmation that your management system complies with the requirements of ISO 22000:2018.

Please note that this gap analysis is for your own internal use only and should not be returned to Global Standards

Introduction

NEW 0.1 – General

This section explains the benefits of a food safety management system (FSMS) and references the Plan Do Check Act (PDCA) cycle which underpins the management system. This was not in the previous version of the standard.

NEW 0.2 – FSMS Principles

This is a new subsection. Principles common to an ISO management system have been added.

NEW 0.3 – Process approach

This is a new subsection. PDCA cycle and risk-based thinking have been included and their relations to HACCP.

NEW 0.4 – Relationships with other management system standards

This is a new subsection and explains how the new version of the standard integrates better with other management systems.

NEW Clause 4 - Context of the Organisation

This clause underpins the 2018 standard and establishes the context of the Food Safety Management System (FSMS).

It gives you the opportunity to identify all internal and external issues that are relevant, and may affect, the strategic direction of the organisation and the FSMS. You will also need to identify the needs and expectations of all interested parties that are relevant to your management system. These groups can include workers, customers, suppliers, shareholders, sub-contractors, regulatory groups etc. Finally, you'll need to establish, implement, maintain and continually improve the FSMS.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
4.1 Understanding the organisation and its context	<p>You will need to be able to demonstrate that you have determined external and internal issues that are relevant to your organisation's purpose and that affect its ability to achieve the intended outcome(s) of its FSMS. Depending on the size and/or complexity of operations, a simple approach such as asking "what if" questions can be useful, or more structured tools such as SWOT (Strengths, Weaknesses, Opportunities, Threats) or PESTLE (Political, Economic, Social, Technological, Legal, Environmental) analysis can be used.</p> <p>Please provide information on:</p> <ul style="list-style-type: none"> • The internal and external issues relevant to your organisation • The process of monitoring the internal and external issues and how you have considered the impact of any changes to the issues 						

NEW Clause 4 - Context of the Organisation

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
NEW 4.2 Understanding the needs and expectations of workers and other interested parties	<p>You need to demonstrate that you have identified, monitored and reviewed all interested parties that are relevant to the FSMS and its requirements.</p> <p>Please provide information on:</p> <ul style="list-style-type: none"> • Other interested parties (in addition to workers) that are relevant to the FSMS • The needs and expectations of workers and other interested parties • Which of these needs and expectations are or could become legal requirements 						
4.3 Determining the scope of the FSMS	<p>The standard requires you to consider the context of the organisation (Clause 4.1) and interested parties (Clause 4.2). You need to identify any boundaries to your scope and applicability of the system. This could include the whole organisation or specific functions. The word “services” has been added and “activities that could have an influence on the safety of the end products”.</p> <p>Please provide information on:</p> <ul style="list-style-type: none"> • The boundary and applicability of the scope • Products and/or services included in your FSMS • Planned or performed work-related activities • If the scope changed and if so how • Any identified activities which could have an influence on the safety of the end products 						

NEW Clause 4 - Context of the Organisation

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
4.4 Food Safety Management System	<p>To comply with this clause, you need to establish, implement, maintain and continually improve your FSMS. This requires the adoption of a process approach. Although every organisation will be different, documented information such as processes or written methods and procedures could support this.</p> <p>Please provide information on the process-based system including:</p> <ul style="list-style-type: none"> • A list of processes, process sequences and interactions • Methods to manage the processes (including those of procured services) • Resources to support processes • Process responsibilities and authorities • Risks and opportunities of each process • How you ensure the system improves the processes and the FSMS 						

Clause 5 - Leadership and Commitment

Top management and their workers are required to be involved in the input and operation of the FSMS. They must ensure that the requirements are integrated into the organisation's FSMS processes and that the policy and objectives are compatible with the strategic direction of the organisation. The standard requires top management to take overall responsibility and accountability for the FSMS and the overall safety of the end products.

Finally, the clause places requirements on top management to assign relevant responsibilities and to support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
5.1 Leadership and commitment	<p>The requirements within this clause are generally self-explanatory. You need to provide information on how top management ensures the FSMS is compatible with the strategic direction as well as taking responsibility and promoting a food safety culture to ensure that the management system achieves its intended outcome(s).</p> <p><i>Please provide information on how top management ensures the FSMS achieves the intended results.</i></p>						

Clause 5 - Leadership and Commitment

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
5.2 Policy	<p>Top management needs to establish, implement and maintain an FSMS policy that includes a commitment to satisfy applicable food safety requirements, including statutory and regulatory requirements and mutually agreed customer requirements related to food safety. It should be appropriate to the purpose, size and context of the organisation and to the specific nature of its FSMS risks and opportunities. The policy must be communicated and set out the framework for establishing measurable food safety objectives and targets.</p> <p><i>Please provide information on when the policy was last reviewed/amended and details of any changes required to meet the requirements of Clause 5.2.</i></p>						
5.3 Organisational roles, responsibilities and authorities	<p>Top management needs to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organisation. This shall include the appointment of a foodsafety team and a food safety team leader. This must be maintained as documented evidence.</p> <p><i>Please provide information on how top management has established and communicated responsibilities and authorities for the effective operation of the FSMS and how reporting on the performance of the management system is communicated to top management.</i></p> <p>All persons shall have the responsibility to report problem(s) with regards to the FSMS to identified person(s).</p>						

Clause 6 - Planning

There is a focus on ensuring that planning is considered within the context of the organisation and interested parties. There is a requirement to identify risks and opportunities, and the impact these may have on the FSMS and how you plan to address these.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
NEW 6.1 Actions to address risks and opportunities	<p>This clause requires you to identify the risks and opportunities that need to be managed. Planning should be proportionate to the level of risk identified and the objectives of the organisation as a whole, taking into account the context of the organisation, including the needs and expectations of relevant interested parties. Whilst the organisation should consider all potential risks to food product safety, it is not necessary to keep detailed documented information for all of them. The focus should be on those hazards which are most likely to occur and/or have the most impact and lead to the most significant risks. New requirements have been added related to determining risks and opportunities, actions to address them and their planning. An important note has been added (in 6.1.1) to clarify the concept of risks and opportunities in the context of the standard (events and their consequences relating to performance & effectiveness of the FSMS).</p> <p><i>Please provide information on how the organisation determines and assesses the risks that can affect food product safety and the needs and expectations of interested parties, and how it manages these risks, including hazard identification, legal requirements and performance assessment.</i></p>						

Clause 6 - Planning

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
6.2 Objectives of the FSMS and planning to achieve them	<p>The organisation must establish food safety objectives that are linked to the food safety risks, opportunities and performance criteria which the organisation has identified as having the highest priority. These should be proportionate to the scale, complexity and nature of the organisation.</p> <p><i>Please provide information on how the organisation ensures food safety objectives are relevant to the organisation's policy, how they are communicated and how the results are to be evaluated.</i></p>						

Clause 7 - Support

You need to have the right support to ensure the FSMS can function effectively, including the resources, competence, communication, awareness and requirements for documented information to meet your goals.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
7.1.1 General	Consideration of the capability and constraints of existing resources has been added, otherwise there is no change.						
7.1.2 People	The organisation shall ensure that persons necessary to operate and maintain an effective FSMS are competent (see 7.2). Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.						
7.1.3 Infrastructure	There has been a slight wording change only.						
7.1.4 Work environment	There has been a slight wording change only.						

Clause 7 - Support

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
NEW 7.1.5 Externally developed elements of the FSMS	When an organisation establishes, maintains, updates and continually improves its FSMS by using externally developed elements of an FSMS, including PRPs, the hazard analysis and the hazard control plan), the organisation shall ensure that the provided elements are: a) developed in conformance with requirements of the standard b) applicable to the sites, processes and products of the organisation c) specifically adapted to the processes and products of the organisation by the food safety team d) implemented, maintained and updated as required by this document e) retained as documented information						
NEW 7.1.6 Control of externally provided processes, product or service	Requirements for evaluation, selection, monitoring of performance/re-evaluation of external providers have been added as well as requirements for adequate communication. Performance of external providers has also been added as an input for Management Review. <i>Please provide information on how the organisation is able to demonstrate that they meet these requirements.</i>						

Clause 7 - Support

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
NEW 7.2 Competence	<p>You need to determine the necessary competency of people (including external providers) and ensure that these standards are met and maintained. It is important that both the organisation and individual workers understand what it means to be 'competent' and how this can be achieved and demonstrated. Competence of the food safety team has been added as well as staff responsible for operation of the food safety plan.</p> <p><i>Please provide information on how the organisation ensures that competence requirements are established, and that staff at all levels have the relevant competence to carry out their activities in support of the FSMS and to ensure its effectiveness.</i></p>						
7.3 Awareness	<p>This clause covers food safety awareness and staff should also be made aware of the food safety policy, the objectives of the FSMS, their individual contribution to the FSMS and the consequences of not conforming with it.</p> <p><i>Please provide information on how staff are made aware of the FSMS objectives, policy and FSMS performance and how it affects them and how their own actions can affect it.</i></p>						

Clause 7 - Support

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
7.4 Communication	<p>This includes both internal and external communications relevant to the FSMS. You will need to think about what you need to communicate, when, to whom and how.</p> <p><i>Please provide information on how this is achieved.</i></p>						
7.5 Documented information	<p>The standard refers to documented information being held in different formats and can be whatever suits the organisation and the task at hand, e.g. electronic spreadsheets, notes on smart phones, photographs, traditional log books or work instructions, online instruction videos. For many organisations, a mix of different types of documented information work well.</p> <p><i>Please provide information on how the organisation will create, update, control and retain the FSMS documented information.</i></p>						

Clause 8 - Operation

This clause (which now has a new title) provides guidance on the operational planning and control necessary for the FSMS. It includes eliminating hazards and reducing food safety risks, managing change, emergency preparedness and response as well as requirements regarding outsourcing, procurement and contractors.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
8.1 Operational planning and control	<p>Processes needed to meet requirements of the organisation need to be planned, implemented and controlled, as do the actions identified in Clause 6. The organisation needs to exercise control in relation to the management of change, elimination of hazards and reduction of food safety risks (hierarchy of control) and procurement.</p> <p><i>Please provide information on how this is achieved.</i></p>						
NEW 8.2 Pre-requisite programs	<p>The organisation shall establish, implement, maintain and update PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment. Supplier approval and product information/consumer awareness have been included in the list of minimal PRP needed by the organisation. PRP's documented information shall now also specify their selection, applicable monitoring and verification.</p> <p><i>Please identify the PRP's relevant to your organisation.</i></p>						

Clause 8 - Operation

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
NEW 8.3 Traceability system	The wording has been changed. Minimum requirements when establishing a traceability system have been added (including reworking). Requirement for verification and testing of the effectiveness of the traceability system has been added. A note has been added regarding the reconciliation of quantities of end products and ingredients. <i>Please provide information on how the additional requirements are met.</i>						
8.4 Emergency preparedness and response	This clause requires the organisation to establish, implement and maintain a process(es) needed to prepare for and respond to potential emergency situations. Please provide information on how you intend to: <ul style="list-style-type: none"> • Establish a planned response to emergency situations • Provide adequate resources for the provision of training • Test and evaluate emergency response performance <i>Documented information required and procedures need to be established.</i>						
8.5 Hazard control	The organisation must have in place processes and procedures to identify and control hazards including hazard analysis, flow diagrams, implementation and maintenance of hazard control plans, determination of critical limits and action criteria and monitoring at CCP's. Documented information is required. <i>Please provide information on how compliance with this clause will be demonstrated.</i>						

Clause 9 - Performance Evaluation

Requirements for monitoring, measurement, analysis and evaluation are covered and you'll need to consider what needs to be measured, methods employed, when data should be analysed and reported on and applicable legal requirements. Documented information that provides evidence of this must be retained. Describe how you meet these requirements.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
9.1 Monitoring, measurement, analysis and evaluation	<p>You need to determine when monitoring and measurement will be performed and when the results will be analysed and evaluated.</p> <p><i>Please provide information on how and when the organisation intends to monitor and evaluate the FSMS performance that is determined by the context and the scope of the FSMS.</i></p>						
9.2 Internal audit	<p>You need to define the audit criteria and ensure that the results of the audits are reported to "relevant management". Please provide information on how your organisation addresses internal audit requirements. The results of internal audits must be reported to the food safety team and relevant management.</p>						
9.3 Management review	<p>Requirements include the consideration of changes in external and internal issues that are relevant to the FSMS. Please provide information on how your organisation addresses these changes. Management review now includes actions and decisions related to continual improvement opportunities.</p>						

Clause 10 - Improvement

Organisations should determine and identify opportunities for improvement, such as improved processes, to achieve continual improvement in the long term.

Clause	Plain English Description	Yes	No	Evidence/Corrective Action Required	Owner	Target Date	Date Completed
10.1 Non-conformity and corrective action	Where non-conformity occurs the organisation shall react to the non-conformity, evaluate the need for action to eliminate the cause and implement any action needed. Changes to the FSMS shall be made where needed. Documented information is required. <i>Please provide information on how the organisation intends to achieve this.</i>						
10.2 Continual improvement	The organisation shall continually improve the suitability, adequacy and effectiveness of the FSMS. <i>Please provide information on how the organisation intends to achieve this.</i>						

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