WEBINAR: ISO 22000:2018 TRANSITION

Maria Constable

24th August 2021

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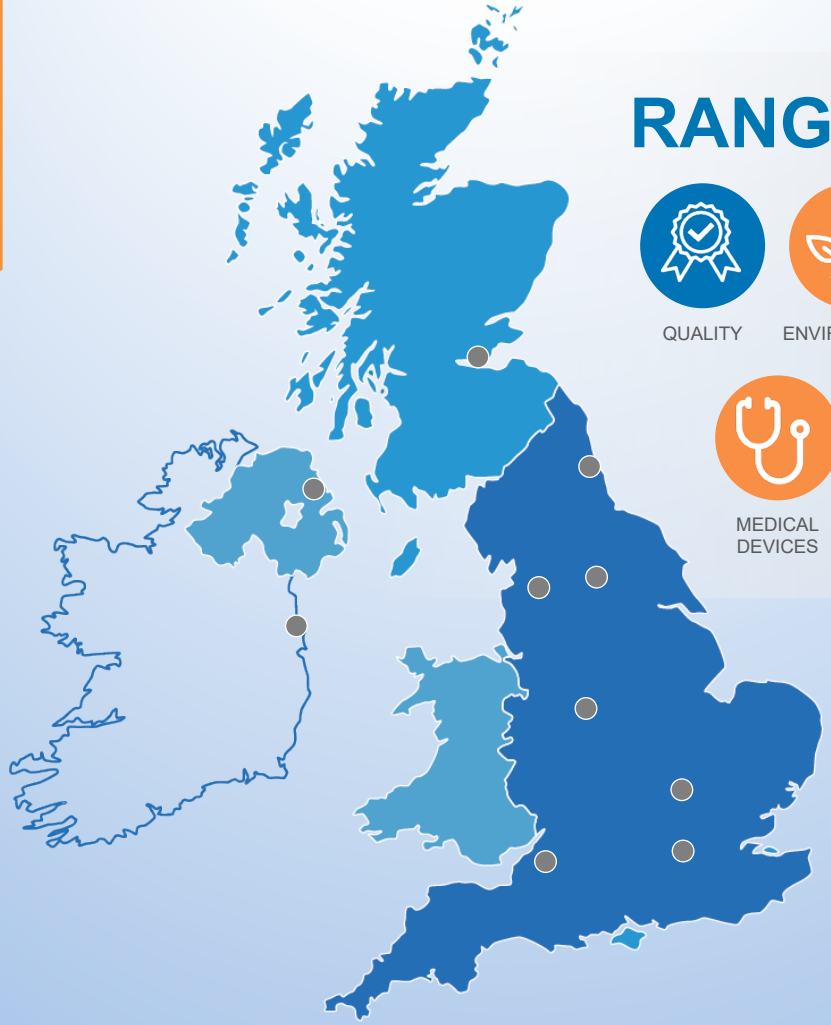

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YOUR PRESENTER

KEY INFO

- 45 minute webinar
- Questions in the chat box
- Q&A at the end
- Recording of webinar circulated shortly

Maria Constable

ISO 22000, FSSC 22000

Food Certification Manager

Maria has worked in the certification industry for 15+ years, specialising in food safety for the food chain from farm to fork and worked with many different Standard owners, clients and stakeholders. Her role as Food Certification Manager is to oversee the accreditation and certification of NQA's Food Safety Management Systems Standards globally whilst ensuring technical knowledge and changes within the industry are cascaded accordingly to clients, stakeholders and NQA's auditors.

WHAT WILL YOU LEARN?

- You will receive an overview of the ISO 22000:2018 Food Safety Standard
- Tips and techniques for managing the standard and ensuring continual improvement
- Interpretations of the new or updated clauses
- How to prepare for your transition to ISO 22000:2018
- Common queries or issues when auditing or implementing ISO 22000

WHAT IS ISO 22000?

ISO 22000 was initially published in 2005 as a response to:

- A number of successive food crises, such as the mad cow disease, adulteration of wines with ethylene glycol and its derivatives etc
- The globalisation of food supply chains creating uncertainty with regard to the origin of food products
- The need from the food industry to demonstrate that systems were established and operating in accordance to applicable laws and the requirements specified by the Codex Alimentarius
- A need to facilitate the harmonisation of international food safety regulations

REVISION & TRANSITION TIMELINE

Revision steps

The revision of ISO 22000:2005 commenced in September 2014. All participants, the technical committee and national mirror committees, agreed on the need to revise the standard with the purpose of addressing emergent food safety challenges.

After a long period of discussions, in June 2018 ISO 22000:2018 was published. One of the main motivations for its revision was the alignment of the strategic direction of an organization with its food safety management.

Additionally, the adoption of the Annex SL structure allows an easy integration with other international standards such as ISO 9001, ISO 14001 and ISO 45001, making a smooth road for auditors and auditees.

ISO 22000 was reissued in 2018 with an original deadline to transition by June 2021. This deadline has been extended until 31st December 2021 and many certified organisations have taken this opportunity to transition later in 2021!

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ANNEX SL

High level structure

Annex SL consists of 10 core clauses:

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

The common terms and core definitions cannot be changed.

Requirements may not be removed or altered, however discipline-specific requirements and recommendations may be added.

All management systems require a consideration of the context of the organisation, a set of objectives relevant to the discipline, in this case food safety, and aligned with the strategic direction of the organisation; a documented policy to support the management system and its aims; internal audits and management review.

Where multiple management systems are in place, many of these elements can be combined to address more than one standard.

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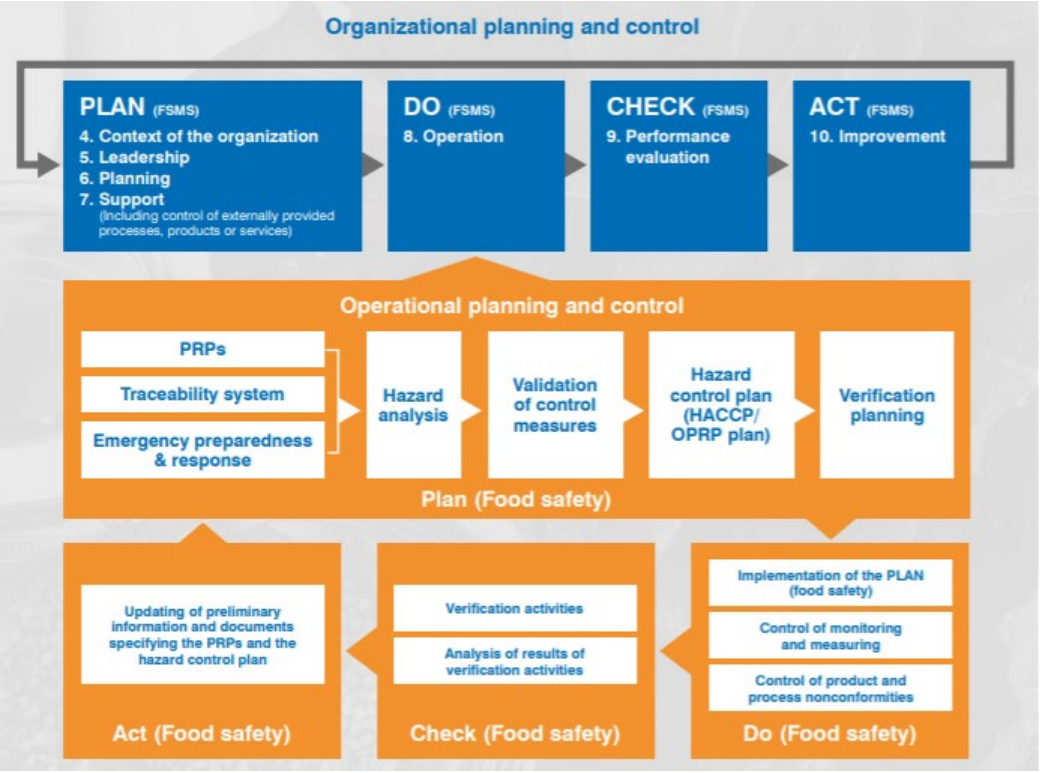
PDCA

The recently updated ISO 22000 requires that in addition to the organisational Plan-Do-Check-Act (PDCA) cycle, also known by the Deming Cycle wheel or Shewhart cycle, and following the high level structure, another PDCA cycle must coexist covering the operational processes within the food safety system.



STRUCTURAL CHANGES

2005:

- Interactive Communication
- System management
- Prerequisite programmes
- Hazard Analysis and Critical Control Points (HACCP) principles

2018: (Retains the above whilst adding the common ISO management system principles)

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

PROCESS BASED THINKING/AUDIT

"Process: set of interrelated or interacting activities which transforms inputs to outputs" ISO 22000:2018 Terms and Definitions.

"Understanding and managing interrelated processes as a system contributes to the organisation's effectiveness and efficiency in achieving its intended results."

This also applies where processes, or parts of processes, are outsourced. Understanding exactly how this affects or could affect the outcome and communicating this clearly to the business partner (providing the outsourced product or service) ensures clarity and accountability in the process.

The final process step is to review the outcome of the audit and ensure the information obtained is put to good use. A formal Management Review is the opportunity to reflect on the performance of the FSMS and to make decisions on how and where to improve. The Management Review process is covered in more depth in Section 9 – Performance Evaluation.

RISK BASED THINKING/AUDITS

The best way to consider frequency of an activity is to look at the risks involved in the process.

Any process which is high risk, either because it has a high potential to go wrong or because the consequences would be severe if it did go wrong, then you will want to audit/conduct that process more frequently than a low risk process.

How you assess risk is entirely up to you.

ISO 22000 doesn't dictate any particular method of risk assessment or risk management, apart from addressing this concept on two levels, organisational and operational levels.

However, the standard requires you to describe and retain as documented information the methodology used when conducting a risk assessment.

DEFINITIONS

This section of the Standard sets out the terms and definitions that are used in the Standard which may need further clarification in order to apply the Standard to a particular organisation.

There are some definitions to mentioned due to the changes on the 2018 version:

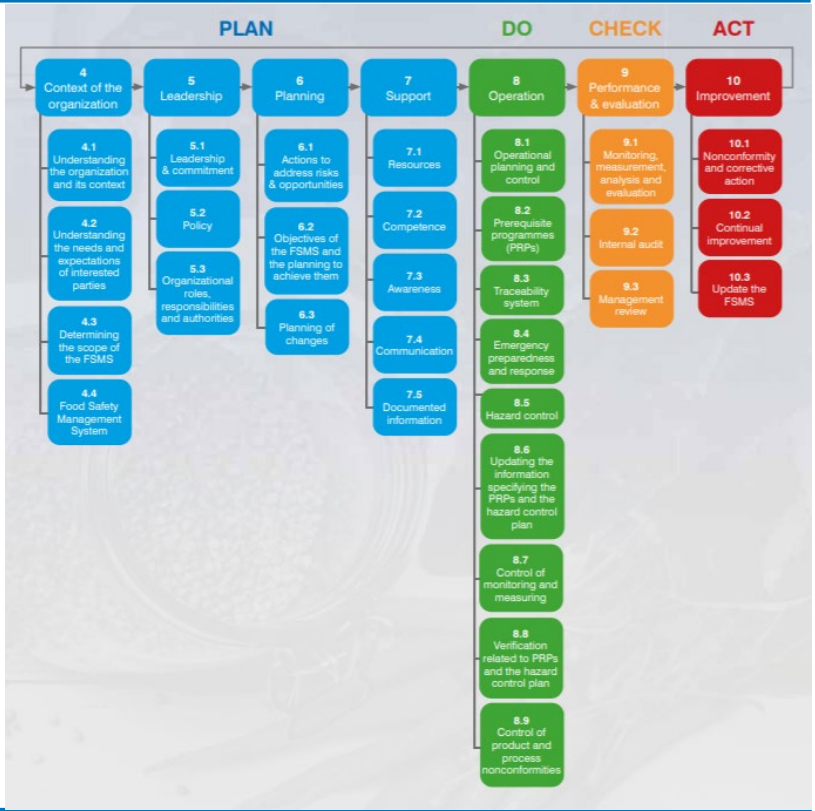
- Significant food safety hazard
- Control measures
- Action criterion
- Competence
- Interested party
- Outsource
- Risk

Additionally, some terms have been redefined in order to provide a better understating to users: ‘Critical Control Point (CCP)’ ‘Operational Prerequisite Programme (OPRP)’ ‘Monitoring’ Validation’ ‘Verification’.

STANDARD REQUIREMENTS

Sections, 4 to 10, provide the requirements of the Standard.

When reading the Standard it is important that as with past ISO 22000 versions, the word **“shall”** indicates the **mandatory requirements** that an organisation must meet and external auditors, such as NQA, are required to verify conformance and effectiveness against.



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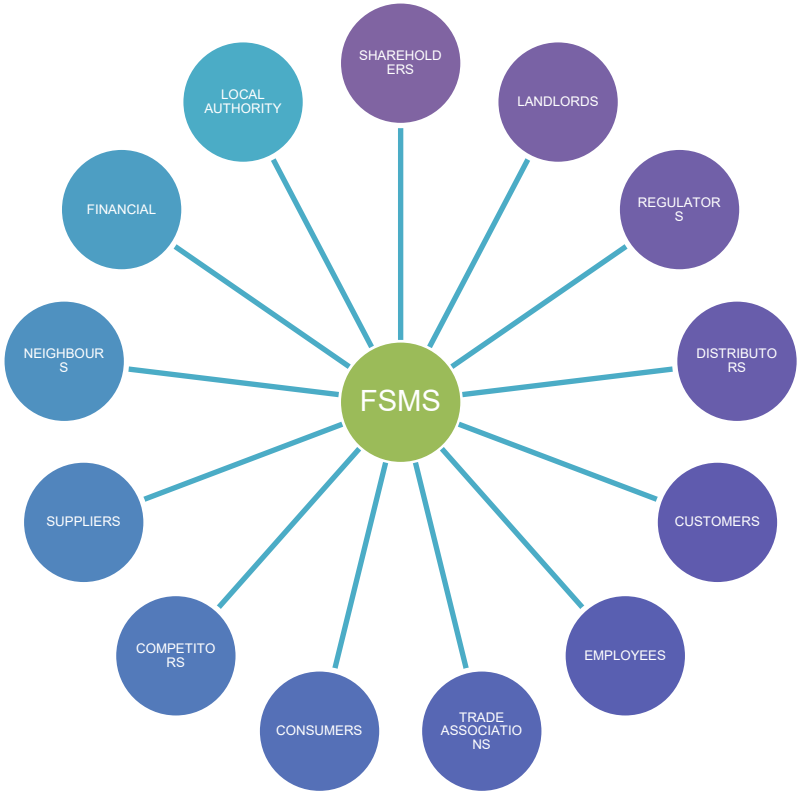
CONTEXT OF THE ORGANISATION

To understand the context of an organisation it is necessary to identify internal and external issues:

External Issues	Internal Issues
• Cultural, social, political, legal, financial, technological, economic and natural surroundings including the environment in which the organisation operates • Who the competitors are and any contractors, subcontractors, suppliers, partners and providers • National and international law • Industry drivers and trends which have influence on the organisation • The organisation products and services and their influence on food safety • Availability and variety of external providers of services/ products • Changes in consumption patterns • Capacity of changes regarding premises (landlord)	• Governance, organisational structure, roles and accountabilities • Policies, objectives and the strategies in place to achieve them • Competence of personnel • Food Safety culture within the organisation and the relationship with workers • Process for the introduction of new products, materials, services, tools, software, premises and equipment • Working conditions • Resources (under-utilisation of resources) • Retention of skilled employees • Number and variety of clients/ customers • Linkage to a certain activity, location

UNDERSTANDING THE NEEDS OF INTERESTED PARTIES



You need to identify all interested parties and analyse how they can affect the achievement of the main objective of a FSMS that is to ensure food is safe.

SCOPE OF FSMS

This is not a new concept but it has been revised in order to refer to the physical and / or geographical site within which your operations take place, the products / services included in the FSMS, the relevant parties you have identified and the special characteristics such as type of packaging used, storage or shelf-life conditions of the product/s . Your scope statement must be maintained as documented information.

For example: *'The fermentation, carbonation and packing of red wine into glass bottles'*

LEADERSHIP

The standard states that top management shall demonstrate leadership and commitment with respect to the FSMS. But who is top management? According to ISO 22000, top management is the person or group of people who direct or control an organisation at the highest level.

An external auditor will expect to discuss leadership with those who manage the organisation.

The previous version of ISO 22000 already included examples of how leadership can be demonstrated within the FSMS management system:

- Establishing the food safety policy
- Demonstrating that food safety is supported by the objectives of the organization
- Provision of appropriate and sufficient resources
- Facilitating the culture of continual improvement
- Communicating appropriately amongst interested parties
- Ensuring the integration of the FSMS requirements into the organization's business processes
- Leading the management review meetings

Additionally, the 2018 version states that top management shall also:

- Ensure that the strategic plans of the organization and the food safety objectives are compatible and integrated within the organization
- Ensure the integration of the FSMS requirements into the organization's business processes

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PLANNING

Planning is one of the key components of any management system. This section sets out a framework that asks an organisation to analyse itself to determine the risks and opportunities of its activities and then how to address them.

Action!

If you've been thorough in your assessment of context and the needs and expectations of interested parties, then the potential risks and opportunities will likely have made themselves quite apparent. You're looking to answer the following questions:

1. What are we trying to achieve?
2. What could stop us from achieving our objectives?
3. How will we address these issues?
4. How can risks be turned into opportunities?
5. How can opportunities help us to improve?
6. Who will be responsible for actions?
7. When will we need to take action by?
8. How will we know whether our actions were effective?

- Risks not only involve food safety but also those risks than can impact your FSMS losing productivity and effectiveness.
- ISO 22000 differentiates between different types of risks.
- Operational risks that can be controlled through the establishment and maintenance of PRPs, OPRPs, CCPs and emergency preparedness
- And also the risks that affect the entire management system and could make an impact into food safety.
- The latter are those that could happen but there is no history of them happening or, if they did, that was a sporadic event. Therefore, recurrent events are not to be considered as organisational risks and these must be controlled by the establishment of corrective actions.
- E.G Covid pandemic, we could never have expected this to happen, but we could have had a process in place to help us manage this.

OBJECTIVES

It is a requirement of the standard to set achievable food safety objectives with the means to periodically measure progress, demonstrating continuous improvement.

The objectives need to be:

- ✓ Consistent with the food safety policy
- ✓ Measurable
- ✓ Consistent with applicable food safety requirements, including statutory, regulatory and customer requirements
- ✓ Monitored and verified
- ✓ Communicated
- ✓ Maintained and updated
- ✓ Documented

Putting objectives into a simple matrix can help to clarify the objectives, however if you already record this type of information somewhere else, there is no need to duplicate.

SUPPORT

- Resources include people, infrastructure and work environment
- Control of external providers include ALL providers, not just suppliers
- Competence is not measured by completed training, think was the training effective? Experience is often a bigger factor in a persons competence
- Communication - The Standard is helpful in providing a framework in order to depict the communication process within an organisation
- Documented information, you must ensure that all documents relating to your FSMS are easily identifiable, are in a suitable format, are protected from unintended alteration or destruction, and are available to the right people in the right version at the point of which they are needed and are maintained (up to date)

OPERATION

This is the core of a FSMS, where most HACCP principles are integrated and the “Do” of your PDCA!

Prerequisite programmes (PRPs)

2018 version suggests the use of specific ISO/TS 22002 series depending on the sector you are working in, to determine the PRPs applicable to your organisation that will assist in controlling food safety hazards. The idea is to implement PRPs that are appropriate to your context, size and activities conducted. These prerequisites will be established before conducting the hazard analysis, and its selection, implementation, monitoring and verification must be also documented.

Traceability & Emergency Response

Established a traceability system and also a procedure to respond to emergency situations
Examples of emergency situations could be natural disasters, an earthquake, sabotage, blockage of main utilities, environmental accidents, COVID etc.

OPERATION

Hazard Control

Before carrying out the analysis of hazards, A multidisciplinary team with a defined leader needs to be established. This is the first step of HACCP, and although ISO 22000 does not specify this requirement in this section, it is mandated as part of the responsibilities of top management. Once established the characteristics of raw materials, end products, intended use and a very detailed flow diagram/s, as the standard now requires.

The evaluation of hazards, based on their severity of harm and probability of occurrence, will include the establishment of specific measures or combination of them to prevent or reduce the significant food safety hazards to acceptable levels.

Your hazard control plan must contain, as a minimum, the following information for all identified CCPs and OPRPs:

- What food safety hazard are you controlling with this CCP or OPRP
- What measure have you put in place to do so
- The critical limit/s or action criteria in place that can't be exceed
- How do you monitor this activity
- Which corrections and corrective actions will be carried out if critical limits or action criteria is not met
- Who is responsible for this activity (defined responsibilities and authorities)
- What records do you maintain as monitoring evidence

OPERATION

Control of non-conforming products and processes

All staff responsible for corrections and corrective actions must be competent and have the authority to carry out these activities.

Within section 8 of the ISO 22000 standard, the specified corrective actions and corrections are focused at the operational level, so this will include all immediate actions to be taken when limits established for OPRPs and CCPs are exceeded and also actions that will be done to avoid their recurrence.

When critical limits for a CCP or action criteria for an ORP are not met, you must treat the product as potentially unsafe from entering the food chain. These products must be identified and retained at your organisation at all times until its evaluation and disposition is determined.

If the product is already out of your premises, then you must initiate a withdrawal or recall and notify all relevant interested parties.

PERFORMANCE EVALUATION

There are three main ways in which performance of a FSMS is evaluated:

- Process monitoring
- Internal audits
- Management review

ISO 22000:2018 includes new elements to be considered during management review meetings:

- Changes in context (internal and external issues) that may affect the FSMS
- Information on the performance and the effectiveness of the FSMS, including trends in:
  - Review of identified risks and opportunities and effectiveness of actions taken
  - Performance of providers of services, processes or products
  - Non-conformities and corrective actions
  - Monitoring and measuring results
  - Whether the objectives have been achieved
- The adequacy of resources
- Opportunities for continual improvement
- With regard to outputs, your organisation must consider the decisions and actions related to continual improvement opportunities and any other need for changes and updates of the FSMS.

IMPROVEMENT

A methodology to capture, manage and resolve needs to be undertaken and documented

React to the nonconformity and, as applicable:

- Take action to control and correct it
- Deal with the consequences, including mitigating adverse environmental impacts

Evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by:

- Reviewing the nonconformity
- Determining the causes of the nonconformity determining if similar nonconformities exist, or could potentially occur
- Implement any action needed
- Review the effectiveness of any corrective action taken
- Make changes to the FSMS, if necessary

Update of the food safety management system

This section has not changed in 2018 version, as a summary, top management must provide the resources needed to ensure the system is continually updated. The food safety team shall evaluate the FSMS at planned intervals, considering the hazard analysis, and identified OPRPs and CCPs. The evaluation must be based on:

- Internal and external communication
- Conclusions from analysis of results of verification activities
- Outputs from management review meetings
- Any other information related to the adequacy and effectiveness of the FSMS

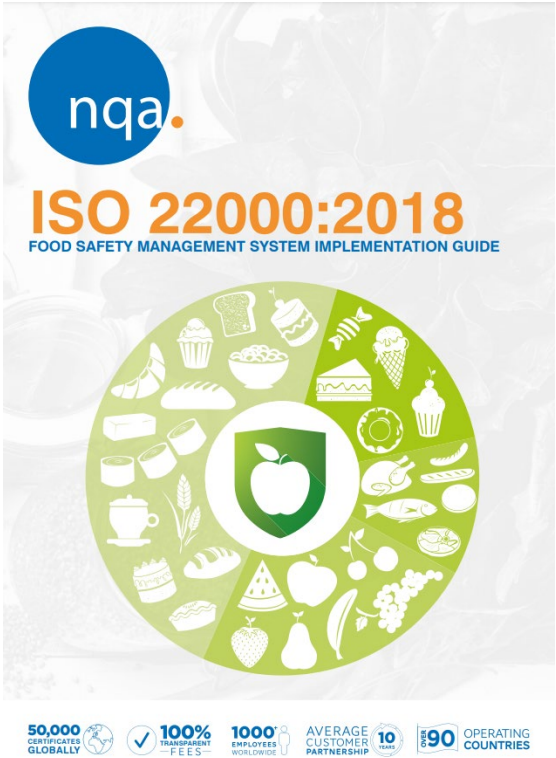
These updates must be retained as documented information and reported as input of the management review.

CONTINUAL IMPROVEMENT

If the requirements of ISO 22000 are established and implemented, regularly reviewed and challenged then continual improvement will occur.

NQA RESOURCES

- Regular FSMS Updates and blogs via our website
- ISO 22000:2018 Implementation guide
- ISO 22000:2018 Transition Checklist
- NQA Associate Partner Programme



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Q&A

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